
STATUTORY INSTRUMENTS

2013 No. 2033

MEDICINES

The Veterinary Medicines Regulations 2013

<i>Made</i>	- - - -	<i>6th August 2013</i>
<i>Laid before Parliament</i>		<i>20th August 2013</i>
<i>Coming into force</i>	- -	<i>1st October 2013</i>

The Secretary of State is a Minister designated⁽¹⁾ for the purposes of making Regulations under section 2(2) of the European Communities Act 1972⁽²⁾ in relation to measures in the veterinary and phytosanitary fields for the protection of public health.

The Secretary of State has carried out the consultation required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽³⁾.

In accordance with section 56(1) of the Finance Act 1973⁽⁴⁾, the Treasury consent to the making of these Regulations.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and by section 56(1) of the Finance Act 1973.

Modifications etc. (not altering text)

- C1** Regulations: power to amend conferred (11.4.2021) by [Medicines and Medical Devices Act 2021](#) (c. 3), **ss. 10(1), 50(2)(c)**
- C2** Regulations applied in part (with modifications) (N.I.) (1.10.2023) by [The Windsor Framework \(Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions\) Regulations 2023](#) (S.I. 2023/959), regs. 1(2), 4(a), **Sch. 1** (with regs. 7, 8)

(1) S.I. 1999/2027.
(2) 1972 c. 68.
(3) OJ No L31, 1.2.2002, p. 1.
(4) 1973 c. 51.

PART 1

Introduction

Title and commencement

1. These Regulations may be cited as the Veterinary Medicines Regulations 2013 and come into force on 1st October 2013.

Definition of “veterinary medicinal product”, interpretation and scope **E+W+S**

2.—(1) In these Regulations “veterinary medicinal product” means—

- (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or
- (b) any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis [^{F1}; or
- (c) any substance or combination of substances that may be used for the purpose of euthanising an animal].

(2) In these Regulations—

[^{F2}“active substance” means any substance or mixture of substances intended to be used in the manufacture of a veterinary medicinal product, that, when used in its production, is responsible for the activity of that veterinary medicinal product;

“adverse environmental event” means an event where a non-target organism, population or ecosystem is adversely affected as a result of exposure to a veterinary medicinal product, its active substances or its metabolites present in soil, water or animal remains;

“adverse event” means any observation in animals that occurs after any use of a veterinary medicinal product, whether or not considered to be product-related, that is unfavourable and unintended;]

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[^{F2}“advertising” means, in relation to veterinary medicinal products, the making of a representation in any form in connection with those products in order to promote their supply, distribution, sale, prescription or use and includes any action taken for this purpose by way of the supply of samples or by means of sponsorship, and “advertise” and “advertisement” are to be construed accordingly;]

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“animal” means all animals other than man and includes birds, reptiles, fish, molluscs, crustacea and bees;

[^{F2}“antibiotic” means any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases;

“antimicrobial” means any substance with a direct action on micro-organisms that is used for treatment or prevention of infections or infectious diseases and includes antibiotics, antivirals, antifungals and antiprotozoals;

“antimicrobial resistance” means the ability of micro-organisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill micro-organisms of the same species;

“ATCvet code” means, in relation to a veterinary medicinal product, the code issued in respect of that product by the World Health Organization Collaborating Centre for Drug Statistics Methodology, and published by that body in the ATCvet index;

“benefit-risk balance” means, in relation to a veterinary medicinal product, an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product—

- (a) any risk to human or animal health relating to the quality, safety or efficacy of the veterinary medicinal product;
- (b) any risk of undesirable effects on the environment; or
- (c) any risk relating to the development of resistance;

“biological substance” means a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physical, chemical and biological testing, together with knowledge of the production process and its control;

“biological veterinary medicinal product” means a veterinary medicinal product where an active substance is a biological substance;]

“the cascade” has the meaning given in paragraph 1 of Schedule 4;

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[^{F2}“complementary feedingstuffs” means compound feed which has a high content of certain substances and which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed;

“complete feed” means compound feed which, by reason of its composition, is sufficient for a daily ration;

“compound feed” means a mixture of at least two feed additives for oral animal-feeding in the form of complete or complementary feed;

“daily ration” means the average total quantity of feedingstuffs, calculated on a moisture content of 12%, required daily by an animal of a given species, age category and yield, to satisfy all its nutritional needs;

“excipient” means any constituent of a veterinary medicinal product other than an active substance;]

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[^{F2}“feed additives” means substances, micro-organisms or preparations, other than feed material and intermediate feedingstuff, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Schedule 5;

“feed materials” means products of vegetable or animal origin whose principal purpose is to meet animals’ nutritional needs, and which are intended for use in oral animal feed either directly, or after processing, or in the preparation of compound feed, or as a carrier of intermediate feedingstuffs;

“feedingstuff” means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

“generic veterinary medicinal product” means a veterinary medicinal product which has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as a reference veterinary medicinal product;

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

“genetically modified organism” or “GMO” means a genetically modified organism for the purposes of the GMO Deliberate Release Regulations;

“GMO Deliberate Release Regulations” means—

- (a) as regards England, the Genetically Modified Organisms (Deliberate Release) Regulations 2002;
- (b) as regards Scotland, the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002;
- (c) as regards Wales, the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;

“good distribution practice” means that part of quality assurance which ensures that products are consistently stored, supplied and controlled in accordance with the quality standards appropriate for their intended use and as required by the applicable marketing authorisation or product specifications;

“good manufacturing practice” means that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use and as required by the applicable marketing authorisation or product specifications;]

“horse passport” means [^{F5}a passport issued in accordance with the provisions of Commission Regulation (EC) No 504/2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards][^{F5}an identification document which complies with Commission Implementing Regulation (EU) 2015/262 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the] methods for the identification of equidae⁽⁸⁾;

[^{F2}“human adverse event” means a reaction that is noxious and unintended and that occurs in a human being following exposure to a veterinary medicinal product;]

“immunological veterinary medicinal product” means a veterinary medicinal product [^{F6}intended to be] administered to [^{F7}an animal] in order to produce active or passive immunity or to diagnose [^{F8}its state] of immunity;

[^{F2}“improvement notice” has the meaning given in regulation 38(1);

“intermediate feedingstuffs” means a feed which is not ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more of the following—

- (a) a medicinal premix;
- (b) a specified feed additive,

with feed materials or compound feed, exclusively intended to be used for the manufacture of a complete feed;

“lack of efficacy” means the apparent inability of an authorised veterinary medicinal product to have the expected efficacy in an animal, whether or not the product was used in accordance with the summary of product characteristics;

“limited market” means a market for one of the following types of veterinary medicinal product—

- (a) a veterinary medicinal product for the treatment or prevention of diseases that occur infrequently or in limited geographical areas;
- (b) a veterinary medicinal product for an animal species other than cattle, sheep for meat production, pigs, chickens, dogs or cats;

(8) OJ No L 149, 7.6.2008, p. 3.

“manufacturing authorisation”, except as regards Schedule 7, has the meaning given in paragraph 1 of Schedule 2;

“medicated feedingstuffs” means a feed which is ready to be directly fed to animals without any further processing, consisting of a homogenous mixture of one or more medicinal premixes or intermediate feedingstuff with feed materials or compound feed;

“medicinal premix” means a veterinary medicinal product authorised for incorporation into feedingstuffs;

“metaphylactic purposes”, in relation to the administration of a veterinary medicinal product, means the administration of the veterinary medicinal product to a group of animals after a diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at risk and which may already be subclinically infected;

“novel therapy” means a veterinary medicinal product which is considered to be in a nascent field in veterinary medicine, including a product of a type not previously authorised, and “novel therapies” is to be construed accordingly;

“person responsible for release” and “PRR” have the meaning given in paragraph 16 of Schedule 2;

“pharmacologically equivalent” means containing an active substance in the same proportions, in the same dosage form and concentration (in the case of a liquid dose) and meeting the same or comparable standards in relation to the clinical needs of a patient at the time of use;

“pharmacovigilance” means the science and activities relating to the detection, assessment, understanding and prevention of suspected adverse events or any other problem related to a medicinal product;

“pharmacovigilance system master file” means a detailed description of the pharmacovigilance system used by the holder of the marketing authorisation in relation to one or more authorised veterinary medicinal products;

“principles of good laboratory practice” has the meaning given in regulation 2(1) of the Good Laboratory Practice Regulations 1999;

“prophylactic purposes”, in relation to the administration of a veterinary medicinal product, means the administration of the veterinary medicinal product to an animal or group of animals before clinical signs of disease in order to prevent the occurrence of disease or infection;

“qualified person (manufacture)”, in relation to a veterinary medicinal product, means a person appointed under paragraph 9 of Schedule 2 with responsibility for that product;

“qualified person (pharmacovigilance)” has the meaning given in paragraph 56(9) of Schedule 1;

“reference veterinary medicinal product” has the meaning given in paragraph 10(1) of Schedule 1;]

[^{F9}“Regulation (EC) No 178/2002” means Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(6);]

[^{F10}“Regulation (EC) No 1831/2003” means Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition(7);]

^{F11} ...

(6) OJ No L334, 12.12.2008, p.7.

(7) OJ No L 15, 20.1.2010, p. 1.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

[^{F12}“Regulation (EC) No 183/2005” means Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene(9);]

“Regulation (EC) No 470/2009 of the European Parliament and of the Council” means Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin(9);

“Regulation (EC) No 767/2009 of the European Parliament and of the Council” means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed in relation to feedingstuffs containing specified feed additives(10)[^{F13}, as last amended by Regulation (EU) No 2017/2279];

[^{F14}“Regulation (EU) 2017/625” means Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products;]

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[^{F2}“serious adverse event” means an adverse reaction that results in death, is life-threatening, results in significant disability or incapacity, is a congenital anomaly or birth defect, or that results in permanent or prolonged signs in the animals treated;

“signal management process” has the meaning given in paragraph 56C of Schedule 1;]

[^{F15}“strength” means the content of active substances in a veterinary medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the pharmaceutical form;]

[^{F2}“wholesale dealing” means all activities consisting of procuring, holding, supplying, distributing or exporting veterinary medicinal products whether for profit or not, but does not include retail supply of veterinary medicinal products to the public;

“wholesale qualified person” has the meaning given in paragraph 17(2)(d) of Schedule 3;

“withdrawal period” means the minimum period under normal conditions of use between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which is necessary to ensure that such foodstuffs do not contain residues in quantities harmful to public health]

[^{F16}(2A) In these Regulations, a biological veterinary medicinal product is treated as a single product even when more than one solvent is used in the preparation of different preparations of the final product (which may be for administration by different routes or methods).]

^{F17}(3)

^{F18}(4)

(5) For the avoidance of doubt, these Regulations apply to veterinary medicinal products irrespective of whether or not there is other legislation controlling a product.

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

(9) OJ No L152, 16.6.2009, p. 11.

(9) OJ No L152, 16.6.2009, p. 11.

(10) OJ No L229, 1.9.2009, p. 1. Regulation (EC) No 767 2009 was last amended by Regulation (EC) 939/2010 (OJ No L277, 20.10. 2010, p. 4).

Textual Amendments

- F1** Words in reg. 2(1) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **4(a)**
- F2** Words in reg. 2(2) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **4(b)(i)**
- F3** Words in reg. 2(2) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **4(b)(iv)**
- F4** Words in reg. 2(2) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(2)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F5** Words in reg. 2 substituted (E.) (1.10.2018) by The Equine Identification (England) Regulations 2018 (S.I. 2018/761), regs. 1(1), **49**
- F6** Words in reg. 2(2) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **4(b)(ii)(aa)**
- F7** Words in reg. 2(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **4(b)(ii)(bb)**
- F8** Words in reg. 2(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **4(b)(ii)(cc)**
- F9** Words in reg. 2(2) inserted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(2)(b)**
- F10** Words in reg. 2(2) inserted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(2)(c)**
- F11** Words in reg. 2(2) omitted (E.) (14.12.2019) by virtue of The Official Controls (Animals, Feed and Food, Plant Health Fees etc.) Regulations 2019 (S.I. 2019/1488), regs. 1(1), **27(a)(i)**; and words omitted (W.) (31.1.2020) by virtue of The Official Controls (Animals, Feed and Food, Plant Health Fees etc.) (Wales) Regulations 2020 (S.I. 2020/44), regs. 1(2), **24(1)(a)(i)**; and words omitted (S.N.I.) (31.12.2020) by virtue of The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) (No. 2) Regulations 2020 (S.I. 2020/1631), regs. 1(2), **3(2)(a)**
- F12** Words in reg. 2(2) inserted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(2)(e)**
- F13** Words in reg. 2(2) inserted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(2)(f)**
- F14** Words in reg. 2(2) inserted (E.) (14.12.2019) by The Official Controls (Animals, Feed and Food, Plant Health Fees etc.) Regulations 2019 (S.I. 2019/1488), regs. 1(1), **27(a)(ii)**; and words inserted (W.) (31.1.2020) by The Official Controls (Animals, Feed and Food, Plant Health Fees etc.) (Wales) Regulations 2020 (S.I. 2020/44), regs. 1(2), **24(1)(a)(ii)**; and words inserted (S.N.I.) (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) (No. 2) Regulations 2020 (S.I. 2020/1631), regs. 1(2), **3(2)(b)**
- F15** Words in reg. 2(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **4(b)(iii)**
- F16** Reg. 2(2A) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **4(c)**
- F17** Reg. 2(3) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **4(d)**
- F18** Reg. 2(4) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU

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Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(2)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Definition of “veterinary medicinal product”, interpretation and scope **N.I.**

2.—(1) In these Regulations “veterinary medicinal product” means—

- (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or
- (b) any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

(2) In these Regulations—

“adverse reaction” means a reaction to a veterinary medicinal product that is harmful and unintended and that occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or to restore, correct or modify a physiological function;

“the Agency” means the European Medicines Agency established by Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(5);

“animal” means all animals other than man and includes birds, reptiles, fish, molluscs, crustacea and bees;

“the cascade” has the meaning given in paragraph 1 of Schedule 4;

“Commission Regulation (EC) No 1234/2008” means Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products(6)^{F655}, as last amended by Regulation (EU) No 712/2012(5);

“Commission Regulation (EU) No 37/2010” means Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin(7);

“extension variation” has the same meaning as “Extension of a marketing authorisation” in Article 2 of Commission Regulation EC No 1234/2008;

“horse passport” means a passport issued in accordance with the provisions of Commission Regulation (EC) No 504/2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae(8);

“immunological veterinary medicinal product” means a veterinary medicinal product administered to animals in order to produce active or passive immunity or to diagnose the state of immunity;

^{F656}“Regulation (EC) No 178/2002” means Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(6);

(5) OJ No L136, 30.4.2004, p. 1.

(6) OJ No L334, 12.12.2008, p.7.

(5) OJ No L136, 30.4.2004, p. 1.

(7) OJ No L 15, 20.1.2010, p. 1.

(8) OJ No L 149, 7.6.2008, p. 3.

(6) OJ No L334, 12.12.2008, p.7.

[^{F657}“Regulation (EC) No 1831/2003” means Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition(7);]

^{F658} ...

[^{F659}“Regulation (EC) No 183/2005” means Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene(9);]

“Regulation (EC) No 470/2009 of the European Parliament and of the Council” means Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin(9);

“Regulation (EC) No 767/2009 of the European Parliament and of the Council” means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed in relation to feedingstuffs containing specified feed additives(10)[^{F660}, as last amended by Regulation (EU) No 2017/2279];

[^{F661}“Regulation (EU) 2017/625” means Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products;]

“risk-benefit balance” means an evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to—

- (a) any risk to human or animal health relating to the quality, safety or efficacy of the veterinary medicinal product; or
- (b) any risk of undesirable effects on the environment;

“strength” means the amount of active substances in a dosage unit or unit of volume or weight.

(3) In these Regulations references to types of variation are to those specified in [Commission Regulation \(EC\) No 1234/2008](#);

(4) In these Regulations any reference to a member State is a reference to a member State of the European Union and Norway, Iceland and Liechtenstein.

(5) For the avoidance of doubt, these Regulations apply to veterinary medicinal products irrespective of whether or not there is other legislation controlling a product.

Extent Information

E171 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F655 Words in reg. 2(2) inserted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(a), **2(2)(a)**

F656 Words in reg. 2(2) inserted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(a), **2(2)(b)**

(7) OJ No L 15, 20.1.2010, p. 1.

(9) OJ No L152, 16.6.2009, p. 11.

(9) OJ No L152, 16.6.2009, p. 11.

(10) OJ No L229, 1.9.2009, p. 1. Regulation (EC) No 767 2009 was last amended by Regulation (EC) 939/2010 (OJ No L277, 20.10. 2010, p. 4).

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- F657** Words in reg. 2(2) inserted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(2)(c)**
- F658** Words in reg. 2(2) omitted (S.N.I.) (31.12.2020) by virtue of The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) (No. 2) Regulations 2020 (S.I. 2020/1631), regs. 1(2), **3(2)(a)**
- F659** Words in reg. 2(2) inserted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(2)(e)**
- F660** Words in reg. 2(2) inserted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(2)(f)**
- F661** Words in reg. 2(2) inserted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(2)**; and also inserted (S.N.I.) (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) (No. 2) Regulations 2020 (S.I. 2020/1631), regs. 1(2), **3(2)(b)**

Products to which these Regulations do not apply

3.—(1) These Regulations do not apply to a veterinary medicinal product based on radio-active isotopes.

(2) They do not apply in relation to a product intended for administration in the course of a procedure licensed under the Animals (Scientific Procedures) Act 1986(**11**), except that, if the animals are to be put into the human food chain, the only products that may be administered to the animals are—

- (a) authorised veterinary medicinal products administered in accordance with their marketing authorisation; or
- (b) products administered in accordance with an animal test certificate granted under paragraph 9 of Schedule 4.

PART 2

Authorised veterinary medicinal products

Placing a veterinary medicinal product on the market **E+W+S**

4.—^[F19](1) No person may place a veterinary medicinal product on the market unless the Secretary of State has—

- (a) as regards a product to which Schedule 1B applies, issued a QNIG certificate in respect of that product;
- (b) otherwise, granted a marketing authorisation in respect of that product.]

(2) No person may certify data in relation to an application for a marketing authorisation or in relation to an existing marketing authorisation if they know that those data are false, or do not believe that they are accurate.

(3) Schedule 1 (marketing authorisations) has effect.

^[F20](4) Schedule 1A (converted EU marketing authorisations) has effect.]

[^{F21}(5) Schedule 1B (Northern Ireland qualifying good marketing authorisations) has effect.]

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F19 Reg. 4(1) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1, **3(3)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)** **(3)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F20 Reg. 4(4) inserted (E.W.S.) (31.12.2020) by [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F21 Reg. 4(5) inserted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(b), **4(2)**

Placing a veterinary medicinal product on the market **N.I.**

4.—(1) No person may place a veterinary medicinal product on the market unless that product has been granted a marketing authorisation by the Secretary of State or the Agency.

(2) No person may certify data in relation to an application for a marketing authorisation or in relation to an existing marketing authorisation if they know that those data are false, or do not believe that they are accurate.

(3) Schedule 1 (marketing authorisations) has effect.

Extent Information

E172 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Manufacture of veterinary medicinal products

5.—(1) The holder of a marketing authorisation must ensure that every stage in the manufacture of the veterinary medicinal product is carried out by the manufacturer specified in the marketing authorisation⁽¹²⁾.

(2) Schedule 2 (the manufacture of veterinary medicinal products) has effect.

[^{F22}(3) “Manufacture” includes any part of the manufacture of a veterinary medicinal product until the finished product is ready for sale in its final form as specified in the marketing authorisation but does not include the manufacture of an ingredient or breaking open the package of a veterinary medicinal product⁽¹³⁾.]

⁽¹²⁾ If the manufacture is carried out in the United Kingdom the manufacturer must hold a manufacturing authorisation for that type of product granted by the Secretary of State.

⁽¹³⁾ For provisions on breaking open packages see regulation 7(3).

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Textual Amendments

F22 Reg. 5(3) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 5

Marketing of products not in accordance with a marketing authorisation

6. The holder of a marketing authorisation for a veterinary medicinal product is guilty of an offence if either the holder or the manufacturer supplies a product that is not completely in accordance with the marketing authorisation.

Classification, supply and possession of the product

7.—(1) Schedule 3 (classification and supply, wholesale dealers and sheep dip) has effect.

(2) No person may supply a veterinary medicinal product [^{F23}(including a veterinary medicinal product which has been incorporated into a medicated feedingstuff or intermediate feedingstuff)] that has passed its expiry date.

(3) No person may open the package (including the outer package) of a veterinary medicinal product before it has been supplied to the final user, other than as permitted under Schedule 3.

(4) No person may supply an authorised human medicinal product for administration to an animal (other than a product supplied by a veterinary surgeon or in accordance with a written prescription from a veterinary surgeon that includes all the information specified in paragraph 6 of Schedule 3).

(5) No person may be in possession of a veterinary medicinal product that was supplied to that person other than in accordance with Schedule 3.

Textual Amendments

F23 Words in [reg. 7\(2\)](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 6

Administration of the product **E+W+S**

8. No person may administer a veterinary medicinal product to an animal unless—

- (a) the product has a marketing authorisation authorising its administration in the United Kingdom, and the administration is in accordance with that marketing authorisation; or
- (b) it is administered in accordance with Schedule 4 (administration of a veterinary medicinal product outside the terms of a marketing authorisation) or Schedule 6 (exemptions for small pet animals).

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Administration of the product **N.I.**

8. No person may administer a veterinary medicinal product to an animal unless—

- (a) the product has a marketing authorisation authorising its administration in [^{F662}Northern Ireland], and the administration is in accordance with that marketing authorisation; or
- (b) it is administered in accordance with Schedule 4 (administration of a veterinary medicinal product outside the terms of a marketing authorisation) or Schedule 6 (exemptions for small pet animals).

Extent Information

E173 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F662 Words in [reg. 8\(a\)](#) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(3)**

Importation of authorised veterinary medicinal products **E+W+S**

9.—^{F24}(1) No person may import, or move into Great Britain from Northern Ireland, a veterinary medicinal product authorised for use in Great Britain except in accordance with this regulation.]

(2) A holder of a marketing authorisation for a veterinary medicinal product may import that veterinary medicinal product.

(3) A holder of a manufacturing authorisation may import a veterinary medicinal product to which that authorisation relates.

(4) An authorised wholesale dealer may import a veterinary medicinal product if—

- (a) the authorisation covers the product; and
- (b) the dealer has notified the holder of the marketing authorisation in writing before importation.

(5) A veterinary surgeon or a pharmacist may import any authorised veterinary medicinal product.

(6) A suitably qualified person (registered in accordance with paragraph 14 of Schedule 3) may import any authorised veterinary medicinal product that that person is permitted to supply.

(7) There are no restrictions on the importation of an authorised veterinary medicinal product in category AVM-GSL.

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F24 [Reg. 9\(1\)](#) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(b), **4(3)**

Importation of authorised veterinary medicinal products **N.I.**

9.—(1) No person may import a veterinary medicinal product authorised for use in [^{F663}Northern Ireland] except in accordance with this regulation.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(2) A holder of a marketing authorisation for a veterinary medicinal product may import that veterinary medicinal product.

(3) A holder of a manufacturing authorisation may import a veterinary medicinal product to which that authorisation relates.

(4) An authorised wholesale dealer may import a veterinary medicinal product if—

- (a) the authorisation covers the product; and
- (b) the dealer has notified the holder of the marketing authorisation in writing before importation.

(5) A veterinary surgeon or a pharmacist may import any authorised veterinary medicinal product.

(6) A suitably qualified person (registered in accordance with paragraph 14 of Schedule 3) may import any authorised veterinary medicinal product that that person is permitted to supply.

(7) There are no restrictions on the importation of an authorised veterinary medicinal product in category AVM-GSL.

Extent Information

E174 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F663 Words in [reg. 9\(1\)](#) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(4)**

Advertising the product **E+W+S**

10.—^[F25](1) No person may issue an advertisement relating to a relevant substance unless that advertisement—

- (a) is set out in such a way that it is clear that the message is an advertisement for the purpose of promoting the supply, sale, prescription, distribution or use of the substance;
- (b) encourages responsible use of the substance while presenting its characteristics in an objective manner;
- (c) contains no information which—
 - (i) is misleading;
 - (ii) is incompatible with the summary of product characteristics in relation to the substance;
 - (iii) might encourage improper use of the substance; or
 - (iv) where the relevant substance is a veterinary medicinal product, might suggest that the substance is a feedingstuff or a biocide.

(1A) No person may advertise a veterinary medicinal product, other than a product which is placed on the market in accordance with Schedule 6, unless—

- (a) a marketing authorisation has been granted in respect of that product, and
- (b) that authorisation is not currently suspended in accordance with paragraph 38 of Schedule 1.]

(2) No person may advertise an authorised human medicinal product for administration to animals (including sending a price list of, or including, authorised human medicinal products to a veterinary surgeon or veterinary practice).

(3) Paragraph (2) does not apply to the holder of a wholesale dealer's authorisation who supplies a list of authorised human medicinal products, together with prices, to a veterinary surgeon for use under the cascade provided that—

- (a) the list is sent following a request from the veterinary surgeon to whom it is sent; and
- (b) the list states clearly that the product does not have a marketing authorisation as a veterinary medicinal product, and may only be prescribed and administered under the cascade.

[^{F26}(4) In this regulation, subject to paragraph (5), “relevant substance” means—

- (a) a veterinary medicinal product;
- (b) a medicinal premix;
- (c) an intermediate feedingstuff; or
- (d) a compound feed.

(5) In this regulation, coccidiostats and histomonostats are not relevant substances.]

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F25 Reg. 10(1)(1A) substituted for reg. 10(1) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **7(a)** (with reg. 201)

F26 Reg. 10(4)(5) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **7(b)** (with reg. 201)

Advertising the product **N.I.**

10.—(1) No person may advertise a veterinary medicinal product if the advertisement is misleading or contains any medicinal claim that is not in the summary of product characteristics.

(2) No person may advertise an authorised human medicinal product for administration to animals (including sending a price list of, or including, authorised human medicinal products to a veterinary surgeon or veterinary practice).

(3) Paragraph (2) does not apply to the holder of a wholesale dealer's authorisation who supplies a list of authorised human medicinal products, together with prices, to a veterinary surgeon for use under the cascade provided that—

- (a) the list is sent following a request from the veterinary surgeon to whom it is sent; and
- (b) the list states clearly that the product does not have a marketing authorisation as a veterinary medicinal product, and may only be prescribed and administered under the cascade.

Extent Information

E175 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F27}Inducements and hospitality

10A.—(1) Subject to paragraphs (2) and (4), where veterinary medicinal products are being promoted to persons qualified to prescribe or supply veterinary medicinal products, no person may supply, offer or promise to any person any gift, pecuniary advantage or benefit in kind unless it is inexpensive and relevant to the practice of veterinary medicine or pharmacy.

(2) The provisions of paragraph (1) do not prevent any person offering hospitality (including the payment of travelling or accommodation expenses) at events for purely professional or scientific purposes to persons qualified to prescribe or supply veterinary medicinal products, provided that—

- (a) it is subordinate to the main scientific objective of the event; and
- (b) it is offered only to animal health professionals.

(3) Subject to paragraph (4), no person may offer hospitality (including the payment of travelling or accommodation expenses) at a meeting or event held for the promotion of veterinary medicinal products unless—

- (a) it is subordinate to the main purpose of the meeting or event, and
- (b) the person to whom it is offered is an animal health professional.

(4) Nothing in this regulation affects measures or trade practices relating to prices, margins or discounts which were in existence on the date on which the Veterinary Medicines (Amendment, etc.) Regulations 2024 came into force.

(5) No person qualified to prescribe or supply veterinary medicinal products may solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship prohibited by this regulation.]

Textual Amendments

F27 [Reg. 10A](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **8**

Advertising of prescription products and products containing psychotropic drugs or narcotics

11.—(1) No person may advertise a veterinary medicinal product that—

- (a) is available on veterinary prescription only; or
- (b) contains psychotropic drugs or narcotics.

(2) In the case of a product containing psychotropic drugs or narcotics, paragraph (1) does not apply to advertisements aimed at veterinary surgeons or pharmacists.

(3) Subject to paragraph (4) in the case of POM-V medicines, paragraph (1) does not apply to price lists, or to advertisements aimed at—

- (a) veterinary surgeons;
- (b) veterinary nurses;
- (c) pharmacists; or
- (d) professional keepers of animals.

(4) No person may advertise [^{F28}antimicrobials] to professional keepers of animals.

(5) In the case of POM-VPS medicines, paragraph (1) does not apply to price lists, or to advertisements aimed at—

- (a) veterinary surgeons;

- (b) pharmacists;
 - (c) suitably qualified persons registered in accordance with paragraph 14 of Schedule 3;
 - (d) other veterinary health care professionals; or
 - (e) professional keepers of animals.
- [^{F29}(6) A person advertising a veterinary medicinal product must—
- (a) include in that advertisement the statement “prescription decisions are for the person issuing the prescription alone”;
 - (b) ensure that all factual statements concerning the characteristics of the product in the advertisement are consistent with the summary of product characteristics submitted in respect of the product under Schedule 1, as amended.]

Textual Amendments

- F28** Word in reg. 11(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **9(a)** (with reg. 201)
- F29** Reg. 11(6) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **9(b)** (with reg. 201)

Defence of publication in the course of business

12. In proceedings for an offence under these Regulation 43(g), it is a defence for the person charged to prove—

- (a) that that person’s business is to publish or arrange for the publication of advertisements, and
- (b) that the advertisement was received in the ordinary course of business and the person charged did not know and had no reason to suspect that its publication would amount to an offence under these Regulations.

Wholesale dealing

13. No person may buy a veterinary medicinal product, other than by retail or for the purposes of retail supply in accordance with Schedule 3, unless the buyer has a wholesale dealer’s authorisation granted by the Secretary of State under this regulation and Schedule 3.

Feedingstuffs

14. Schedule 5 (medicated feedingstuffs and specified feed additives) has effect.

Exemptions **E+W+S**

15.—(1) These Regulations do not apply to an inactivated autogenous vaccine that is manufactured, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal and used for the treatment of that animal.

(2) Schedule 1 and Part 1 of Schedule 2 do not apply in relation to an inactivated autogenous vaccine that is—

- (a) manufactured by a person and in premises authorised in accordance with Part 2 of Schedule 2, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal; and
- (b) used for the treatment of—

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Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (i) other animals on the same site;
 - (ii) animals intended to be sent to those premises; or
 - (iii) animals on a site that receives animals from those premises.
- (3) Schedule 1 and Part 1 of Schedule 2 do not apply in relation to—
- (a) blood or blood constituents from a blood bank authorised in accordance with [^{F30}Part 2] of Schedule 2;
 - (b) a product manufactured for administration under the cascade by a person and in premises authorised in accordance with [^{F31}Part 2] of Schedule 2; or
 - (c) ^{F32}... stem cell products for use as an autologous treatment for [^{F33}non-food producing animals] from an ^{F32}... collection centre authorised in accordance with [^{F34}Part 2] of Schedule 2.
- (4) Schedule 6 (exemptions for small pet animals) has effect.

Extent Information

- E6** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F30** Words in [reg. 15\(3\)\(a\)](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), **10(a)**
- F31** Words in [reg. 15\(3\)\(b\)](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), **10(b)**
- F32** Word in [reg. 15\(3\)\(c\)](#) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), **10(c)(i)**
- F33** Words in [reg. 15\(3\)\(c\)](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), **10(c)(ii)**
- F34** Words in [reg. 15\(3\)\(c\)](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), **10(c)(iii)**

Exemptions **N.I.**

15.—(1) These Regulations do not apply to an inactivated autogenous vaccine that is manufactured, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal and used for the treatment of that animal.

(2) Schedule 1 and Part 1 of Schedule 2 do not apply in relation to an inactivated autogenous vaccine that is—

- (a) manufactured by a person and in premises authorised in accordance with Part 2 of Schedule 2, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal; and
- (b) used for the treatment of—
 - (i) other animals on the same site;
 - (ii) animals intended to be sent to those premises; or
 - (iii) animals on a site that receives animals from those premises.

(3) Schedule 1 and Part 1 of Schedule 2 do not apply in relation to—

- (a) blood or blood constituents from a blood bank authorised in accordance with Part 3 of Schedule 2;
 - (b) a product manufactured for administration under the cascade by a person and in premises authorised in accordance with Part 4 of Schedule 2; or
 - (c) equine stem cell products for use as an autologous treatment for horses from an equine collection centre authorised in accordance with Part 5 of Schedule 2.
- (4) Schedule 6 (exemptions for small pet animals) has effect.

Extent Information

E176 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Fees

16. Schedule 7 (fees) has effect.

PART 3

Records

Food-producing animals: proof of purchase of veterinary medicinal products

17. The keeper of a food-producing animal must keep proof of purchase of all veterinary medicinal products acquired for the animal (or, if they were not bought, documentary evidence of how they were acquired).

Food-producing animals: records of administration by a veterinary surgeon

18. A veterinary surgeon who administers a veterinary medicinal product to a food-producing animal must [^{F35}as soon as is reasonably practicable] either enter the following information personally in the keeper's records or give it to the keeper in writing (in which case the keeper must enter the following into those records)—

- (a) the name of the veterinary surgeon;
- (b) the name of the product and the batch number;
- (c) the date of administration of the product;
- (d) the amount of product administered;
- (e) the identification of the animals treated; and
- (f) the withdrawal period.

Textual Amendments

F35 Words in [reg. 18](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\), 11](#)

Food-producing animals: records of acquisition and administration

19.—(1) When a veterinary medicinal product is bought or otherwise acquired for a food-producing animal the keeper must, at the time, record—

- (a) the name of the product and the batch number;
- (b) the date of acquisition;
- (c) the quantity acquired; and
- (d) the name and address of the supplier.

(2) At the time of administration (unless the administration is by a veterinary surgeon in which case the record must be in accordance with regulation 18) the keeper must record—

- (a) the name of the product;
- (b) the date of administration;
- (c) the quantity administered;
- (d) the withdrawal period; and
- (e) the identification of the animals treated.

(3) A keeper who disposes of any or all of the veterinary medicinal product other than by treating an animal must record—

- (a) the date of disposal;
- (b) the quantity of product involved; and
- (c) how and where it was disposed of.

Food-producing animals: retention of records

20. The keeper of a food-producing animal must keep the documentation on the acquisition of a veterinary medicinal product and the records relating to the product for at least five years following the administration or other disposal of the product, irrespective of whether or not the animal concerned is no longer in that keeper's possession or has been slaughtered or has died during that period.

Records by a holder of a manufacturing authorisation E+W+S

21.—^{F36}(1) The holder of a manufacturing authorisation must record the following information in respect of any veterinary medicinal product supplied by the holder—

- (a) the name of the veterinary medicinal product and marketing authorisation number if applicable;
- (b) the pharmaceutical form and strength of the product;
- (c) the quantity of product supplied;
- (d) the batch number and expiry date;
- (e) the date of the transaction under which the product was supplied;
- (f) the company name and the permanent address or registered place of business of the recipient of the supply.]

(2) The holder must keep with the record all certification provided by the qualified person (manufacturer) in relation to that batch.

(3) The holder must keep all records and certificates for at least five years from the date the veterinary medicinal product is placed on the market ^{F37}or for one year after the date of expiry of the batch, whichever is the longer.].

Extent Information

- E7** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F36** Reg. 21(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **12(a)**
- F37** Words in reg. 21(3) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **12(b)**

Records by a holder of a manufacturing authorisation **N.I.**

21.—(1) A holder of a manufacturing authorisation must, as soon as is reasonably practicable, make a record of each batch of veterinary medicinal product manufactured, assembled or supplied, which must include—

- (a) the name of the product;
- (b) the quantity manufactured, assembled or supplied;
- (c) the date of manufacture, assembly or supply;
- (d) the batch number and expiry date; and
- (e) in the case of supply, the name and address of the recipient.

(2) The holder must keep with the record all certification provided by the qualified person (manufacture) in relation to that batch.

(3) The holder must keep all records and certificates for at least five years from the date the veterinary medicinal product is placed on the market.

Extent Information

- E177** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Records by a holder of a wholesale dealer's authorisation **E+W+S**

22. A holder of a wholesale dealer's authorisation must record the following as soon as is reasonably practicable after each incoming or outgoing transaction (including disposal) relating to a veterinary medicinal product—

- (a) the date ^{F38}... of the transaction,
- (b) the name of the veterinary medicinal product,
- [^{F39}(ba) the pharmaceutical form and strength of the product;]
- (c) the ^{F40}... batch number,
- (d) the expiry date,
- (e) the quantity, and
- [^{F41}(f) the company name and permanent address or registered place of business of—
 - (i) in respect of a purchase, the supplier, and
 - (ii) in respect of a sale, the recipient,]

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Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

and must keep the records for at least ^{F42}five years].

Extent Information

E8 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F38 Words in reg. 22(a) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **13(a)**

F39 Reg. 22(ba) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **13(b)**

F40 Word in reg. 22(c) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **13(c)**

F41 Reg. 22(f) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **13(d)**

F42 Words in reg. 22 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **13(e)**

Records by a holder of a wholesale dealer's authorisation **N.I.**

22. A holder of a wholesale dealer's authorisation must record the following as soon as is reasonably practicable after each incoming or outgoing transaction (including disposal) relating to a veterinary medicinal product—

- (a) the date and nature of the transaction,
- (b) the name of the veterinary medicinal product,
- (c) the manufacturer's batch number,
- (d) the expiry date,
- (e) the quantity, and
- (f) the name and address of the supplier or recipient,

and must keep the records for at least three years.

Extent Information

E178 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Records of the receipt or supply of prescription products **E+W+S**

23.—^{F43}(1) Any person permitted under these Regulations to supply a veterinary medicinal product classified as POM-V or POM-VPS or prescribed under the cascade who receives or supplies any such veterinary medicinal product must keep all documents relating to the transaction which show—

- (a) the date of the transaction under which the product was received or supplied;
- (b) the name of the veterinary medicinal product;
- (c) the pharmaceutical form and strength of the product;
- (d) the batch number;

- (e) the quantity of product received or supplied;
- (f) the company name and the permanent address or registered place of business of—
 - (i) in respect of a purchase, the supplier;
 - (ii) in respect of a sale, the recipient;
- (g) if there is a written prescription the name and contact details of the prescriber;
- (h) the expiry date.

(1A) Where the duty in paragraph (1) applies in respect of a veterinary medicinal product for a non-food producing animal, the duty in respect of sub-paragraph (d) is satisfied by recording the batch number—

- (a) on the date on which the batch is received, or
- (b) on the date on which a veterinary medicinal product from the batch is first supplied.]

(2) If the documents do not include this information that person must make a record of the missing information as soon as is reasonably practicable following the transaction.

(3) As an alternative to paragraphs (1) and (2) that person may make a record of all the information required there provided that this is done as soon as is reasonably practicable following the transaction.

(4) The documentation and records must be kept for at least five years.

Textual Amendments

F43 Reg. 23(1)(1A) substituted for reg. 23(1) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **14**

Records of the receipt or supply of prescription products **N.I.**

23.—(1) Any person permitted under these Regulations to supply a veterinary medicinal product classified as POM-V or POM-VPS who receives or supplies any such veterinary medicinal product must keep all documents relating to the transaction that show—

- (a) the date;
- (b) the name of the veterinary medicinal product;
- (c) the batch number (except that, in the case of a product for a non-food-producing animal, this need only be recorded either on the date of receipt of the batch or the date a veterinary medicinal product from the batch is first supplied);
- (d) the quantity;
- (e) the name and address of the supplier or recipient; and
- (f) if there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription.

(2) If the documents do not include this information that person must make a record of the missing information as soon as is reasonably practicable following the transaction.

(3) As an alternative to paragraphs (1) and (2) that person may make a record of all the information required there provided that this is done as soon as is reasonably practicable following the transaction.

(4) The documentation and records must be kept for at least five years.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Records of products administered to a food-producing animal under the cascade

24. A veterinary surgeon administering a veterinary medicinal product to food-producing animals under the cascade, or permitting another person to administer it under that veterinary surgeon's responsibility, must, as soon as is reasonably practicable, record—

- (a) the date of examination of the animals;
- (b) the name and address of the owner;
- (c) the identification and number of animals treated;
- (d) the result of the veterinary surgeon's clinical assessment;
- (e) the trade name of the product if there is one;
- (f) the manufacturer's batch number shown on the product if there is one;
- (g) the name and quantity of the active substances;
- (h) the doses administered or supplied;
- (i) the duration of treatment; and
- (j) the withdrawal period,

and must keep the record for at least five years.

[^{F44}Reporting of sales and usage data in relation to antibiotics

24A.—(1) Where the Secretary of State serves a notice in writing on any person mentioned in paragraph (2) requiring that person to provide any information held by that person in relation to sales and usage of antibiotics from any records made for the purposes of these Regulations the person must provide that information.

- (2) The persons are—
- (a) the holder of a manufacturing authorisation;
 - (b) the holder of a marketing authorisation;
 - (c) the holder of a wholesale dealer's authorisation;
 - (d) a keeper of food-producing animals;
 - (e) a feedingstuffs manufacturer;
 - (f) a veterinary surgeon.]

Textual Amendments

F44 Reg. 24A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 15

PART 4

Unauthorised veterinary medicinal products

Importation of an unauthorised veterinary medicinal product **E+W+S**

25.—(1) No person may import or be concerned in the importation of an unauthorised veterinary medicinal product except in accordance with this regulation.

(2) A holder of a marketing authorisation may import an unauthorised veterinary medicinal product if it is for the purpose of the manufacture of a veterinary medicinal product for which the importer holds the marketing authorisation.

(3) A holder of a manufacturing authorisation may import an unauthorised veterinary medicinal product if it is for the manufacture of a veterinary medicinal product that the importer is permitted to manufacture.

(4) A holder of a wholesale dealer's authorisation may import an unauthorised veterinary medicinal product for the purposes of re-export.

(5) A veterinary surgeon may import an unauthorised veterinary medicinal product that is authorised in another [^{F45}country] if it is for the purpose of administration by that veterinary surgeon or under that veterinary surgeon's responsibility under the cascade or administration in exceptional circumstances in accordance with Schedule 4; the import must be in accordance with the appropriate certificate granted by the Secretary of State, and the product may be imported by the veterinary surgeon personally or by using a wholesale dealer or pharmacist as an agent.

(6) A wholesale dealer or a pharmacist may import an unauthorised veterinary medicinal product for the purpose of storing it pending administration by a veterinary surgeon under the cascade or administration in exceptional circumstances in accordance with Schedule 4 if—

- (a) the veterinary medicinal product is authorised in another ^{F46}... country;
- (b) the Secretary of State has issued a certificate certifying that—
 - (i) the disease or condition is such that the veterinary medicinal product is likely to be needed as a matter of urgency for the treatment of an animal;
 - (ii) delay in administering the product will seriously affect the health or welfare of the animal; and
 - (iii) there is no suitable veterinary medicinal product authorised in [^{F47}Great Britain]; and
- (c) in the case of a wholesale dealer, the product is within the terms of the authorisation.

[^{F48}(6A) A pharmacist may supply a product to which paragraph (6) applies to a veterinary surgeon for the purposes mentioned in that paragraph notwithstanding paragraph 2(1) of Schedule 3.]

(7) The holder of an animal test certificate granted under paragraph 9 of Schedule 4 may import anything specified in the animal test certificate in accordance with the conditions in that certificate.

(8) The Secretary of State may authorise in writing the importation of any product or substance for use under a licence granted under the Animals (Scientific Procedures) Act 1986.

[^{F49}(9) For the purposes of this regulation, references to the import or importation of an unauthorised veterinary medical product include the movement of such a product into Great Britain from Northern Ireland.]

Extent Information

- E9** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F45** Word in reg. 25(5) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(4)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F46** Words in reg. 25(6)(a) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment](#)

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(4)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

- F47** Words in reg. 25(6)(b)(iii) substituted (E.W.S.) (31.12.2020) by **The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020** (S.I. 2020/1461), regs. 1(2)(b), **4(4)(a)**
- F48** Reg. 25(6A) inserted (E.W.S.) (17.5.2024) by **The Veterinary Medicines (Amendment etc.) Regulations 2024** (S.I. 2024/567), regs. 1(1), **16**
- F49** Reg. 25(9) inserted (E.W.S.) (31.12.2020) by **The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020** (S.I. 2020/1461), regs. 1(2)(b), **4(4)(b)**

Importation of an unauthorised veterinary medicinal product **N.I.**

25.—(1) No person may import or be concerned in the importation of an unauthorised veterinary medicinal product except in accordance with this regulation.

(2) A holder of a marketing authorisation may import an unauthorised veterinary medicinal product if it is for the purpose of the manufacture of a veterinary medicinal product for which the importer holds the marketing authorisation.

(3) A holder of a manufacturing authorisation may import an unauthorised veterinary medicinal product if it is for the manufacture of a veterinary medicinal product that the importer is permitted to manufacture.

(4) A holder of a wholesale dealer's authorisation may import an unauthorised veterinary medicinal product for the purposes of re-export.

(5) A veterinary surgeon may import an unauthorised veterinary medicinal product that is authorised in [^{F664}a] member State if it is for the purpose of administration by that veterinary surgeon or under that veterinary surgeon's responsibility under the cascade or administration in exceptional circumstances in accordance with Schedule 4; the import must be in accordance with the appropriate certificate granted by the Secretary of State, and the product may be imported by the veterinary surgeon personally or by using a wholesale dealer or pharmacist as an agent.

(6) A wholesale dealer or a pharmacist may import an unauthorised veterinary medicinal product for the purpose of storing it pending administration by a veterinary surgeon under the cascade or administration in exceptional circumstances in accordance with Schedule 4 if—

- (a) the veterinary medicinal product is authorised in [^{F665}a] member State or a third country;
- (b) the Secretary of State has issued a certificate certifying that—
 - (i) the disease or condition is such that the veterinary medicinal product is likely to be needed as a matter of urgency for the treatment of an animal;
 - (ii) delay in administering the product will seriously affect the health or welfare of the animal; and
 - (iii) there is no suitable veterinary medicinal product authorised in [^{F666}Northern Ireland]; and
- (c) in the case of a wholesale dealer, the product is within the terms of the authorisation.

(7) The holder of an animal test certificate granted under paragraph 9 of Schedule 4 may import anything specified in the animal test certificate in accordance with the conditions in that certificate.

(8) The Secretary of State may authorise in writing the importation of any product or substance for use under a licence granted under the Animals (Scientific Procedures) Act 1986.

[^{F667}(9) For the purpose of this regulation, references to import or importation of an unauthorised veterinary medicinal product include the movement of such a product from Great Britain to Northern Ireland.]

Extent Information

E179 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F664** Word in reg. 25(5) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(5)(a)**
- F665** Word in reg. 25(6)(a) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(5)(a)**
- F666** Words in reg. 25(6)(b)(iii) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(5)(b)**
- F667** Reg. 25(9) inserted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(5)(c)**

Possession of an unauthorised veterinary medicinal product **E+W+S**

- 26.**—(1) No person may be in possession of an unauthorised veterinary medicinal product.
- (2) No person may be in possession of an unauthorised veterinary medicinal product with the intention of supplying that product to another person.
- (3) This regulation does not apply to—
- a veterinary medicinal product imported in accordance with a certificate granted by the Secretary of State under these Regulations;
 - a product prescribed by a veterinary surgeon under the cascade;
 - a holder of a manufacturing authorisation if the possession is for export;
 - a holder of a wholesale dealer’s authorisation if the possession is for export or re-export; or
 - a holder of a manufacturer’s authorisation or marketing authorisation if the intention is to manufacture a veterinary medicinal product.
- (4) A veterinary surgeon who practises in both [^{F50}Great Britain] and another [^{F51}country] may hold veterinary medicinal products authorised in the other [^{F51}country] provided that the amount held does not exceed the amount expected to be used in that [^{F51}country].
- (5) It is a defence for a person charged with failing to comply with paragraph (1) to prove that the product was for the purposes of research or development of a veterinary medicinal product.
- (6) A veterinary surgeon may have possession of an authorised human medicinal product intended for administration to animals under the cascade, provided that the amount held does not exceed the amount expected to be used under the cascade.

Extent Information

E10 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Textual Amendments

- F50** Words in [reg. 26\(4\)](#) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(b), **4(5)**
- F51** Word in [reg. 26\(4\)](#) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(5)** (as amended by [S.I. 2020/1461](#), regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Possession of an unauthorised veterinary medicinal product **N.I.**

26.—(1) No person may be in possession of an unauthorised veterinary medicinal product.

(2) No person may be in possession of an unauthorised veterinary medicinal product with the intention of supplying that product to another person.

(3) This regulation does not apply to—

- (a) a veterinary medicinal product imported in accordance with a certificate granted by the Secretary of State under these Regulations;
- (b) a product prescribed by a veterinary surgeon under the cascade;
- (c) a holder of a manufacturing authorisation if the possession is for export;
- (d) a holder of a wholesale dealer’s authorisation if the possession is for export or re-export; or
- (e) a holder of a manufacturer’s authorisation or marketing authorisation if the intention is to manufacture a veterinary medicinal product.

[^{F668}(4) A veterinary surgeon who practices in Northern Ireland and a member State may hold veterinary medicinal products authorised in the member State provided that the amount held does not exceed the amount expected to be used in that member State.]

(5) It is a defence for a person charged with failing to comply with paragraph (1) to prove that the product was for the purposes of research or development of a veterinary medicinal product.

(6) A veterinary surgeon may have possession of an authorised human medicinal product intended for administration to animals under the cascade, provided that the amount held does not exceed the amount expected to be used under the cascade.

Extent Information

- E180** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F668** [Reg. 26\(4\)](#) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(6)**

Supply of an unauthorised veterinary medicinal product

27.—(1) No person may supply an unauthorised veterinary medicinal product.

(2) This regulation does not apply to—

- (a) a veterinary medicinal product prescribed by a veterinary surgeon under the cascade; or
- (b) a product supplied in accordance with a certificate granted by the Secretary of State under these Regulations.

(3) It is a defence for a person charged with failing to comply with paragraph (1) to prove that the supply was for the purposes of research or development of a veterinary medicinal product.

PART 5

Miscellaneous provisions, enforcement and offences

The Veterinary Products Committee

28.—(1) There shall continue to be a Veterinary Products Committee.

(2) The Secretary of State may appoint members of the Committee from professional people who are eminent in their field, and any lay members as the Secretary of State sees fit.

(3) The function of the Committee is to provide scientific advice on any aspect of veterinary medicinal products asked for by the Secretary of State and to carry out any functions specified in these Regulations.

(4) The Secretary of State may pay members of the Committee such amounts as the Secretary of State may decide.

(5) The Secretary of State may consult the Committee at any time.

Veterinary Products Committee appeals procedure

29.—(1) The following procedure applies when any person receives a notification from the Secretary of State informing that person (the appellant) of a right to an appeal to the Veterinary Products Committee.

(2) The appellant must inform the Secretary of State of an intention to appeal within 28 days of the notification which is the subject of the appeal.

(3) The appeal may be written or oral, or both, at the choice of the appellant.

(4) The appellant may not present to the Committee any new data not available to the Secretary of State at the time of the original decision.

(5) The Committee must consider the appeal and any representations made by the Secretary of State, and report its findings in writing to the Secretary of State together with its recommendations.

(6) The Secretary of State must send a copy of the report to the appellant on request.

(7) The Secretary of State must consider the report and then form a provisional decision.

(8) The Secretary of State must then notify the provisional decision to the appellant, together with the reasons for it.

Appeals to an appointed person **E+W+S**

30.—(1) A person aggrieved by a provisional decision of the Secretary of State under regulation 29 [^{F52}or a body aggrieved by a decision to suspend or revoke its recognition under paragraph 14(1) of Schedule 3] may appeal against the decision to a person appointed for the purpose by the Secretary of State in accordance with this regulation.

(2) So may an applicant for—

(a) a manufacturing authorisation;

[^{F53}(aa) a variation to a manufacturing authorisation;]

(b) appointment as a Qualified Person for the purposes of a manufacturing authorisation;

(c) authorisation for a person or premises to manufacture autogenous vaccines;

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (d) an authorisation of a blood bank;
 - (e) authorisation of a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade;
 - (f) authorisation of [^{F54}a stem cell centre];
 - (g) a wholesale dealer's authorisation;
 - [^{F55}(ga) registration in relation to active substances]
 - (h) the [^{F56}authorisation] of premises for the supply of POM-VPS or NFA-VPS veterinary medicinal products by a suitably qualified person,
- if such an application is refused.
- (3) A holder of any of the above authorisations [^{F57}or appointments] may appeal against a suspension [^{F58}, revocation] or compulsory variation in the same way.
- (4) The appointed person must consider the appeal (but may not consider any new data not available to the Secretary of State at the time of the original decision) and any representations made by the Secretary of State and report in writing, with a recommended course of action, to the Secretary of State.
- (5) The Secretary of State must then reach a final decision and notify the appellant, together with the reasons for it.

Extent Information

- E11** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F52** Words in reg. 30(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **17(a)**
- F53** Reg. 30(2)(aa) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **17(b)(i)**
- F54** Words in reg. 30(2)(f) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **17(b)(ii)**
- F55** Reg. 30(2)(ga) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **17(b)(iii)**
- F56** Word in reg. 30(2)(h) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **17(b)(iv)**
- F57** Words in reg. 30(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **17(c)(i)**
- F58** Word in reg. 30(3) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **17(c)(ii)**

Appeals to an appointed person **N.I.**

30.—(1) A person aggrieved by a provisional decision of the Secretary of State under regulation 29 may appeal against the decision to a person appointed for the purpose by the Secretary of State in accordance with this regulation.

- (2) So may an applicant for—
- (a) a manufacturing authorisation;
 - (b) appointment as a Qualified Person for the purposes of a manufacturing authorisation;

- (c) authorisation for a person or premises to manufacture autogenous vaccines;
- (d) an authorisation of a blood bank;
- (e) authorisation of a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade;
- (f) authorisation of an equine stem cell centre;
- (g) a wholesale dealer's authorisation;
- (h) the approval of premises for the supply of POM-VPS or NFA-VPS veterinary medicinal products by a suitably qualified person,

if such an application is refused.

(3) A holder of any of the above authorisations, appointment or approvals may appeal against a suspension or compulsory variation in the same way.

(4) The appointed person must consider the appeal (but may not consider any new data not available to the Secretary of State at the time of the original decision) and any representations made by the Secretary of State and report in writing, with a recommended course of action, to the Secretary of State.

(5) The Secretary of State must then reach a final decision and notify the appellant, together with the reasons for it.

Extent Information

E181 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Exports **E+W+S**

31.—(1) No person may export a veterinary medicinal product for use in another [^{F59}country] unless the veterinary medicinal product may be lawfully supplied or administered in that [^{F59}country].

(2) If a veterinary medicinal product has been manufactured in accordance with a marketing authorisation, or if a product without a marketing authorisation has been manufactured under a manufacturing authorisation, and the product is intended for export ^{F60}..., the Secretary of State must, at the request of the exporter or the competent authorities of the country to which it is being exported, provide a certificate [^{F61}that (as the case may be)—

- (a) the manufacturer holds a manufacturing authorisation;
- (b) the manufacturer holds a certificate of good manufacturing practice; or
- (c) the product has been marketed under a marketing authorisation].

(3) When issuing the certificate the Secretary of State must take account of [^{F62}any relevant administrative arrangements in relation to the form and content of such certificates which are in existence between the United Kingdom and the country to which the product is to be exported].

(4) If the veterinary medicinal product is authorised in the United Kingdom the Secretary of State must ensure that the exporter or the competent authorities of the [^{F63}importing] country has access to the summary of product characteristics.

Extent Information

E12 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

- F59** Word in reg. 31(1) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(6)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F60** Word in reg. 31(2) omitted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(6)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F61** Words in reg. 31(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024](#) (S.I. 2024/567), regs. 1(1), **18(a)**
- F62** Words in reg. 31(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024](#) (S.I. 2024/567), regs. 1(1), **18(b)**
- F63** Word in reg. 31(4) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(6)(c)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Exports **N.I.**

31.—(1) No person may export a veterinary medicinal product for use in another [^{F669}country] unless the veterinary medicinal product may be lawfully supplied or administered in that [^{F669}country].

(2) If a veterinary medicinal product has been manufactured in accordance with a marketing authorisation, or if a product without a marketing authorisation has been manufactured under a manufacturing authorisation, and the product is intended for export outside the European Union, the Secretary of State must, at the request of the exporter or the competent authorities of the country to which it is being exported, provide a certificate to that effect.

(3) When issuing the certificate the Secretary of State must take account of the model certificates issued by the World Health Organization(**14**).

(4) If the veterinary medicinal product is authorised in the United Kingdom the Secretary of State must ensure that the exporter or the competent authorities of the third country has access to the summary of product characteristics.

Extent Information

- E182** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F669** Word in reg. 31(1) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(7)**

Time limits

32.—(1) In any provision in these Regulations requiring the Secretary of State to issue an authorisation within a set time, the clock does not start to run until the Secretary of State has checked that the application dossier is in accordance with these Regulations and has validated the application.

(2) In calculating the period during which the Secretary of State must issue any authorisation requires the clock is stopped when the Secretary of State requires an applicant to provide further data until all the further data required have been provided.

(3) The clock is also stopped during any period that the applicant is given to provide oral or written explanations [^{F64}or to provide any sample].

(4) The Secretary of State may stop the clock pending payment of outstanding fees.

Textual Amendments

F64 Words in [reg. 32\(3\)](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\), 19](#)

Appointment of inspectors

33. The Secretary of State must appoint inspectors for the purposes of the enforcement of these Regulations and in these Regulations “inspector” means an inspector appointed under this regulation or a veterinary inspector appointed under the Animal Health Act 1981(15).

Powers of entry **E+W+S**

34.—(1) An inspector may, on giving reasonable notice, and on producing a duly authenticated authorisation if required, enter any premises at any reasonable hour for the purpose of ensuring that the provisions of these Regulations are being complied with; and in this regulation “premises” includes any place, vehicle, trailer, container, stall, moveable structure, ship or aircraft.

(2) The requirement to give notice does not apply—

- (a) where the entry is pursuant to any provision of an [^{F65}enactment] which requires inspection without notice;
- (b) where the requirement has been waived;
- (c) where reasonable efforts to agree an appointment have failed;
- (d) where an inspector has reasonable suspicion of a failure to comply with these Regulations; or
- (e) in an emergency.

(3) Paragraph (1) does not apply in relation to any premises which are used wholly or mainly as a private dwelling, unless those premises, or any part of them, are ^{F66}... registered or authorised for the sale of veterinary medicines under paragraph 8, 10, 14(4) or 18 of Schedule 3 or for use as a feed business under paragraph 5(2)(e) or 7(2) of Schedule 5.

(4) Paragraphs (1) and (3) do not affect any right of entry conferred by a warrant issued by a justice of the peace.

[^{F67}(5) An inspector may be accompanied by such other persons as the inspector considers necessary.]

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(6) If a justice of the peace, on sworn information in writing, is satisfied that there are reasonable grounds for entry into any premises for the purposes of the enforcement of these Regulations, and either—

- (a) admission has been refused, or a refusal is expected, and (in either case) that notice to apply for a warrant has been given to the occupier;
- (b) asking for admission, or the giving of such a notice, would defeat the object of the entry;
- (c) the case is one of urgency; or
- (d) the premises are unoccupied or the occupier is temporarily absent,

the justice may by signed warrant authorise an inspector to enter the premises, if need be by reasonable force.

(7) A warrant under this regulation is valid for one month.

(8) An inspector who enters any unoccupied premises must leave them as effectively secured against unauthorised entry as they were before entry.

(9) An inspector may enter the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and the premises of the marketing authorisation holder.

^{F68}(10)

(11) In this regulation, a reference to a justice of the peace —

- (a) in Scotland includes a reference to the sheriff and to a magistrate; and
- (b) in Northern Ireland, is a reference to a lay magistrate.

Extent Information

E13 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F65** Word in reg. 34(2)(a) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(7)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F66** Word in reg. 34(3) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **20**
- F67** Reg. 34(5) substituted (E.W.S) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(7)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F68** Reg. 34(10) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(7)(c)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Powers of entry **N.I.**

34.—(1) An inspector may, on giving reasonable notice, and on producing a duly authenticated authorisation if required, enter any premises at any reasonable hour for the purpose of ensuring that the provisions of these Regulations are being complied with; and in this regulation “premises” includes any place, vehicle, trailer, container, stall, moveable structure, ship or aircraft.

(2) The requirement to give notice does not apply—

- (a) where the entry is pursuant to any provision of an EU instrument which requires inspection without notice;
- (b) where the requirement has been waived;
- (c) where reasonable efforts to agree an appointment have failed;
- (d) where an inspector has reasonable suspicion of a failure to comply with these Regulations;
or
- (e) in an emergency.

(3) Paragraph (1) does not apply in relation to any premises which are used wholly or mainly as a private dwelling, unless those premises, or any part of them, are approved, registered or authorised for the sale of veterinary medicines under paragraph 8, 10, 14(4) or 18 of Schedule 3 or for use as a feed business under paragraph 5(2)(e) or 7(2) of Schedule 5.

(4) Paragraphs (1) and (3) do not affect any right of entry conferred by a warrant issued by a justice of the peace.

(5) An inspector may be accompanied by—

- (a) such other persons as the inspector considers necessary; ^{F670} ...

^{F670}(b)

(6) If a justice of the peace, on sworn information in writing, is satisfied that there are reasonable grounds for entry into any premises for the purposes of the enforcement of these Regulations, and either—

- (a) admission has been refused, or a refusal is expected, and (in either case) that notice to apply for a warrant has been given to the occupier;
- (b) asking for admission, or the giving of such a notice, would defeat the object of the entry;
- (c) the case is one of urgency; or
- (d) the premises are unoccupied or the occupier is temporarily absent,

the justice may by signed warrant authorise an inspector to enter the premises, if need be by reasonable force.

(7) A warrant under this regulation is valid for one month.

(8) An inspector who enters any unoccupied premises must leave them as effectively secured against unauthorised entry as they were before entry.

(9) An inspector may enter the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and the premises of the marketing authorisation holder.

(10) An inspector may carry out an inspection at the request of [^{F671}a] member State, the European Commission or the Agency.

[^{F672}(11) In this regulation, a reference to justice of the peace is a reference to a lay magistrate.]

Extent Information

E183 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F670 Reg. 34(5)(b) and word omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs., 1(3), 10(8(a))

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

F671 Word in reg. 34(10) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(8)(b)**

F672 Reg. 34(11) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(8)(c)**

Powers of an inspector **E+W+S**

- 35.**—(1) An inspector entering premises under the previous regulation may—
- (a) inspect the premises, and any plant, machinery or equipment;
 - (b) search the premises;
 - (c) take samples;
 - ^[F69](ca) purchase prescription only veterinary medicines for the purpose of carrying out tests;
 - (cb) verify the destruction of a controlled drug listed in Schedule 2, 3 or 4 of the Misuse of Drugs Regulations 2001;]
 - (d) seize any computers and associated equipment;
 - (e) seize any veterinary medicinal product or any additive to which Schedule 5 applies, if it is not authorised in the United Kingdom;
 - (f) seize any ^[F70]intermediate feedingstuff] or feedingstuff that contains a veterinary medicinal product or additive to which Schedule 5 applies that is not authorised in the United Kingdom;
 - (g) seize any veterinary medicinal product, any additive to which Schedule 5 applies, any ^[F71]intermediate feedingstuff] or feedingstuff if—
 - (i) it has not been lawfully manufactured, incorporated or supplied in accordance with these Regulations;
 - (ii) it has been stored in a way that affects its safety, quality or efficacy; or
 - (iii) it is sold or offered for sale by a person not permitted to supply it under these Regulations;
 - (h) carry out any inquiries, examinations and tests;
 - (i) have access to, and inspect and copy or seize any documents or records (in whatever form they are held) relating to these Regulations; and
 - (j) have access to, inspect and check the operation of any computer and any associated apparatus or material that is or has been in use in connection with the records; and for this purpose may require any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material to afford such assistance as may reasonably be required and, where a record is kept by means of a computer, may require the records to be produced in a form in which they may be taken away.
- ^[F72](2) The inspector may seize and retain an item appearing to the inspector to be an item mentioned in paragraph (1)(d) to (g) if the inspector reasonably believes that an offence under these Regulations is being or has been committed in relation to, or by means of, that item]
- (3) An officer of any local authority who has entered premises exercising any statutory power of entry for the purposes of enforcing any legislation relating to food hygiene, feed hygiene or animal health, may inspect any records made under these Regulations (in whatever form they are held) relating to food-producing animals, and may remove them to enable them to be copied.

(4) Where an inspector has entered any premises and it is not reasonably practicable to determine at the time whether documents on those premises are relevant to these Regulations, the inspector may seize them to ascertain whether or not they are relevant.

Extent Information

E14 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F69 Reg. 35(1)(ca)(cb) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **21(a)(i)**

F70 Words in reg. 35(1)(f) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **21(a)(ii)**

F71 Words in reg. 35(1)(g) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **21(a)(iii)**

F72 Reg. 35(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **21(b)**

Powers of an inspector **N.I.**

- 35.—**(1) An inspector entering premises under the previous regulation may—
- (a) inspect the premises, and any plant, machinery or equipment;
 - (b) search the premises;
 - (c) take samples;
 - (d) seize any computers and associated equipment;
 - (e) seize any veterinary medicinal product or any additive to which Schedule 5 applies, if it is not authorised in the United Kingdom;
 - (f) seize any premixture or feedingstuff that contains a veterinary medicinal product or additive to which Schedule 5 applies that is not authorised in the United Kingdom;
 - (g) seize any veterinary medicinal product, any additive to which Schedule 5 applies, any premixture or feedingstuff if—
 - (i) it has not been lawfully manufactured, incorporated or supplied in accordance with these Regulations;
 - (ii) it has been stored in a way that affects its safety, quality or efficacy; or
 - (iii) it is sold or offered for sale by a person not permitted to supply it under these Regulations;
 - (h) carry out any inquiries, examinations and tests;
 - (i) have access to, and inspect and copy or seize any documents or records (in whatever form they are held) relating to these Regulations; and
 - (j) have access to, inspect and check the operation of any computer and any associated apparatus or material that is or has been in use in connection with the records; and for this purpose may require any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material to afford such assistance as may reasonably be required and, where a record is kept by means of a computer, may require the records to be produced in a form in which they may be taken away.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(2) The powers of seizure under sub-paragraph (1)(e), (f) and (g) include a power to seize anything which purports to be, or which an inspector reasonably believes to be, something the inspector is entitled to seize under these powers.

(3) An officer of any local authority who has entered premises exercising any statutory power of entry for the purposes of enforcing any legislation relating to food hygiene, feed hygiene or animal health, may inspect any records made under these Regulations (in whatever form they are held) relating to food-producing animals, and may remove them to enable them to be copied.

(4) Where an inspector has entered any premises and it is not reasonably practicable to determine at the time whether documents on those premises are relevant to these Regulations, the inspector may seize them to ascertain whether or not they are relevant.

Extent Information

E184 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Inspection of pharmacies

36. In relation to a pharmacy, all the powers of an inspector to enforce these Regulations may also be exercised by an officer of the General Pharmaceutical Council appointed for the purpose.

Obstruction

37. No person may—

- (a) intentionally obstruct any person acting in the execution of these Regulations;
- (b) without reasonable cause, fail to give to any person acting in the execution of these Regulations any assistance or information that that person may reasonably require under these Regulations;
- (c) furnish to any person acting in the execution of these Regulations any information knowing it to be false or misleading; or
- (d) fail to produce a record when required to do so to any person acting in the execution of these Regulations.

Improvement notices

38.—(1) An inspector who has reasonable grounds for believing that any person is failing to comply with these Regulations may serve a notice on that person (in these Regulations referred to as an “improvement notice”) that—

- (a) states the inspector’s grounds for believing this;
- (b) specifies the matters that constitute the failure to comply;
- (c) specifies the measures that, in the inspector’s opinion, the person must take in order to secure compliance; and
- (d) requires the person to take those measures, or measures at least equivalent to them, within the period (being not less than 14 days) specified in the notice.

[^{F73}(1A) If the inspector considers that the matters constituting a person’s perceived failure to comply involve risks to animal or human health or of damage to the environment which are so serious that, until steps have been taken to reduce or remove that failure, one or more activity carried on by the person ought to be prohibited or restricted, the improvement notice must state—

- (a) the activity which is to be prohibited or restricted;
- (b) the reasons why such prohibition or restriction is considered appropriate;
- (c) the time and date at which the prohibition or restriction is to take effect (which may be immediately after the notice is served);
- (d) that the person must not carry out the activity in breach of the prohibition or restriction until—
 - (i) that person has provided evidence to the inspector that measures have been undertaken to secure compliance, and
 - (ii) the inspector has confirmed to that person that the notice is revoked.

(1B) Where the person on whom an improvement notice to which paragraph (1A) applies has been served provides evidence to the inspector that the measures specified in the notice (or measures at least equivalent to them) have been undertaken to secure compliance, and the inspector is satisfied that the measures have been satisfactorily performed, the inspector must revoke the notice and inform the person of this.]

- (2) An improvement notice must state—
 - (a) the right of appeal to a magistrates' court or to the sheriff; and
 - (b) the period within which such an appeal may be brought.

Textual Amendments

F73 Reg. 38(1A)(1B) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **22**

Appeals against improvement notices **E+W+S**

39.—(1) Any person who is aggrieved by an improvement notice may appeal to a magistrates' court or, in Scotland, to the sheriff.

(2) The procedure on an appeal to a magistrates' court under paragraph (1) is by way of complaint, and the Magistrates' Courts Act 1980(16) applies to the proceedings.

(3) An appeal to the sheriff under paragraph (1) is by summary application.

(4) The period within which an appeal may be brought is 28 days or the period specified in the improvement notice, whichever ends the earlier.

(5) A court may suspend an improvement notice pending an appeal.

Extent Information

E15 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Appeals against improvement notices **N.I.**

39.—(1) Any person who is aggrieved by an improvement notice may appeal to a magistrates' court ^{F673}....

(16) 1980 c. 43; sections 51 and 52 have been substituted by the Courts Act 2003 (c.39), section 47.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(2) The procedure on an appeal to a magistrates' court under paragraph (1) is by way of complaint, and the Magistrates' Courts Act 1980(16) applies to the proceedings.

^{F674}(3)

(4) The period within which an appeal may be brought is 28 days or the period specified in the improvement notice, whichever ends the earlier.

(5) A court may suspend an improvement notice pending an appeal.

Extent Information

E185 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F673 Words in [reg. 39\(1\)](#) omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), [regs. 1\(3\)](#), [10\(9\)\(a\)](#)

F674 [Reg. 39\(3\)](#) omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), [regs. 1\(3\)](#), [10\(9\)\(b\)](#)

Powers of a court on appeal

40. On an appeal against an improvement notice, the court may either cancel the notice or confirm it, with or without modification.

Seizure notices **E+W+S**

41.—(1) An inspector must follow the procedures set out in this regulation when seizing anything under these Regulations.

(2) The inspector must serve on the person appearing to be in charge of the seized [^{F74}item] a notice (referred to in these Regulations as a “seizure notice”)—

- (a) giving the grounds for seizing the [^{F74}item]; and
- (b) informing that person of the rights under this regulation to make a claim, and the address for the service of the claim.

(3) An inspector who is not able to remove [^{F75}items] seized immediately may mark the [^{F75}items] in any way, and serve a notice on the person in charge of the [^{F75}items] identifying them, and prohibiting the removal of the [^{F75}items] from the premises until they are collected by an inspector, and no person other than an inspector may remove [^{F75}items] identified under this paragraph from the premises.

(4) The person on whom the seizure notice was served or the owner of the seized [^{F76}item] may, within 28 days of seizure, notify any claim that the [^{F76}item] was not liable to seizure to the Secretary of State at the address specified in the seizure notice, setting out the grounds in full.

(5) If a notification of a claim is not received within 28 days, the Secretary of State may destroy the [^{F77}item].

(16) 1980 c. 43; sections 51 and 52 have been substituted by the Courts Act 2003 (c.39), section 47.

(6) If a notification of a claim is received within 28 days, then, unless the [F78: item] seized is being held for the purposes of pending or contemplated criminal proceedings, or for a criminal investigation, the Secretary of State must either return the [F78: item] or take proceedings for an order for the confirmation of the seizure notice and the destruction of the [F79: item] in a magistrates' court (or, in Scotland, the sheriff court), and if the court confirms the notice it must order its destruction.

(7) The procedure in a magistrates' court under this regulation is by way of complaint, and the Magistrates' Courts Act 1980 applies to the proceedings.

(8) The procedure before the sheriff is by summary application.

(9) The person on whom the seizure notice was served is liable for the costs of transport, storage for up to 28 days and destruction of the [F80: item] seized unless a claim is made to a court and the court directs otherwise.

Extent Information

E16 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F74 Word in reg. 41(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **23(a)**

F75 Word in reg. 41(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **23(b)**

F76 Word in reg. 41(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **23(c)**

F77 Word in reg. 41(5) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **23(d)**

F78 Word in reg. 41(6) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **23(e)(ii)**

F79 Word in reg. 41(6) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **23(e)(i)**

F80 Word in reg. 41(9) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **23(f)**

Seizure notices **N.I.**

41.—(1) An inspector must follow the procedures set out in this regulation when seizing anything under these Regulations.

(2) The inspector must serve on the person appearing to be in charge of the seized product a notice (referred to in these Regulations as a “seizure notice”)—

- (a) giving the grounds for seizing the product; and
- (b) informing that person of the rights under this regulation to make a claim, and the address for the service of the claim.

(3) An inspector who is not able to remove products seized immediately may mark the products in any way, and serve a notice on the person in charge of the products identifying them, and prohibiting the removal of the products from the premises until they are collected by an inspector, and no person other than an inspector may remove products identified under this paragraph from the premises.

(4) The person on whom the seizure notice was served or the owner of the seized product may, within 28 days of seizure, notify any claim that the product was not liable to seizure to the Secretary of State at the address specified in the seizure notice, setting out the grounds in full.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(5) If a notification of a claim is not received within 28 days, the Secretary of State may destroy the product.

(6) If a notification of a claim is received within 28 days, then, unless the product seized is being held for the purposes of pending or contemplated criminal proceedings, or for a criminal investigation, the Secretary of State must either return the product or take proceedings for an order for the confirmation of the seizure notice and the destruction of the veterinary medicinal product in a magistrates' court ^{F675}..., and if the court confirms the notice it must order its destruction.

(7) The procedure in a magistrates' court under this regulation is by way of complaint, and the Magistrates' Courts Act 1980 applies to the proceedings.

^{F676}(8)

(9) The person on whom the seizure notice was served is liable for the costs of transport, storage for up to 28 days and destruction of the product seized unless a claim is made to a court and the court directs otherwise.

Extent Information

E186 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F675 Words in [reg. 41\(6\)](#) omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(10)(a)**

F676 [Reg. 41\(8\)](#) omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(10)(b)**

Publication

42.—(1) The Secretary of State must publicise all improvement notices and seizure notices issued under these Regulations and the suspension or revocation of anything issued under these Regulations, and may do so in such manner as the Secretary of State sees fit.

(2) This does not apply in relation to a seizure notice issued to a common carrier who does not own the seized goods.

Offence **E+W+S**

43. It is an offence⁽¹⁷⁾ to fail to comply with—

- (a) regulation 4(1) or (2);
- (b) regulation 5(1);
- (c) regulation 7(2), (3), (4) or (5);
- (d) regulation 8;
- (e) regulation 9(1);
- (f) regulation 10^[F81](1), (1A)] or (2);

^[F82](fa) regulation 10A(1), (3) or (5);]

(17) Other offences are set out at the end of Schedules 1, 2, 3, 4 and 5.

- (g) regulation 11(1) [^{F83}or (4) or (6)];
- (h) regulation 13;
- (i) regulation 17;
- (j) regulation 18
- (k) regulation 19
- (l) regulation 20
- (m) regulation 21
- (n) regulation 22
- (o) regulation 23
- (p) regulation 24;
- [^{F84}(pa) regulation 24A(1)]
- (q) regulation 25(1);
- (r) regulation 26(1), (2) or (6);
- (s) regulation 27(1);
- (t) regulation 31(1);
- (u) regulation 37;
- (v) an improvement notice issued under regulation 38; or
- (w) regulation 41(3).

Textual Amendments

- F81** Words in [reg. 43\(f\)](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), [24\(a\)](#)
- F82** [Reg. 43\(fa\)](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), [24\(b\)](#)
- F83** Words in [reg. 43\(g\)](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), [24\(c\)](#)
- F84** [Reg. 43\(pa\)](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), [24\(d\)](#)

Offence **N.I.**

- 43.** It is an offence(17) to fail to comply with—
- (a) regulation 4(1) or (2);
 - (b) regulation 5(1);
 - (c) regulation 7(2), (3), (4) or (5);
 - (d) regulation 8;
 - (e) regulation 9(1);
 - (f) regulation 10(1) or (2);
 - (g) regulation 11(1);
 - (h) regulation 13;

(17) Other offences are set out at the end of Schedules 1, 2, 3, 4 and 5.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (i) regulation 17;
- (j) regulation 18
- (k) regulation 19
- (l) regulation 20
- (m) regulation 21
- (n) regulation 22
- (o) regulation 23
- (p) regulation 24;
- (q) regulation 25(1);
- (r) regulation 26(1), (2) or (6);
- (s) regulation 27(1);
- (t) regulation 31(1);
- (u) regulation 37;
- (v) an improvement notice issued under regulation 38; or
- (w) regulation 41(3).

Penalties

44.—(1) [^{F85}As regards England and Wales,] A person guilty of an offence under these Regulations is liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding six months or both, or
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.

[^{F86}(1A) As regards Scotland, a person guilty of an offence under these Regulations is liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding 12 months or both, or
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.]

(2) Where a body corporate is guilty of an offence under these Regulations, and that offence is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of—

- (a) a qualified person appointed as such for the purposes of these Regulations;
- (b) any director, manager, secretary or other similar person of the body corporate; or
- (c) any person who was purporting to act in any such capacity,

that person is guilty of the offence as well as the body corporate.

(3) If an offence under these Regulations committed by a partnership is shown—

- (a) to have been committed with the consent or connivance of a partner; or
- (b) to be attributable to any neglect on their part,

the partner as well as the partnership is guilty of the offence and liable to be proceeded against and punished accordingly.

(4) For the purposes of paragraph (2) above, “director”, in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

(5) Where an offence that has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner, the partner as well as the partnership is guilty of the offence.

Textual Amendments

- F85** Words in [reg. 44\(1\)](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), **25(a)**
- F86** [Reg. 44\(1A\)](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\)](#), **25(b)**

Northern Ireland **E+W+S**

^{F87}**45.**

Textual Amendments

- F87** [Reg. 45](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), [regs. 1\(2\)\(b\)](#), **4(6)**

Northern Ireland **N.I.**

45.—(1) This regulation has effect in relation to the enforcement of these Regulations in Northern Ireland.

(2) The Department of Agriculture and Rural Development or the Department of Health, Social Services and Public Safety (or both Departments acting jointly) instead of the Secretary of State exercise the powers of the Secretary of State in—

- (a) regulation 33 (appointment of inspectors);
- (b) regulation 41 (seizure notices);
- (c) regulation 42 (publication); and
- (d) sub-paragraph (4) of paragraph 14 of Schedule 3 (approval of premises for suitably qualified persons).

(3) The Department of Agriculture and Rural Development is the competent authority for—

- [^{F677}(a) Regulation [\(EC\) No 178/2002](#)];
- [^{F678}(b) Regulation [\(EC\) No 1831/2003](#)];
- [^{F679}(c) Regulation [\(EU\) 2017/625](#); and]
- [^{F680}(d) Regulation [\(EC\) No 183/2005](#).]

(4) In relation to pharmacies, an officer of the Pharmaceutical Society of Northern Ireland appointed by the Society for the purpose has all the powers of an inspector to enforce these Regulations.

(5) In proceedings in a magistrates' court relating to an improvement notice under regulation 38 or a seizure notice under regulation 41, the Magistrates' Courts (Northern Ireland) Order 1981(**18**) applies.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Extent Information

E187 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F677 Reg. 45(3)(a) substituted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(a), **2(3)(a)**

F678 Reg. 45(3)(b) substituted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(a), **2(3)(b)**

F679 Reg. 45(3)(c) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(11)**; and substituted (N.I.) (31.12.2020) by [The Official Controls \(Animals, Feed and Food, Plant Health etc.\) \(Amendment\) \(EU Exit\) \(No. 2\) Regulations 2020 \(S.I. 2020/1631\)](#), regs. 1(2), **3(3)**

F680 Reg. 45(3)(d) substituted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(a), **2(3)(d)**

Review **E+W+S**

46.—(1) Before the end of each review period, the Secretary of State must—

- (a) carry out a review of these Regulations other than the fees provisions;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

^{F88}(2)

^{F89}(3)

(4) The report must in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations, other than the fees provisions;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(5) In this regulation—

- (a) “review period” means the period of five years [^{F90}ending on 31st December 2028], and, subject to paragraph (6), each successive period of five years thereafter; and
- (b) “the fees provisions” means regulation 16 and Schedule 7.

(6) If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

Extent Information

E17 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F88** Reg. 46(2) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **26(a)**
- F89** Reg. 46(3) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **26(a)**
- F90** Words in reg. 46(5) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **26(b)**

Review **N.I.**

46.—(1) Before the end of each review period, the Secretary of State must—

- (a) carry out a review of these Regulations other than the fees provisions;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the EU instruments, or provisions of EU instruments, to which this regulation applies are implemented in ^{F681}... member States.

(3) The EU instruments, and provisions of EU instruments, to which this regulation applies are—

- (a) Council [Directive 90/167/EEC](#) laying down conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, so far it is not superseded by Regulation [\(EC\) No 183/2005\(19\)](#);
- (b) Commission [Directive 91/412/EEC](#) laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products⁽²⁰⁾;
- (c) [Directive 2001/82/EC](#) of the European Parliament and of the Council on the Community code relating to veterinary medicinal products⁽²¹⁾;
- (d) Regulation [\(EC\) No 178/2002](#) of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, in so far as it applies to veterinary medicinal products used in feedingstuffs;
- (e) Regulation [\(EC\) No 1831/2003](#) of the European Parliament and of the Council on additives for use in animal nutrition, in so far as it applies to veterinary medicinal products used in feedingstuffs;
- ^{F682}(f) Regulation (EU) 2017/625;]
- (g) Regulation [\(EC\) No 183/2005](#) of the European Parliament and of the Council laying down requirements for feed hygiene, in so far as it applies to veterinary medicinal products used in feedingstuffs;
- (h) [Commission Regulation \(EC\) No 1234/2008\(22\)](#);
- (i) Regulation [\(EC\) No 470/2009](#) of the European Parliament and of the Council⁽²³⁾;

(19) OJ No L 92, 7.4.1990, p. 42.

(20) OJ No L 228, 17.8.1991, p. 70.

(21) OJ No L311, 28.11.2001, p. 1; last amended by Regulation [\(EC\) No 596/2009](#) of the European Parliament and of the Council (OJ No L188, 18.7.2009, p. 14).

(22) OJ No L334, 12.12.2008, p. 7.

(23) OJ No L152, 16.6.2009, p. 11.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (j) Article 8 of Regulation (EC) No 767/2009 of the European Parliament and of the Council, and Articles 15 and 17 of that Regulation as they refer to the labelling requirements for feedstuffs containing specified feed additives⁽²⁴⁾; and
 - (k) Commission Regulation (EU) No 37/2010⁽²⁵⁾.
- (4) The report must in particular—
- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations, other than the fees provisions;
 - (b) assess the extent to which those objectives are achieved; and
 - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.
- (5) In this regulation—
- (a) “review period” means the period of five years beginning with the day on which these Regulations come into force, and, subject to paragraph (6), each successive period of five years thereafter; and
 - (b) “the fees provisions” means regulation 16 and Schedule 7.
- (6) If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

Extent Information

E188 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F681 Word in reg. 46(2) omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(12)(a)**

F682 Reg. 46(3)(f) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(12)(b)**

Revocations

47. The following Regulations are revoked—
- (a) the Veterinary Medicines Regulations 2011⁽²⁶⁾; and
 - (b) the Veterinary Medicines (Amendment) Regulations 2012⁽²⁷⁾.

David Heath
Minister of State for Agriculture and Food
Department for Environment, Food and Rural
Affairs

⁽²⁴⁾ OJ No L229, 1.9.2009, p. 1, last amended by Commission Regulation (EU) No 939/2010 (OJ L277, 21.10.2010, p. 14).

⁽²⁵⁾ OJ No L293, 11.11.2010, p.72; corrected at OJ L293, 11.11.2010, p. 72.

⁽²⁶⁾ S.I. 2011/2159.

⁽²⁷⁾ S.I. 2012/2711.

We consent

Anne Milton
Mark Lancaster
Two of the Lords Commissioners of Her
Majesty's Treasury

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

SCHEDULE 1

Regulation 4(3)

Marketing authorisations [^{F91}in Great Britain][^{F92}in Northern Ireland]

Textual Amendments

- F91** Words in Sch. 1 heading inserted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(b), **4(7)(a)**
- F92** Words in Sch. 1 heading inserted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(a)**

PART 1

Application for a marketing authorisation

Application for a marketing authorisation

1. An application under these Regulations for a marketing authorisation for a veterinary medicinal product must be made to the Secretary of State.

^{F93}Information with the application: general **E+W+S**

- 2.—(1) An application must include the matters mentioned in sub-paragraph (2) and—
- (a) where the veterinary medicinal product is an antimicrobial, the matters mentioned in sub-paragraph (4);
 - (b) subject to sub-paragraph (6), where the product is to be administered to a food-producing animal and is a product containing pharmacologically active substances that are not permitted under Regulation (EC) No 470/2009 of the European Parliament and of the Council, the matter mentioned in sub-paragraph (5);
 - (c) where the product contains or consists of genetically modified organisms, the matters mentioned in sub-paragraph (7).
- (2) For the purposes of sub-paragraph (1) the matters are—
- (a) the name of the person who will hold the marketing authorisation and that person's address or registered place of business;
 - (b) the name and the address or registered place of business of—
 - (i) the manufacturer of the finished product;
 - (ii) any importer of the finished product;
 - (iii) the manufacturer of any active substances involved at each stage of the manufacture;
 - (c) the name and address of the sites where—
 - (i) each stage of the manufacture is carried out;
 - (ii) any imported products are held; or
 - (iii) any control or batch release is carried out;
 - (d) the nature of the marketing authorisation being applied for, and the provisions in Part 2 of Schedule 1 which are relevant to the application;
 - (e) in relation to the veterinary medicinal product—

- (i) the name and the ATCvet code;
 - (ii) a description of the active substances within the product and, if applicable, a description of any diluent;
 - (iii) the strength of the product, or, in the case of an immunological veterinary medicinal product or a biological veterinary medicinal product that is not immunological, the biological activity, potency or titre;
 - (iv) the pharmaceutical form of the product;
 - (v) the route of administration;
 - (vi) a description of the target species;
- (f) a document showing that the manufacturer is authorised to produce veterinary medicinal products or a certificate of good manufacturing practice issued by the Secretary of State or equivalent certification issued by an authority recognised by the Secretary of State for that purpose, together with a description of the manufacturing process for the active substances and finished product which falls within scope of that authorisation or certificate;
- (g) the reference number and a summary of the pharmacovigilance system master file in relation to the product and, where appropriate, the risk management plan that the applicant will put in place;
- (h) the proposed summary of product characteristics;
- (i) a description of the final presentation, the packaging and labelling of the product;
- (j) the proposed text of the information to be included on the immediate packaging, the outer packaging and the information leaflet accompanying the product;
- (k) details of any country where—
- (i) a marketing authorisation has been granted or revoked in relation to the product;
 - (ii) a marketing authorisation has been submitted or refused;
- (l) a summary of product characteristics included in the terms of any marketing authorisation granted by another country;
- (m) technical documentation demonstrating the quality, safety and efficacy of the product;
- (n) a report (a “critical expert report”) on the quality, safety and efficacy of the product.
- (3) For the purposes of sub-paragraph (2)(n), each critical expert report must—
- (a) be prepared with regard to the state of scientific knowledge at the time of the application;
 - (b) include an evaluation of each test and trial referred to in the application, addressing all aspects relevant to quality, safety and efficacy, with detailed results and precise bibliographic references (including copies of the referenced material);
 - (c) where technical documentation within sub-paragraph (2)(m) is referenced, include precise cross-references;
 - (d) be signed and dated by the author, and include details of the author’s educational background, training and occupational experience, and the author’s professional relationship with the applicant.
- (4) For the purposes of sub-paragraph (1)(a), the matters are—
- (a) information on the direct or indirect risks to public or animal health or to the environment arising from use of the antimicrobial product in animals;
 - (b) information about the methods of mitigating the development of antimicrobial resistance as a result of the use of the product.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

(5) For the purposes of sub-paragraph (1)(b), the matter is a document certifying that a valid application for the establishment of maximum residue levels has been submitted to the Secretary of State.

- (6) Sub-paragraph (1)(b) does not apply in respect of a veterinary medicinal product which—
- (a) is for administration to a horse that has been declared on its horse passport as not intended for slaughter for human consumption, and
 - (b) includes an active substance that has been classified under Article 14 of Regulation (EC) No 470/2009 of the European Parliament and of the Council as prohibited for use in food-producing animals.
- (7) For the purposes of sub-paragraph (1)(c) the matters are—
- (a) a copy of the written consent to the deliberate release into the environment of the genetically modified organisms for research and development purposes issued under the GMO Deliberate Release Regulations;
 - (b) the complete technical file containing the information provided in respect of the application for that consent under the GMO Deliberate Release Regulations;
 - (c) the environmental risk assessment provided in respect of the application for that consent under the GMO Deliberate Release Regulations;
 - (d) the results of any investigations performed for the purposes of research or development.
- (8) In assembling the application for an authorisation under this Schedule, the applicant must—
- (a) take into account the most up-to-date veterinary medicinal knowledge and scientific guidelines relating to the quality, safety and efficacy of veterinary medicinal products (including relevant monographs of the European Pharmacopoeia and British Pharmacopoeia);
 - (b) include in the application all information which is relevant to the evaluation of the veterinary medicinal product to which it relates, whether favourable or unfavourable to the product (including information relating to any incomplete or abandoned study or trial);
 - (c) ensure that the application supports, by reference to specific studies and trials, each claim made by the applicant with regard to the properties, effects and uses of the veterinary medicinal product to which it relates;
 - (d) otherwise ensure the accuracy of the information in the application.

(9) For the purposes of sub-paragraph (8)(c), pharmacological, toxicological, residue and pre-clinical studies and clinical trials must be carried out in conformity with the principles of good laboratory practice, where applicable.]

Extent Information

E18 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F93 Sch. 1 paras. 2-2C substituted for Sch. 1 para. 2 (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), 28

Information with the application **N.I.**

2.—(1) An application must include all necessary administrative information, and all scientific documentation necessary for demonstrating the safety, quality and efficacy of the product.

(2) In particular, the applicant must provide all the data required in Annex I to [Directive 2001/82/EC](#) of the European Parliament and of the Council on the Community code relating to veterinary medicinal products⁽²⁸⁾, generated in accordance with that Annex.

(3) The application must contain the following information—

- (a) the name of the person who will hold the marketing authorisation, that person's address and, if different, the name and address of all the manufacturers involved in each stage of the manufacture, and the sites where the manufacture will take place;
- (b) the name of the veterinary medicinal product, which may be either—
 - (i) an invented name provided that this is not liable to be confused with the common name of the product or the international non-proprietary name (INN) recommended by the World Health Organization; or
 - (ii) a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder;
- (c) the qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its INN recommended by the World Health Organization, where an INN exists, or its chemical name;
- (d) a description of the method of manufacture;
- (e) all therapeutic indications, contra-indications and adverse reactions;
- (f) the dosage for each species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;
- (g) any proposed precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals or disposing of waste, together with an indication of potential risks that the veterinary medicinal product might pose to the environment, to human or animal health or to plants, together with the reasons;
- (h) in the case of medicinal products intended for food-producing species, the proposed withdrawal period necessary to ensure that the maximum residue limits specified in Regulation [\(EC\) No 470/2009](#) of the European Parliament and of the Council are not exceeded;
- (i) a description of the testing methods to be used during manufacture;
- (j) the results of—
 - (i) pharmaceutical (physico-chemical, biological or microbiological) tests;
 - (ii) safety tests and residue tests;
 - (iii) pre-clinical and clinical trials;
 - (iv) tests assessing the potential risks to the environment from the product;
- (k) a detailed description of the pharmacovigilance system and, where appropriate, the risk management system that the applicant will put in place;
- (l) a summary of the product characteristics, mock-ups of all proposed packaging and the proposed package leaflet, if any;
- (m) a document showing that the manufacturer is authorised to produce veterinary medicinal products;
- (n) copies (which must be updated if there are any changes while the application is being considered) of—

⁽²⁸⁾ OJ No L 211, 28.11.2001, p. 1 as last amended by Regulation [\(EC\) No 470/2009](#) of the European Parliament and of the Council (OJ No L 152, 16.6.2009, p. 11). Annex I was inserted by Commission [Directive 2009/9/EC](#) (OJ No L 44, 14.2.2009, p. 10).

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (i) any marketing authorisation obtained in [^{F683}a] member State or in a third country for the relevant veterinary medicinal product, and a list of any ^{F684}... member States in which an application for authorisation of the product has been submitted;
- (ii) if the product is already authorised outside the United Kingdom, the summary of product characteristics for each authorisation;
- (iii) any decision to refuse authorisation, whether in the Community or a third country and the reasons for that decision;
- (o) proof that the applicant has the services of a qualified person responsible for pharmacovigilance (referred to in these Regulations as a qualified person (pharmacovigilance)) and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country;
- (p) if the veterinary medicinal product is intended for food-producing species and contains one or more pharmacologically active substances not yet included for the species in question in Commission Regulation (EU) No 37/2010, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council.

(4) All documents relating to the results of tests or trials must be accompanied by a detailed and critical expert report that has been drafted and signed by a person with the requisite technical or professional qualifications and that has a brief curriculum vitae of the person signing the report attached to it.

(5) In the case of immunological products, the applicant must submit a description of the methods used to establish that the manufacturing process will consistently produce a veterinary medicinal product that is in accordance with the marketing authorisation.

Extent Information

E189 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F683 Word in Sch. 1 para. 2(3)(n)(i) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(b)**

F684 Word in Sch. 1 para. 2(3)(n)(i) omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(b)**

[^{F93}Information with the application: format

2A.—(1) An application must be submitted electronically.

(2) Subject to sub-paragraph (3), the application must be structured as a single dossier in four parts—

- (a) Part 1 (administrative information);
- (b) Part 2 (pharmaceutical quality (physicochemical, biological or microbiological) data);
- (c) Part 3 (safety documentation, including safety and residue tests);
- (d) Part 4 (efficacy documentation, including pre-clinical studies and clinical trials).

(3) An application concerning the release of GMOs must set out the environmental risk assessment in respect of that release as a separate document, and that assessment must be presented in accordance with the following provision of the GMO Deliberate Release Regulations—

- (a) as regards England or Scotland, regulation 6;
- (b) as regards Wales, regulation 7.

Textual Amendments

F93 Sch. 1 paras. 2-2C substituted for Sch. 1 para. 2 (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), 28

Information with the application: animal testing

2B.—(1) Where information to be included in an application under paragraph 2(8) includes information concerning experiments on animals, this paragraph applies in respect of that information.

(2) The application must state whether the information was obtained from an experiment conducted in accordance with the requirements in sub-paragraph (4).

(3) The Secretary of State must, in assessing the application, disregard any information to which this paragraph applies which was not obtained from an experiment conducted in accordance with the requirements in sub-paragraph (4).

(4) The requirements are—

- (a) the experiment was conducted in accordance with a detailed written protocol prepared in advance;
- (b) the experiment was designed to use the minimum number of animals and cause the least pain, suffering or lasting harm, and there was no satisfactory alternative in vitro test available to be used which would have reduced these impacts;
- (c) informed consent to the experiment and its consequences (including as regards disposal of treated animals and the taking of produce from treated animals) was obtained in writing from the owner of the animal before the animal was first treated under the experiment;
- (d) the welfare of the animals was subject to veterinary supervision throughout the experiment.

Textual Amendments

F93 Sch. 1 paras. 2-2C substituted for Sch. 1 para. 2 (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), 28

Information with the application: POM-VPS, NFA-VPS and AVM-GSL

2C.—(1) Where an applicant proposes, under paragraph 2(2)(d), that a marketing authorisation be granted on the basis that the veterinary medicinal product is classified as POM-VPS, NFA-VPS or AVM-GSL, the requirements in this paragraph apply.

(2) The application must include a document which sets out a detailed justification for the suitability of such classification, having regard to—

- (a) animal safety (both as regards treated animals and other animals);
- (b) public health; and
- (c) environmental safety.]

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

F93 Sch. 1 paras. 2-2C substituted for Sch. 1 para. 2 (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 28

[^{F94}Summary of product characteristics **E+W+S**

3.—(1) Subject to sub-paragraph (2), the summary of product characteristics required under paragraph 2(2)(h) must include the following information in the order indicated below—

1.	Name of the veterinary medicinal product, followed by its strength and pharmaceutical form.
2.	Qualitative and quantitative composition of the active substances and qualitative composition of excipients and other constituents stating their common name or their chemical description and their quantitative composition, if that information is essential for proper administration of the veterinary medicinal product.
3.	Clinical information as regards—
3.1	target species;
3.2	indications for use for each target species;
3.3	contra-indications;
3.4	special warnings;
3.5	special precautions for use, including in particular special precautions for safe use in the target species, special precautions to be taken by the person administering the veterinary medicinal product to the animals and special precautions for the protection of the environment;
3.6	frequency and seriousness of adverse events;
3.7	use during pregnancy, lactation or lay;
3.8	interaction with other medicinal products and other forms of interaction;
3.9	administration route and dosage;
3.10	symptoms of overdose and, where applicable, emergency procedures and antidotes in the event of overdose;
3.11	special restrictions for use;
3.12	special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance;
3.13	if applicable, withdrawal periods, even if such periods are zero.
4.	Pharmacological information as regards—
4.1	the ATCvet Code;
4.2	pharmacodynamics;
4.3	pharmacokinetics.
5.	Pharmaceutical particulars as regards—

5.1	major incompatibilities;
5.2	shelf-life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time;
5.3	special precautions for storage;
5.4	nature and composition of immediate packaging;
5.5	requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products.
6.	Name of the holder of the marketing authorisation.
7.	Marketing authorisation number or numbers.
8.	Date of the first marketing authorisation.
9.	Date of the last revision of the summary of product characteristics.
10.	If applicable, the statement—
10.1	“marketing authorisation granted for a limited market and therefore assessment based on customised requirements for documentation”; or
10.2	“marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation”.
11.	Information on the take-back schemes referred to in point 5.5 applicable to the veterinary medicinal product concerned.
12.	Classification of the veterinary medicinal product.

(2) In the case of an immunological veterinary medicinal product or a biological veterinary medicinal product that is not immunological, in place of the information at points 4, 4.1, 4.2 and 4.3, the summary of product characteristics must include immunological information.]

Textual Amendments

F94 [Sch. 1 para. 3](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **29**

Summary of product characteristics **N.I.**

3. The summary of product characteristics required under the preceding paragraph must include the following information, set out in the same format—

Summary of product characteristics

- 1 Name of the veterinary medicinal product, followed by its strength and pharmaceutical form.
- 2 The name and proportion of each active substance, and of any excipient if knowledge of the excipient is needed for safety reasons.
- 3 Pharmaceutical form.

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Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- 4 Clinical particulars—
 - 4.1 target species;
 - 4.2 indications for use, specifying the target species;
 - 4.3 contra-indications;
 - 4.4 special warnings for each target species;
 - 4.5 special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals;
 - 4.6 adverse reactions (frequency and seriousness);
 - 4.7 use during pregnancy, lactation or lay;
 - 4.8 interaction with other medicinal products and other forms of interaction;
 - 4.9 amounts to be administered and administration route;
 - 4.10 overdose (symptoms, emergency procedures, antidotes) if necessary;
 - 4.11 withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero.
 - 5 Pharmacological properties—
 - 5.1 pharmacodynamic properties;
 - 5.2 pharmacokinetic particulars;
 - 6 Pharmaceutical particulars—
 - 6.1 list of excipients;
 - 6.2 major incompatibilities;
 - 6.3 shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time;
 - 6.4 special precautions for storage;
 - 6.5 nature and contents of immediate packaging;
 - 6.6 special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate;
 - 7 Marketing authorisation holder;
 - 8 Marketing authorisation number;
 - 9 Date of the first authorisation or date of renewal of the authorisation;
 - 10 Date of any revision of the text;
 - 11 Any other information required by the Secretary of State.
-

Supply of a copy of the summary of product characteristics

4. A holder of a marketing authorisation must supply a copy of the summary of product characteristics to any person on demand.

Time limits for applications for products for use in food-producing animals **E+W+S**

^{F95}5.

Extent Information

E19 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F95 Sch. 1 para. 5 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 30

Time limits for applications for products for use in food-producing animals **N.I.**

5. In the case of a veterinary medicinal product for food-producing animals, a marketing authorisation may not be applied for until at least six months after a valid application has been made for the establishment of a maximum residue limit in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council.

Extent Information

E190 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

PART 2

Derogations from some of the requirements in Part 1

Scope

6. This Part provides for applications for marketing authorisations in which not all the information required in Part 1 is required, but for the avoidance of doubt any applicant may apply for a marketing authorisation using Part 1 if the applicant wishes to do so.

Bibliographic application **E+W+S**

7.—(1) An applicant for a marketing authorisation need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials [^{F96}if the applicant demonstrates that the active substances of the veterinary medicinal product have been in well-established veterinary use for at least 10 years, that their efficacy is documented and that they provide an acceptable level of safety].

[^{F97}(1A) Sub-paragraph (1) does not apply to applications for—

- (a) biological (including immunological) veterinary medicinal products;
- (b) novel therapies.]

(2) The applicant may use any publicly available document.

(3) If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another food-producing species, new residue studies, together with further clinical trials, a third party may not use those studies or trials in an application for a pharmacologically

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equivalent product for a period of three years from the grant of the authorisation for the additional species.

Extent Information

E20 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F96 Words in Sch. 1 para. 7(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **31(a)**

F97 Sch. 1 para. 7(1A) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **31(b)**

Bibliographic application **N.I.**

7.—(1) An applicant for a marketing authorisation need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if the active substance of the veterinary medicinal product has been in an authorised veterinary medicinal product for that species in the Community for at least ten years, and the applicant provides appropriate scientific literature to demonstrate this.

(2) The applicant may use any publicly available document.

(3) If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another food-producing species, new residue studies, together with further clinical trials, a third party may not use those studies or trials in an application for a pharmacologically equivalent product for a period of three years from the grant of the authorisation for the additional species.

Extent Information

E191 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for a product using a new combination of active substances

8.—^[F98](1) If an application is for a veterinary medicinal product containing active substances already used in an authorised veterinary medicinal product but not previously used in that combination in a veterinary medicinal product, the applicant need not provide the safety and efficacy data for the individual active substances.

^[F99](2) Notwithstanding sub-paragraph (1) the applicant must provide a sound scientific justification based on valid therapeutic principles for the combination of active substances, including clinical data, which demonstrates the need for and contribution of all active substances at the moment of treatment.]

Textual Amendments

F98 Sch. 1 para. 8 renumbered as Sch. 1 para. 8(1) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **32(a)**

F99 Sch. 1 para. 8(2) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), 32(b)

Application using existing data

9. If the Secretary of State has granted a marketing authorisation, the Secretary of State may, with the permission of the holder, use the data submitted in support of that marketing authorisation when assessing an application for another marketing authorisation.

Application for a ^{F100}generic veterinary medicinal product **E+W+S**

10.—(1) ^{F101}Subject to sub-paragraphs (2A), (9) and (10) and paragraph 10A,] an applicant need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if the applicant can demonstrate that the veterinary medicinal product is ^{F102}a generic of a] veterinary medicinal product already authorised in the ^{F103}United Kingdom][^{F104}(“the reference veterinary medicinal product”), provided that the applicant provides data demonstrating the matters referred to in sub-paragraph (2)].

(2) For the purposes of this paragraph a product is ^{F105}a generic of] an existing product if—

- (a) it has the same qualitative and quantitative composition in active substances;
- (b) it has the same pharmaceutical form ^{F106}as the reference product]; and

^{F107}(c) bioequivalence with the reference product has been demonstrated]

^{F108}(2A) Sub-paragraph (1) does not apply to applications for biological (including immunological) veterinary medicinal products.]

(3) For the purposes of this paragraph—

- (a) the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and
- (b) if they do differ significantly in properties with regard to efficacy or safety, additional information intended to provide proof of the safety or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.

(4) Different immediate-release oral pharmaceutical forms are regarded as the same pharmaceutical form.

(5) Bioavailability studies are not required if the bioequivalence guidelines produced by the ^{F109}European Medicines] Agency ^{F110}or the Secretary of State] exempt the product.

^{F111}(6)

^{F112}(7) For the purposes of these Regulations, subject to sub-paragraph (8), the summary of product characteristics of a generic veterinary medicinal product must be essentially similar to the summary of product characteristics for the reference product.

(8) The requirement in sub-paragraph (7) does not apply in relation to those parts of the summary of product characteristics of the reference product that refer to indications or pharmaceutical forms which are covered by patents at the time when the generic veterinary medicinal product is authorised.

(9) Notwithstanding sub-paragraph (1), in respect of generic veterinary medicinal products intended to be administered by intramuscular, subcutaneous or transdermal routes, the applicant must provide—

- (a) administration site target animal tolerance data;

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Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(b) in respect of products intended for administration to food-producing species only, residues depletion data from the site of administration.

(10) Notwithstanding sub-paragraph (1), in respect of generic veterinary medicinal products containing antimicrobial or antiparasitic substances, the applicant must provide all available data (including published data) on the current level of resistance, together with a review of that data as it relates to target pathogens to the active substances concerned.

(11) An applicant must provide an environmental risk assessment for a generic veterinary medicinal product where—

(a) the marketing authorisation for the reference veterinary medicinal product was granted before 1st October 2005, and

(b) no marketing authorisation has been granted since 1st October 2005 in respect of a veterinary medicinal product which has the same active substance and pharmaceutical form as the reference veterinary medicinal product, and which is indicated for use in the same target species when administered at the same or a higher total dose,

unless the Secretary of State holds an environmental risk assessment for the reference veterinary medicinal product and has confirmed this to the applicant.]

Extent Information

E21 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F100 Words in Sch. 1 para. 10 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **33(g)**

F101 Words in Sch. 1 para. 10(1) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **33(a)(i)**

F102 Words in Sch. 1 para. 10(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **33(a)(ii)**

F103 Words in Sch. 1 para. 10(1) substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(13)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F104 Words in Sch. 1 para. 10(1) added (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **33(a)(iii)**

F105 Words in Sch. 1 para. 10(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **33(b)(i)**

F106 Words in Sch. 1 para. 10(2)(b) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **33(b)(ii)**

F107 Sch. 1 para. 10(2)(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **33(b)(iii)**

F108 Sch. 1 para. 10(2A) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **33(c)**

F109 Words in Sch. 1 para. 10(5) inserted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(13)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F110 Words in Sch. 1 para. 10(5) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **33(d)**

F111 Sch. 1 para. 10(6) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **33(e)**

F112 Sch. 1 para. 10(7)-(11) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **33(f)**

Application for a pharmacologically equivalent medicinal product **N.I.**

10.—(1) An applicant need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if the applicant can demonstrate that the veterinary medicinal product is pharmacologically equivalent to a veterinary medicinal product already authorised in the Community.

(2) For the purposes of this paragraph a product is pharmacologically equivalent to an existing product if—

- (a) it has the same qualitative and quantitative composition in active substances;
- (b) it has the same pharmaceutical form; and
- (c) bioequivalence has been demonstrated by means of appropriate bioavailability studies.

(3) For the purposes of this paragraph—

- (a) the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and
- (b) if they do differ significantly in properties with regard to efficacy or safety, additional information intended to provide proof of the safety or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.

(4) Different immediate-release oral pharmaceutical forms are regarded as the same pharmaceutical form.

(5) Bioavailability studies are not required if the bioequivalence guidelines produced by the Agency exempt the product.

(6) In the case of a reference product authorised in [^{F685}a] member State but not in [^{F686}Northern Ireland], the Secretary of State must be satisfied that the risk-benefit balance of the original product is appropriate for the product to be placed on the market in the United Kingdom, and if the data provided under Article 13, third paragraph of [Directive 2001/82/EC](#) by the member State in which the product is authorised are insufficient for the Secretary of State to be satisfied of this, the Secretary of State may notify the applicant and require the applicant to provide further data.

Extent Information

E192 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F685 Word in Sch. 1 para. 10(6) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(c)(i)**

F686 Words in Sch. 1 para. 10(6) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(c)(ii)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

[^{F113}Hybrid veterinary medicinal products

10A. An applicant for a marketing authorisation must provide the results of relevant pre-clinical studies or clinical trials where—

- (a) bioavailability studies are not capable of demonstrating bioequivalence between the veterinary medicinal product for which the authorisation is sought and a reference veterinary medicinal product for the purposes of paragraph 10; or
- (b) the veterinary medicinal product for which the authorisation is sought is not pharmacologically equivalent to a reference veterinary medicinal product for the purposes of paragraph 10 as a result of a difference in relation to—
 - (i) the active substance or substances contained in the product;
 - (ii) the strength of the product;
 - (iii) the indications for use of the product;
 - (iv) the pharmaceutical form of the product;
 - (v) the route of administration of the product;
 - (vi) the withdrawal period for the product.]

Textual Amendments

F113 Sch. 1 para. 10A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 34

Time limits for marketing authorisations granted under the procedure for a [^{F114}generic veterinary medicinal] product **E+W+S**

11.—(1) This paragraph establishes the time limits relating to granting a marketing authorisation under the procedure for a [^{F115}generic veterinary medicinal] product.

(2) An application for a marketing authorisation cannot be made until two years before the product may be placed on the market in accordance with this paragraph.

[^{F116}(3) The product may not be placed on the market until the end of the longest of the following periods which is relevant—

- (a) subject to sub-paragraph (3A), 10 years in the case of a veterinary medicinal product authorised for major species;
- (b) 18 years in the case of a veterinary medicinal product authorised for bees; and
- (c) 14 years for a veterinary medicinal product authorised for all other species.

(3A) Where the product—

- (a) is intended for administration to a major species; and
- (b) contains an active substance which is an antimicrobial which has not been an active substance in a veterinary medicinal product previously subject to a marketing authorisation in Great Britain,

the period mentioned in sub-paragraph (3)(a) is 14 years.

(3B) Where a patent in relation to a reference product has lapsed, the summary of product characteristics of the relevant generic product must be updated in order to include the protected information.

(3C) Where, as a result of a variation to an existing marketing authorisation a product is accorded a new marketing authorisation number any relevant protection period applies in relation to that product.

(3D) In this regulation “major species” means cattle, sheep (for meat production), pigs, chickens, dogs and cats.]

(4) Time limits in this paragraph are calculated from the first grant of the marketing authorisation for the reference product.

Textual Amendments

F114 Words in Sch. 1 para. 11 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **35(c)**

F115 Words in Sch. 1 para. 11(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **35(a)**

F116 Sch. 1 para. 11(3)-(3D) substituted for Sch. 1 para. 11(3) (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **35(b)**

Time limits for marketing authorisations granted under the procedure for a pharmacologically equivalent product **N.I.**

11.—(1) This paragraph establishes the time limits relating to granting a marketing authorisation under the procedure for a pharmacologically equivalent product.

(2) An application for a marketing authorisation cannot be made until two years before the product may be placed on the market in accordance with this paragraph.

(3) The product may not be placed on the market until ten years (or, in the case of medicinal products for fish or bees where the application for a marketing authorisation was submitted after 30th October 2005, thirteen years) have elapsed from the initial authorisation of the reference product.

(4) Time limits in this paragraph are calculated from the first grant of the marketing authorisation for the reference product.

Extension of time limits **E+W+S**

12.—^{F117}(1)

[^{F118}(2) Subject to sub-paragraph (2B), if a person submits an application for a marketing authorisation or for a variation to a marketing authorisation for a product, and within five years of the original marketing authorisation being granted, the marketing authorisation is extended to include an additional major species or a new antimicrobial product, the relevant protection period is extended by one year for each additional major species added to the marketing authorisation.

(2A) Subject to sub-paragraph (2B), if a person submits an application for a marketing authorisation mentioned in sub-paragraph (2) and the marketing authorisation is extended to include an additional minor species, the relevant protection period is extended by four years.

(2B) Sub-paragraphs (2) and (2A) do not apply where the application to extend the marketing authorisation is made fewer than three years before the expiration of the protection period.]

(3) The total period may not exceed [^{F119}18] years.

^{F120}(4)

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

- F117** Sch. 1 para. 12(1) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **36(a)**
- F118** Sch. 1 para. 12(2)-(2B) substituted for Sch. 1 para. 12(2) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **36(b)**
- F119** Word in Sch. 1 para. 12(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **36(c)**
- F120** Sch. 1 para. 12(4) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **36(d)**

Extension of time limits **N.I.**

- 12.**—(1) This paragraph applies in relation to veterinary medicinal products that—
- (a) are intended for administration to food-producing species; and
 - (b) contain a new active substance that was not authorised in the Community by 30th April 2004.

(2) If a person submitted an application for a marketing authorisation for a product on or after 30th October 2005, and within 5 years of the original marketing authorisation being granted, the marketing authorisation is extended to include additional food-producing species, the ten-year protection period is extended by one year for each additional food-producing species added to the marketing authorisation.

(3) The total period may not exceed 13 years.

(4) The extension applies only if the marketing authorisation holder originally applied for determination of the maximum residue limits for the active substance.

[^{F121}Time limits – supplementary

12A.—(1) Subject to sub-paragraph (3), a study, residue test or pre-clinical study in relation to the establishment of residue limits submitted by an applicant in relation to an application for a marketing authorisation or a variation of a marketing authorisation may not be used for any other such application or variation until the period of five years from that submission has elapsed.

(2) Subject to sub-paragraph (3), a study, residue test or pre-clinical study submitted by an applicant for a marketing authorisation or a variation in a marketing authorisation which demonstrates a reduction in antimicrobial resistance in relation to a reference product may not be used for any other such application until a period of four years in addition to the relevant protection period has elapsed.

(3) Sub-paragraphs (1) and (2) do not apply where an applicant has obtained a written authorisation to access a study, residue test or pre-clinical study mentioned in the relevant sub-paragraph.]

Textual Amendments

- F121** Sch. 1 para. 12A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **37**

Parallel imports **E+W+S**

^{F122}**13.**

Extent Information

E22 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F122 Sch. 1 para. 13 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **38**

Parallel imports **N.I.**

13.—(1) The Secretary of State may grant a marketing authorisation in relation to a veterinary medicinal product authorised in [^{F687}a] member State and imported into [^{F688}Northern Ireland] from that member State in accordance with this paragraph without the data required in Part 1 if the applicant can demonstrate compliance with this paragraph.

(2) If the product is for a food-producing species it must be identical to a product authorised in [^{F689}Northern Ireland].

(3) Other products must be therapeutically the same as a product authorised in [^{F690}Northern Ireland] unless the importer can justify any differences.

(4) The member State from which it is imported must have authorised the product in accordance with [Directive 2001/82/EC](#).

(5) The applicant must be established within the Community.

(6) The applicant must hold (or have a contract with the holder of) a wholesale dealer's authorisation in [^{F691}Northern Ireland] appropriate to the type of product to be imported.

(7) If re-labelling is to take place in [^{F692}Northern Ireland] the applicant must also be (or have a contract with) the holder of a suitable manufacturing authorisation in [^{F692}Northern Ireland].

Extent Information

E193 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F687 Word in Sch. 1 para. 13(1) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(d)(i)**

F688 Words in Sch. 1 para. 13(1) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(d)(ii)**

F689 Words in Sch. 1 para. 13(2) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(d)(ii)**

F690 Words in Sch. 1 para. 13(3) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(d)(ii)**

F691 Words in Sch. 1 para. 13(6) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(d)(ii)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

F692 Words in Sch. 1 para. 13(7) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(d)(ii)**

Specific batch control scheme **E+W+S**

14.—(1) Where a veterinary medicinal product (other than a biological veterinary medicinal product) has been granted a marketing authorisation or an animal test certificate, and any starting material (active substance, excipient or packaging) or any batch of the product does not fully meet the requirements of the authorisation or animal test certificate, the holder may apply to the Secretary of State to place one or more batches on the market notwithstanding this.

(2) The Secretary of State may authorise the placing on the market on being satisfied that the safety, quality and efficacy of the product are not compromised, and that in all the circumstances of the case the product should be placed on the market.

^{F123}(3)

^{F124}(4)

Extent Information

E23 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F123 Sch. 1 para. 14(3) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(16)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F124 Sch. 1 para. 14(4) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **39**

Specific batch control scheme **N.I.**

14.—(1) Where a veterinary medicinal product (other than a biological veterinary medicinal product) has been granted a marketing authorisation or an animal test certificate, and any starting material (active substance, excipient or packaging) or any batch of the product does not fully meet the requirements of the authorisation or animal test certificate, the holder may apply to the Secretary of State to place one or more batches on the market notwithstanding this.

(2) The Secretary of State may authorise the placing on the market on being satisfied that the safety, quality and efficacy of the product are not compromised, and that in all the circumstances of the case the product should be placed on the market.

(3) This paragraph does not apply in relation to a product recognised in more than one member State.

(4) In this paragraph a biological veterinary medicinal product is a veterinary medicinal product, the active substance of which is a biological substance; and a biological substance is a substance that is produced by or extracted from a biological source and for which a combination of physico-chemical-biological testing and the production process and its control is needed for its characterisation and the determination of its quality.

Extent Information

E194 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Similar immunological products

[^{F125}15. Where an immunological veterinary medicinal product is pharmacologically equivalent to a reference product other than differences in raw materials or in the manufacturing process, the results of the appropriate pre-clinical tests or clinical trials must be provided, but the applicant need not provide the results of safety tests or residue tests.]

Textual Amendments

F125 Sch. 1 para. 15 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **40**

Marketing a product authorised in another country **E+W+S**

16. Where the health situation so requires, the Secretary of State may authorise the placing on the market of a veterinary medicinal product that has been authorised [^{F126}in another] country.

Extent Information

E24 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F126 Words in Sch. 1 para. 16 substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(17)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Marketing a product authorised in another country **N.I.**

16. Where the health situation so requires, the Secretary of State may authorise the placing on the market of a veterinary medicinal product that has been authorised by [^{F693a} member State or, if there is no such authorised product, authorised in a third country.

Extent Information

E195 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F693 Word in Sch. 1 para. 16 substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(e)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

PART 3

Grant of a marketing authorisation

Time limits

17.—^[F127](1) The Secretary of State must ensure that the procedure for granting an authorisation for a veterinary medicinal product is completed within a maximum of 210 days after the submission of the application.

^[F128](2) Sub-paragraph (1) does not apply where a simultaneous assessment of the application is being conducted by the Secretary of State and the relevant authority in another country.]

Textual Amendments

F127 Sch. 1 para. 17 renumbered as Sch. 1 para. 17(1) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **41(a)**

F128 Sch. 1 para. 17(2) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **41(b)**

^[F129]Place of establishment of applicant **E+W+S**

18. Only an applicant established in the United Kingdom or in a country which the Secretary of State considers to have demonstrated equivalent standards to those in the United Kingdom may be granted (or hold) a marketing authorisation or a veterinary homeopathic registration.]

Extent Information

E25 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F129 Sch. 1 para. 18 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **42**

Place of establishment of applicant **N.I.**

18. Only an applicant established in ^[F694]the United Kingdom or] a member State may be granted a marketing authorisation.

Extent Information

E196 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F694 Words in Sch. 1 para. 18 inserted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(f)(i)**

Procedure

19. The Secretary of State may require the applicant to provide additional information or to generate additional data, including laboratory testing, or may require the applicant to provide samples of any medicinal product, its starting materials and intermediate products or other constituent materials for testing in a laboratory.

Products authorised in another member State **E+W+S**

^{F130}20.

Extent Information

E26 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F130 Sch. 1 para. 20 omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(19)** (as amended by [S.I. 2020/1461](#), regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Products authorised in another member State **N.I.**

20. Where the Secretary of State is informed or discovers that [^{F695}a] member State has authorised a veterinary medicinal product that is the subject of an application for authorisation by the Secretary of State, the Secretary of State must reject the application unless it was submitted in accordance with the mutual recognition procedure or the decentralised procedure in Part 6.

Extent Information

E197 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F695 Word in [Sch. 1 para. 20](#) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(f)(ii)**

Assessment reports

21. The Secretary of State must produce an assessment of the dossier, consisting of an evaluation of the results of the pharmaceutical, safety and residue tests and the pre-clinical and clinical trials of the veterinary medicinal product concerned, and any additional related information.

Grant of a marketing authorisation

- 22.—^{F131}(1) The Secretary of State must, before granting a marketing authorisation—
- (a) verify that the data submitted complies with the requirements set out in these Regulations;
 - (b) assess the application and data submitted in respect of the veterinary medicinal product;
- and

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(c) reach a conclusion in relation to the benefit-risk balance of granting a marketing authorisation in respect of the veterinary medicinal product.]

[^{F132}(2)] When granting a marketing authorisation, the Secretary of State must inform the applicant of the summary of product characteristics that has been approved, and the distribution category of the product.

[^{F133}(3) The Secretary of State must set out any terms and conditions in connection with placing the product on the market when granting a marketing authorisation.

(4) Where the marketing authorisation relates to a veterinary medicinal product that contains an antimicrobial the Secretary of State may require the holder of the marketing authorisation to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive in relation to the development of antimicrobial resistance.]

Textual Amendments

F131 Sch. 1 para. 22(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **43(b)**

F132 Sch. 1 para. 22 renumbered as Sch. 1 para. 22(2) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **43(a)**

F133 Sch. 1 para. 22(3)(4) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **43(c)**

[^{F134}Withdrawal of application for marketing authorisation

22A.—(1) Where an applicant for a marketing authorisation withdraws the application before the Secretary of State has produced an assessment of the dossier under paragraph 21 the applicant must give written reasons for so doing.

(2) Where an applicant withdraws an application for a marketing authorisation in the circumstances mentioned in sub-paragraph (1) the Secretary of State must publish—

- (a) the fact that the application has been withdrawn; and
- (b) a summary of the reasons for withdrawal.]

Textual Amendments

F134 Sch. 1 para. 22A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **44**

Marketing authorisations for food-producing species **E+W+S**

23.—(1) The Secretary of State must not grant a marketing authorisation for a veterinary medicinal product for food-producing species unless [^{F135}maximum residue limits have been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council in respect of] all its pharmacologically active substances ^{F136}....

(2) This does not apply in the case of a marketing authorisation for a veterinary medicinal product for administration to a horse that has been declared on its horse passport as not intended for slaughter for human consumption; but in this case the product must not include an active substance that [^{F137}has been classified under Article 14 of Regulation (EC) No 470/2009 of the European Parliament and of the Council as prohibited for use in food producing animals.]

Extent Information

- E27** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F135** Words in Sch. 1 para. 23(1) inserted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(20)(a)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F136** Words in Sch. 1 para. 23(1) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(20)(a)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F137** Words in Sch. 1 para. 23(2) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(20)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Marketing authorisations for food-producing species **N.I.**

23.—(1) The Secretary of State must not grant a marketing authorisation for a veterinary medicinal product for food-producing species unless all its pharmacologically active substances appear in Table 1 in the Annex to Commission Regulation (EU) No 37/2010.

(2) This does not apply in the case of a marketing authorisation for a veterinary medicinal product for administration to a horse that has been declared on its horse passport as not intended for slaughter for human consumption; but in this case the product must not include an active substance that appears in Table 2 in the Annex to Commission Regulation (EU) No 37/2010 and must not be intended for the treatment of a condition for which a veterinary medicinal product is already authorised for horses.

Extent Information

- E198** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Refusal of a marketing authorisation **E+W+S**

24.—(1) The Secretary of State must refuse to grant a marketing authorisation if the application does not comply with these Regulations.

(2) In addition, the Secretary of State must refuse to grant it if—

- (a) the data submitted with the application are inadequate;
- (b) the [^{F138}benefit-risk balance] of the veterinary medicinal product is unfavourable;
- [^{F139}(c) the applicant has not provided sufficient evidence of the efficacy of the product in relation to the target species;]
- (d) the withdrawal period proposed by the applicant is not long enough to ensure [^{F140}food safety], or is insufficiently substantiated;
- (e) the veterinary medicinal product is for a prohibited use;

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (f) the way that the product will be used will have an unnecessarily undesirable effect on the environment.
- [^{F141}(g) the veterinary medicinal product is a veterinary medicinal product which contains an antimicrobial which is presented for use in order to promote the growth of treated animals or to increase yields from treated animals;
- (h) the risk for public health in case of development of antimicrobial resistance or antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health;
- (i) the risks to public or animal health or to the environment are not sufficiently addressed;
- (j) the qualitative or quantitative composition of the veterinary medicinal product is not as stated in the application;
- (k) the active substance within the veterinary medicinal product meets the criteria for being considered persistent, bio-accumulative and toxic and the veterinary medicinal product is intended to be used in food-producing animals (except where it is demonstrated that the active substance is essential to prevent or control a serious risk to animal health).]
- (3) The Secretary of State may refuse to grant a marketing authorisation—
- (a) if there is ^{F142} ... legislation pending that is incompatible with the requested authorisation; or
- (b) if additional data have been requested and those data are not provided within such time limit as may be stipulated.
- (4) If the Secretary of State, on the grounds of safety, quality or efficacy, intends to refuse an application, or proposes to grant a marketing authorisation that is different from the one applied for, the Secretary of State must notify the applicant accordingly, and the applicant may appeal to the Veterinary Products Committee.

Extent Information

E28 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F138 Words in Sch. 1 para. 24(2)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **45(a)**

F139 Sch. 1 para. 24(2)(c) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **45(b)**

F140 Words in Sch. 1 para. 24(2)(d) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(21)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F141 Sch. 1 para. 24(2)(g)-(k) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **45(c)**

F142 Word in Sch. 1 para. 24(3)(a) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(21)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Refusal of a marketing authorisation **N.I.**

24.—(1) The Secretary of State must refuse to grant a marketing authorisation if the application does not comply with these Regulations.

(2) In addition, the Secretary of State must refuse to grant it if—

- (a) the data submitted with the application are inadequate;
 - (b) the risk-benefit balance of the veterinary medicinal product is unfavourable;
 - (c) the product has insufficient therapeutic effect;
 - (d) the withdrawal period proposed by the applicant is not long enough to ensure that Regulation (EC) No 470/2009 of the European Parliament and of the Council is complied with, or is insufficiently substantiated;
 - (e) the veterinary medicinal product is for a prohibited use;
 - (f) the way that the product will be used will have an unnecessarily undesirable effect on the environment.
- (3) The Secretary of State may refuse to grant a marketing authorisation—
- (a) if there is Community legislation pending that is incompatible with the requested authorisation; or
 - (b) if additional data have been requested and those data are not provided within such time limit as may be stipulated.
- (4) If the Secretary of State, on the grounds of safety, quality or efficacy, intends to refuse an application, or proposes to grant a marketing authorisation that is different from the one applied for, the Secretary of State must notify the applicant accordingly, and the applicant may appeal to the Veterinary Products Committee.

Extent Information

E199 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Publication following the grant [^{F143}, refusal, suspension, variation or revocation] of a marketing authorisation

- 25.**—(1) On granting a marketing authorisation the Secretary of State must publish—
- (a) the notice granting the marketing authorisation;
 - (b) the summary of the product characteristics;
 - (c) the assessment report that has already been prepared but with any commercially confidential or personal information deleted.
- (2) The Secretary of State must update the assessment report whenever new information that is of importance and relates to the quality, safety or efficacy of the veterinary medicinal product becomes available.
- (3) The Secretary of State must send a copy of the assessment report, and any update, to the holder of the marketing authorisation before publication to enable the holder to make representations concerning any confidential or personal information that may be in it, and may specify a date by which representations must be made.
- [^{F144}(4) Where the Secretary of State refuses to grant a marketing authorisation or suspends or revokes an authorisation the Secretary of State must publish that fact.
- (5) Where the Secretary of State varies a marketing authorisation in relation to the summary of product characteristics the Secretary of State must publish the terms of the variation.]

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

- F143** Words in Sch. 1 para. 25 heading inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **46(b)**
- F144** Sch. 1 para. 25(4)(5) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **46(a)**

Marketing authorisations in exceptional circumstances

26.—(1) In exceptional circumstances, and if there is no other product with a full marketing authorisation for the indicated condition in the target species, the Secretary of State may grant an exceptional marketing authorisation consisting of—

- (a) a provisional marketing authorisation subject to a requirement for the applicant to provide further data [^{F145}, taking into account the benefit of the immediate availability on the market of the veterinary medicinal product in comparison to the risks]; or
- (b) a limited marketing authorisation for a product with a limited market [^{F146}, taking into account the benefit in relation to public or animal health of the availability of the product on the market in comparison to the risks.].

[^{F147}(1A) An exceptional marketing authorisation may be granted subject to such further conditions, including any restrictions, as the Secretary of State considers appropriate.]

(2) The Secretary of State must reassess each provisional or limited marketing authorisation annually.

Textual Amendments

- F145** Words in Sch. 1 para. 26(1)(a) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **47(a)**
- F146** Words in Sch. 1 para. 26(1)(b) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **47(b)**
- F147** Sch. 1 para. 26(1A) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **47(c)**

Provisions of samples and expertise

27.—(1) The Secretary of State may require a marketing authorisation holder to provide, at any time and at any stage of the manufacturing process, samples of starting materials or the veterinary medicinal product for testing [^{F148} and to provide the results of any control tests carried out in relation to such materials or the finished product in accordance with the methods to be used under the terms of the marketing authorisation].

(2) At the request of the Secretary of State, the marketing authorisation holder must provide technical expertise to facilitate any analysis of the product.

[^{F149}(3) The Secretary of State may require an applicant for a marketing authorisation to provide samples of a veterinary medicinal product for testing.

(4) The samples mentioned in sub-paragraph (3) may be used—

- (a) to test the veterinary medicinal product and its constituents at any stage of development of the product in order to ensure that the control methods used by the manufacturer are satisfactory; and

- (b) to verify that, where a veterinary medicinal product is intended for administration to a food-producing animal, the means used for residue detection in relation to pharmacologically active substances are satisfactory.]

Textual Amendments

- F148** Words in Sch. 1 para. 27(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **48(a)**
- F149** Sch. 1 para. 27(3)(4) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **48(b)**

[^{F150}Records and] supply of information **E+W+S**

28.—(1) A marketing authorisation holder must immediately inform the Secretary of State on receipt of any new information that might adversely affect the [^{F151}benefit-risk balance] of the veterinary medicinal product.

(2) The holder must immediately inform the Secretary of State of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is authorised.

(3) The Secretary of State may at any time require the marketing authorisation holder to provide data relating to the [^{F151}benefit-risk balance].

[^{F152}(4) A marketing authorisation holder must retain all of the original documents from every clinical trial from which data was derived in support of the application for authorisation under this Schedule, and in support of any variation of the authorisation (whether granted or otherwise), for at least five years from the date on which the authorisation ceases.]

Textual Amendments

- F150** Words in Sch. 1 para. 28 heading inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **49(c)**
- F151** Words in Sch. 1 para. 28 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **49(a)**
- F152** Sch. 1 para. 28(4) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **49(b)**

Supply of information **N.I.**

28.—(1) A marketing authorisation holder must immediately inform the Secretary of State on receipt of any new information that might adversely affect the risk-benefit balance of the veterinary medicinal product.

(2) The holder must immediately inform the Secretary of State of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is authorised.

(3) The Secretary of State may at any time require the marketing authorisation holder to provide data relating to the risk-benefit balance.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Duties on the holder of a marketing authorisation relating to an immunological product **E** **+W+S**

29.—^[F153](1) Before placing an immunological product on the market the holder of the marketing authorisation must notify the Secretary of State asking for written approval to do so.]

(2) If notified under sub-paragraph ^[F154](1)] the Secretary of State must give or refuse a written approval as soon as is reasonably practicable.

(3) No person may place an immunological product on the market without a written approval issued by the Secretary of State ^{F155}....

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F153 Sch. 1 para. 29(1) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(22)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F154 Word in Sch. 1 para. 29(2) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(22)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F155 Words in Sch. 1 para. 29(3) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(22)(c)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Duties on the holder of a marketing authorisation relating to an immunological product **N.I.**

29.—(1) Before placing an immunological product on the market the holder of the marketing authorisation must either—

(a) notify the Secretary of State asking for written approval to do so; or

(b) if the holder has already received written approval from ^[F696]a] member State permitting the release of the product, send a copy of that approval to the Secretary of State.

(2) If notified under sub-paragraph (1)(a) the Secretary of State must give or refuse a written approval as soon as is reasonably practicable.

(3) No person may place an immunological product on the market without a written approval issued by the Secretary of State or (if the approval was issued by ^[F697]a] member State) without sending a copy of that approval to the Secretary of State.

Extent Information

E200 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F696 Word in Sch. 1 para. 29(1)(b) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(13)(f)(iii)**

F697 Word in Sch. 1 para. 29(3) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(13)(f)(iii)**

Control tests

[^{F156}**30.** The holder of a marketing authorisation must give to the Secretary of State on demand evidence that the holder has carried out all control tests required under the marketing authorisation, and the results of those tests.]

Textual Amendments

F156 Sch. 1 para. 30 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024](#) (S.I. 2024/567), regs. 1(1), **50**

Placing on the market **E+W+S**

31.—(1) A holder of a marketing authorisation must notify the Secretary of State when the veterinary medicinal product is first placed on the market in the United Kingdom, and the date on which it was placed on the market.

(2) A holder of a marketing authorisation who removes the veterinary medicinal product from the market in the United Kingdom must notify the Secretary of State at least two months (or a shorter period in exceptional circumstances) before doing so.

[^{F157}(2A) A holder of a marketing authorisation who identifies a shortage of the veterinary medicinal product must notify the Secretary of State as soon as is reasonably practicable.

(2B) For the purposes of sub-paragraph (2A) a shortage of a veterinary medicinal product occurs when supply does not meet demand at a national level within the United Kingdom.]

(3) Upon request by the Secretary of State, the marketing authorisation holder must provide—

- (a) all data relating to the volume of sales of the veterinary medicinal product by the holder; and
- (b) any data in the holder's possession relating to the number of prescriptions written for the product and the total volume supplied under those prescriptions.

Extent Information

E30 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F157 Sch. 1 para. 31(2A)(2B) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024](#) (S.I. 2024/567), regs. 1(1), **51**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Placing on the market **N.I.**

31.—(1) A holder of a marketing authorisation must notify the Secretary of State when the veterinary medicinal product is first placed on the market in [^{F698}Northern Ireland], and the date on which it was placed on the market.

(2) A holder of a marketing authorisation who removes the veterinary medicinal product from the market in [^{F699}Northern Ireland] must notify the Secretary of State at least two months (or a shorter period in exceptional circumstances) before doing so.

- (3) Upon request by the Secretary of State, the marketing authorisation holder must provide—
- (a) all data relating to the volume of sales of the veterinary medicinal product by the holder; and
 - (b) any data in the holder's possession relating to the number of prescriptions written for the product and the total volume supplied under those prescriptions.

Extent Information

E201 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F698 Words in Sch. 1 para. 31(1) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(f)(iv)**

F699 Words in Sch. 1 para. 31(2) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(f)(iv)**

[^{F158}Duration and validity of marketing authorisation **E+W+S**

32. Subject to any power of revocation provided under these Regulations a marketing authorisation is valid indefinitely.]

Extent Information

E31 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F158 Sch. 1 para. 32 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **52**

Duration and validity of a marketing authorisation **N.I.**

32.—(1) A marketing authorisation is initially valid for five years.

(2) The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance.

(3) An application for renewal must be made at least six months, and not more than nine months, before the marketing authorisation ceases to be valid.

(4) An applicant who applies for the renewal of the marketing authorisation must enclose a list of all documents concerning the product that the applicant has submitted to the Secretary of State since the marketing authorisation was granted.

(5) The Secretary of State may require the applicant to provide a copy of any of the listed documents at any time.

(6) Once renewed, the marketing authorisation is valid indefinitely unless, within five years of the renewal, the Secretary of State notifies the holder, on justified grounds relating to pharmacovigilance, that the authorisation will cease to be valid five years from the first renewal unless the holder applies for a further renewal.

(7) The further renewal is not time-limited.

(8) Any marketing authorisation granted under these Regulations that is not followed within three years of its granting by the actual placing on the market of the authorised veterinary medicinal product in [F700Northern Ireland] ceases to be valid.

(9) When a veterinary medicinal product authorised under these Regulations and previously placed on the market in [F701Northern Ireland] is not present on the market in [F701Northern Ireland] for a period of three consecutive years, its marketing authorisation ceases to be valid.

(10) The Secretary of State may, on human or animal health grounds, grant exemptions from sub-paragraphs (8) and (9).

Extent Information

E202 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F700 Words in Sch. 1 para. 32(8) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(f)(v)**

F701 Words in Sch. 1 para. 32(9) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(f)(v)**

PART 4

Variations of marketing authorisations on the application of the holder

Variation of a marketing authorisation **E+W+S**

33.—^{F159}(1)

(2) The holder of a marketing authorisation may apply to the Secretary of State for a variation of that marketing authorisation.

[F160(3) An application for a variation under paragraph (2) may only relate to—

- (a) a single variation, which may relate to one or more marketing authorisations, or
- (b) one or more variations to a single marketing authorisation.]

(4) The Secretary of State, when granting a variation of a veterinary medicinal product, may (unless there are exceptional circumstances necessary to protect human or animal health or the

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Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

environment) specify transitional measures to enable products produced in accordance with the previous authorisation to continue to be marketed for the transitional period.

Textual Amendments

- F159** Sch. 1 para. 33(1) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **53(a)**
- F160** Sch. 1 para. 33(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **53(b)**

Variation of a marketing authorisation **N.I.**

33.—(1) The Secretary of State is the competent authority for the purposes of [Commission Regulation \(EC\) No 1234/2008](#)(**29**).

(2) The holder of a marketing authorisation may apply to the Secretary of State for a variation of that marketing authorisation.

(3) An application for a variation under paragraph (2) may only relate to a “single variation” unless the application is submitted in accordance with—

- (a) Article 7 of [Commission Regulation \(EC\) No 1234/2008](#) (“grouped variations”), or
- (b) Article 20 of [Commission Regulation \(EC\) No 1234/2008](#) (“workshare variations”).

(4) The Secretary of State, when granting a variation of a veterinary medicinal product, may (unless there are exceptional circumstances necessary to protect human or animal health or the environment) specify transitional measures to enable products produced in accordance with the previous authorisation to continue to be marketed for the transitional period.

Extent Information

- E203** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F161}Variation procedure

33A.—(1) Subject to sub-paragraphs (2) and (6), an application for a variation must be submitted to the Secretary of State electronically.

- (2) Sub-paragraph (1) does not apply where the application is an emergency application.
- (3) The application must contain—
 - (a) a description of the proposed variation;
 - (b) information in relation to any of the matters referred to in paragraph 2 which are relevant to the proposed variation;
 - (c) details of any marketing authorisation which may be affected by the proposed variation; and
 - (d) where the proposed variation requires consequential variations to the terms of the marketing authorisation, a description of those variations.
- (4) The Secretary of State must produce an assessment of the application.

(29) OJ No L334, 12.12.2008, p. 7.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

(5) The Secretary of State may require the applicant to provide additional information during the assessment process.

(6) Where the Secretary of State is satisfied that it is not necessary for the application to contain certain information for the purposes of conducting an assessment, having regard to the risks involved with the proposed variation, the Secretary of State may waive the requirement to provide that information under sub-paragraph (3) (and the requirement in sub-paragraph (4) does not apply in respect of that information).

(7) The Secretary of State must send a copy of the assessment mentioned in sub-paragraph (4) to the applicant.

(8) Having assessed the application, the Secretary of State must—

- (a) amend the authorisation to correspond with the proposed variation; or
- (b) reject the proposed variation.

(9) Where the Secretary of State amends the authorisation in accordance with sub-paragraph (8) (a) the Secretary of State must notify the applicant in writing.

(10) The Secretary of State must ensure that the determination of an application for a variation of a marketing authorisation is completed within a maximum of 180 days after the submission of the application.]

Textual Amendments

F161 Sch. 1 para. 33A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **54**

Refusal of a variation of a marketing authorisation **E+W+S**

34.—^{F162}(1)

(2) The grounds on which the Secretary of State may refuse an application for a variation of a marketing authorisation are those set out in paragraph 24 of this Schedule (refusal of a marketing authorisation).

(3) The Secretary of State must give written reasons for refusing to grant a variation; and if—
(a) those reasons are on the grounds of safety, quality or efficacy; and

[^{F163}(b) the Secretary of State produced an assessment in respect of the variation under paragraph 33A(4),]

the applicant may appeal to the Veterinary Products Committee.

Textual Amendments

F162 Sch. 1 para. 34(1) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **55(a)**

F163 Sch. 1 para. 34(3)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **55(b)**

Refusal of a variation of a marketing authorisation **N.I.**

34.—(1) This paragraph applies in relation to the refusal by the Secretary of State of an application for a variation unless the procedure following the refusal of a variation is one of those set out in Article 13 of Regulation 1234/2008.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(2) The grounds on which the Secretary of State may refuse an application for a variation of a marketing authorisation are those set out in paragraph 24 of this Schedule (refusal of a marketing authorisation).

(3) The Secretary of State must give written reasons for refusing to grant a variation; and if—

(a) those reasons are on the grounds of safety, quality or efficacy; and

(b) the variation is Type II or an extension application (whether or not in each case as part of an application for a worksharing or grouped application),

the applicant may appeal to the Veterinary Products Committee.

Extent Information

E204 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Administrative variations

[^{F164}**35.**—(1) The holder of a marketing authorisation may apply for a minor change in a marketing authorisation to be made without the Secretary of State considering any scientific data (an “administrative variation”).

(2) If the Secretary of State grants an administrative variation, and subsequently establishes that this should have been a variation requiring consideration of scientific data, the Secretary of State may notify the marketing authorisation holder, require the holder to submit an application for a variation enabling data to be assessed and revoke the administrative variation.]

Textual Amendments

F164 Sch. 1 para. 35 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 56

Changes after a marketing authorisation has been issued

36. After a marketing authorisation has been issued, the holder must take account of scientific and technical progress in manufacturing and control methods, and apply to the Secretary of State for any variation in the marketing authorisation that may be required to enable that veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

Compulsory variation

37.—(1) If the Secretary of State decides, for any of the reasons for suspending a marketing authorisation specified in paragraph 38, or because the classification of a veterinary medicinal product should be changed, that a variation to a marketing authorisation is necessary, the Secretary of State must by a notification in writing to the holder of the marketing authorisation require that person to apply for a variation of the marketing authorisation, giving reasons for requiring the application to be made.

(2) The notification may specify a time limit within which the marketing authorisation holder must apply for the variation.

(3) If the variation is on the grounds of safety, quality or efficacy, the applicant may, within 28 days of the notification, appeal to the Veterinary Products Committee.

(4) If the marketing authorisation holder fails to apply for the variation within that time limit the Secretary of State may suspend or revoke the marketing authorisation.

PART 5

Suspension, etc. of a marketing authorisation

Suspension [^{F165}, revocation, etc] of a marketing authorisation: grounds **E+W+S**

38.—^{F166}(1) If the Secretary of State is satisfied at any time that the benefit-risk balance of a veterinary medicinal product is not positive or is insufficient to ensure food safety, the Secretary of State may—

- (a) suspend the marketing authorisation;
- (b) require the holder of the marketing authorisation to submit an application for its variation;
- (c) revoke the marketing authorisation.]

(2) The Secretary of State may also suspend a marketing authorisation on being satisfied that a marketing authorisation holder has failed to make an application for a variation to take account of scientific and technical progress in manufacturing and control methods to enable the veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

^{F167}(3) The Secretary of State may take the steps set out in sub-paragraph (1)(a), (b) and (c) on being satisfied at any time that—

- (a) information given in the application documents is incorrect;
- (b) any control tests required have not been carried out;
- (c) changes have been made to the manufacturing process without the authority of the Secretary of State;
- (d) any information required to be supplied to the Secretary of State has not been so supplied;
- (e) the holder of the marketing authorisation has failed to comply with the requirements of these Regulations;
- (f) the pharmacovigilance system in relation to a veterinary medicinal product is inadequate;
- (g) in the case of a generic authorisation, the reference product is updated to show a reduction in antimicrobial resistance;
- (h) the qualified person (pharmacovigilance) has failed to comply with the requirements of these Regulations]

Extent Information

E32 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F165 Words in Sch. 1 para. 38 heading inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), [57\(c\)](#)

F166 Sch. 1 para. 38(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), [57\(a\)](#)

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
The Veterinary Medicines Regulations 2013. (See end of Document for details)

F167 Sch. 1 para. 38(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **57(b)**

Suspension of a marketing authorisation: grounds **N.I.**

38.—(1) The Secretary of State may suspend a marketing authorisation at any time on being satisfied that —

- (a) this is necessary for the protection of animal or public health or the environment;
- (b) the terms of the marketing authorisation have not been complied with; or
- (c) the veterinary medicinal product has insufficient therapeutic effect.

(2) The Secretary of State may also suspend a marketing authorisation on being satisfied that a marketing authorisation holder has failed to make an application for a variation to take account of scientific and technical progress in manufacturing and control methods to enable the veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

(3) The Secretary of State must suspend a marketing authorisation on being satisfied that—

- (a) the risk-benefit balance is unfavourable;
- (b) the withdrawal period does not ensure that residues in foodstuffs obtained from the treated animal comply with Regulation [\(EC\) No 470/2009](#) of the European Parliament and of the Council;
- (c) information given in the application documents is incorrect;
- (d) any control tests required have not been carried out;
- (e) changes have been made to the manufacturing process without the authority of the Secretary of State; or
- (f) any information required to be supplied to the Secretary of State has not been so supplied.

Extent Information
E205 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Suspension of a marketing authorisation: procedure **E+W+S**

39.—(1) If a marketing authorisation is suspended the Secretary of State must notify the holder immediately, and, unless the Secretary of State directs otherwise, the suspension has immediate effect, and continues in effect unless the marketing authorisation is reinstated.

(2) If the suspension is on the grounds of safety, quality or efficacy, the holder may, within 28 days of the notification, appeal to the Veterinary Products Committee.

^{F168}(3)

^{F169}(4)

Extent Information
E33 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F168 Sch. 1 para. 39(3) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(23)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F169 Sch. 1 para. 39(4) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024](#) (S.I. 2024/567), regs. 1(1), **58**

Suspension of a marketing authorisation: procedure **N.I.**

39.—(1) If a marketing authorisation is suspended the Secretary of State must notify the holder immediately, and, unless the Secretary of State directs otherwise, the suspension has immediate effect, and continues in effect unless the marketing authorisation is reinstated.

(2) If the suspension is on the grounds of safety, quality or efficacy, the holder may, within 28 days of the notification, appeal to the Veterinary Products Committee.

(3) If the veterinary medicinal product is authorised in more than one member State, the Secretary of State—

(a) must immediately refer the matter to the Agency, and must comply with a decision of the Commission within 30 days of the decision; and

(b) may suspend the marketing and the use of the veterinary medicinal product in [^{F702}Northern Ireland] pending a decision of the Agency, but must inform the Commission and the ^{F703}... member States no later than the following working day of the reasons for the action.

(4) When a marketing authorisation is suspended, the Secretary of State may in addition prohibit the supply of the veterinary medicinal product, and if necessary require the marketing authorisation holder to recall the product.

Extent Information

E206 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F702 Words in Sch. 1 para. 39(3)(b) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(13)(g)(i)**

F703 Word in Sch. 1 para. 39(3)(b) omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(13)(g)(i)**

Revocation

40. The Secretary of State may revoke any marketing authorisation that has been suspended for more than 28 days unless there is a current appeal to the Veterinary Products Committee, and may publicise a revocation in such manner as the Secretary of State sees fit.

Prohibiting the supply of veterinary medicinal products **E+W+S**

41.—^{F170}(1) The Secretary of State may prohibit the supply of a veterinary medicinal product or require the recall of the product at any time on being satisfied that—

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (a) the benefit-risk balance of the veterinary medicinal product is not positive;
 - (b) the qualitative or quantitative composition of the veterinary medicinal product is not as stated in the summary of product characteristics;
 - (c) the recommended withdrawal period is insufficient to ensure food safety;
 - (d) the required control tests have not been carried out; or
 - (e) the incorrect labelling of the product might lead to a serious risk to human or animal health]
- (2) The prohibition on supply and the requirement for recall may be confined to specific production batches.

^{F171}(3)

Extent Information

E34 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F170 Sch. 1 para. 41(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **59**

F171 Sch. 1 para. 41(3) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(24)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Prohibiting the supply of veterinary medicinal products **N.I.**

41.—(1) In addition to the powers to suspend a marketing authorisation, the Secretary of State, on being satisfied that a product has not been manufactured in accordance with the marketing authorisation, may prohibit the supply of a veterinary medicinal product, and if necessary require the marketing authorisation holder to recall it.

(2) The prohibition on supply and the requirement for recall may be confined to specific production batches.

(3) In the case of an immunological veterinary medicinal product manufactured outside the United Kingdom, if a batch has had all the tests that were originally carried out by the manufacturer repeated by the competent authority of [^{F704}a] member State, the Secretary of State may not prohibit the release of that batch if all the results have been submitted to the Secretary of State and the results demonstrate that the product is within the terms of the authorisation.

Extent Information

E207 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F704 Word in Sch. 1 para. 41(3) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(g)(ii)**

^{F172}Temporary restrictions

41A. Where urgent action is necessary for protecting human or animal health or the environment, the Secretary of State may, on a temporary basis—

- (a) restrict the supply of a veterinary medicinal product;
- (b) restrict the use of a veterinary medicinal product;
- (c) suspend the authorisation of a veterinary medicinal product;
- (d) require the holder of a marketing authorisation for a veterinary medicinal product to submit an application for variation of the authorisation.]

Textual Amendments

F172 Sch. 1 paras. 41A, 41B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **60**

^{F172}Restrictions in relation to immunological veterinary medicines

41B. The Secretary of State may prohibit the manufacture, importation, distribution, supply or use of immunological veterinary medicines in any part of Great Britain where—

- (a) the administration of the product to an animal interferes with the implementation of a programme for the diagnosis, control or eradication of animal disease;
- (b) the administration of the product to an animal causes difficulty in relation to the certifying of absence of disease in live animals or contamination of foodstuffs or other products from treated animals; or
- (c) the strains of disease agents in relation to which the product is intended to confer immunity are largely absent from the territory concerned.]

Textual Amendments

F172 Sch. 1 paras. 41A, 41B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **60**

^{F173}PART 6

Mutual recognition and multiple applications

Textual Amendments

F173 Sch. 1 Pt. 6 omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(25)** (as amended by [S.I. 2020/1461](#), regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Application for a marketing authorisation where one already exists in ^{F174}a] member State

42.—(1) If a veterinary medicinal product has already received a marketing authorisation in ^{F175}a] member State at the time of application, and the holder of the marketing authorisation

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

applies for a marketing authorisation in [^{F176}Northern Ireland], the following procedure (“the mutual recognition procedure”) applies.

(2) The applicant must submit to the Secretary of State a dossier identical to the one submitted to the competent authority of the member State in which the veterinary medicinal product has been authorised (“the reference member State”).

(3) If there is a marketing authorisation current in more than one member State the applicant must identify which member State is acting as the reference member State.

(4) An applicant applying in more than one member State must supply the Secretary of State with a list of all the States in which the applicant is applying.

(5) The Secretary of State must obtain an assessment report from the reference member State and, where appropriate, an explanation of any extension of the period of data protection.

(6) Within 90 days after receipt of the assessment report, the Secretary of State must, subject to the following provisions, either—

- (a) approve the assessment report, the summary of product characteristics, the labelling and the package leaflet, and inform the reference member State accordingly; or
- (b) notify the reference member State that they have not been approved, and provide the reference member State with a detailed statement of the reasons.

(7) The Secretary of State may only refuse an application on the grounds of serious risk to human or animal health or the environment.

(8) If the assessment report, the summary of product characteristics, the labelling and the package leaflet are approved, the Secretary of State must ensure that a decision whether or not to grant a marketing authorisation can be made within 30 days of the approval.

(9) If the Secretary of State is notified by the reference member State that—

- (a) not all member States concerned have within 90 days approved the assessment report, summary of product characteristics, labelling or package leaflet; and
- (b) the reference member State has sent a detailed statement of the reasons to the other member States involved in the application, the applicant and the coordination group for action in accordance with Article 33(3) of [Directive 2001/82/EC](#),

the Secretary of State must within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

(10) The Secretary of State may grant the marketing authorisation even though not all member States have agreed to grant it, but must revoke or vary the authorisation if this is necessary to comply with the decision of the Commission when it is received.

Textual Amendments

F174 Word in Sch. 1 para. 42 heading substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(h)(i)(aa)**

F175 Word in Sch. 1 para. 42(1) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(h)(i)(aa)**

F176 Words in Sch. 1 para. 42(1) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(h)(i)(bb)**

Application in [F177 a] member State

43.—(1) When the Secretary of State has granted a marketing authorisation for a veterinary medicinal product and is notified by the marketing authorisation holder that the marketing authorisation holder has applied to have that veterinary medicinal product authorised in [F178a] member State, the Secretary of State must prepare an assessment report for the product within 90 days of the notification and send it to the member State or States concerned.

(2) If the other member State (or, if there is more than one, all of them) agrees with the assessment report, the summary of product characteristics, the labelling and the package leaflet the Secretary of State need take no further action.

(3) If not all the other member States concerned so agree within a further 90 days the Secretary of State must send a detailed statement setting out why they have disagreed to the other member States, the applicant and the coordination group for action in accordance with Article 33(3) of [Directive 2001/82/EC](#).

(4) The Secretary of State must within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

Textual Amendments

F177 Word in [Sch. 1 para. 43 heading](#) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(h)(ii)(aa)**

F178 Word in [Sch. 1 para. 43\(1\)](#) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(h)(ii)(bb)**

Application for a marketing authorisation in multiple member States where a marketing authorisation does not exist in any member State

44.—(1) If an applicant wishes to apply for a marketing authorisation in more than one member State, and a marketing authorisation does not exist in any member State for the product (“the decentralised procedure”), the applicant must—

- (a) apply simultaneously in all the relevant member States;
- (b) submit a dossier to the Secretary of State that is identical to the dossier being submitted to all the other member States;
- (c) include a list of all member States in which applications have been made; and
- (d) nominate one of them to act as the reference member State to prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet for consideration by the other member States (“the concerned member States”).

(2) If the United Kingdom is the reference member State, the Secretary of State must prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet within 120 days of the receipt of a valid application and must send them to the other concerned member States and to the applicant.

(3) If the United Kingdom is not the reference member State, within 90 days after receipt of the assessment report and drafts of the summary of product characteristics, labelling and package leaflet from the reference member State, the Secretary of State must, subject to the following provisions, either—

- (a) approve the assessment report, the summary of product characteristics, the labelling and the package leaflet, and inform the reference member State accordingly; or

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the Veterinary Medicines Regulations 2013. (See end of Document for details)

- (b) notify the reference member State that the Secretary of State will not approve it, and provide the reference member State with a detailed statement of the reasons.
- (4) The Secretary of State may only refuse an application on the grounds of serious risk to human or animal health or the environment.
- (5) If all the member States involved agree the assessment report, the summary of product characteristics, the labelling and the package leaflet within 90 days, the Secretary of State must ensure that a decision whether or not to grant a marketing authorisation can be made within 30 days.
- (6) If, within 90 days, not all the member States have agreed the assessment report, summary of product characteristics, labelling and package leaflet on grounds of a potential serious risk to human or animal health or to the environment, the Secretary of State (if the United Kingdom is the reference member State) must send a detailed statement of the reasons to the other member States involved in the application, the applicant, and the coordination group to act in accordance with Article 33(3) of [Directive 2001/82/EC](#).
- (7) If reference has been made to the coordination group by any member State, the Secretary of State must within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.
- (8) If the Secretary of State wishes to do so, the Secretary of State may grant the marketing authorisation even though not all member States have agreed to grant it, but must revoke or vary the authorisation if this is necessary to comply with the decision of the Commission when it is received.]

PART 7

Labelling and package leaflets

Approval by the Secretary of State

45. The Secretary of State, when issuing a marketing authorisation, must approve all containers, packaging, labels and package leaflets.

Reference to being authorised **E+W+S**

46. A label and package leaflet of an authorised veterinary medicinal product may contain in legible characters the words “UK authorised veterinary medicinal product” or, if the marketing authorisation provides, other wording specified in the authorisation indicating that the product is authorised in the United Kingdom.

Extent Information

E35 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Reference to being authorised **N.I.**

46. A label and package leaflet of an authorised veterinary medicinal product may contain in legible characters the words “[^{F705}UK(NI)] authorised veterinary medicinal product” or, if the marketing authorisation provides, other wording specified in the authorisation indicating that the product is authorised in [^{F706}Northern Ireland].

Extent Information

E208 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F705 Word in Sch. 1 para. 46 substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(i)(i)**

F706 Words in Sch. 1 para. 46 substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(i)(ii)**

Language

47.—(1) All labels and package leaflets must be in English, but may contain other languages provided that the information given is identical in all the languages.

(2) This requirement does not apply in the case of a product imported by a veterinary surgeon and administered by or under the responsibility of that same veterinary surgeon.

[^{F179} Labelling of immediate packaging of veterinary medicinal products **E+W+S**

48.—(1) Subject to paragraph 50, the following information must be provided on the immediate packaging of a veterinary medicinal product—

- (a) the name of the product, followed by its strength and pharmaceutical form;
- (b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names;
- (c) the batch number, preceded by the word “Lot”;
- (d) the name or company name or logo of the marketing authorisation holder;
- (e) the target species;
- (f) the expiry date, in the format ‘mm/yyyy’, preceded by the abbreviation “Exp.”;
- (g) special storage precautions, if any;
- (h) the route of administration;
- (i) if applicable, the withdrawal period, even if such period is zero.

(2) Where there is no outer packaging for the product, the information set out in paragraph 49 must be included on the immediate packaging of the veterinary medicinal product.

(3) The information referred to in paragraph (1) must appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms.]

Extent Information

E36 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Textual Amendments

F179 Sch. 1 para. 48 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **61** (with reg. 200)

Labelling with all the information on the immediate packaging **N.I.**

48.—(1) If it is reasonably practicable to do so, the following must be provided on the immediate packaging, in legible characters—

- (a) the name, strength and pharmaceutical form of the veterinary medicinal product;
- (b) the name and strength of each active substance, and of any excipient if this is required under paragraph 2 of the summary of product characteristics;
- (c) the route of administration (if not immediately apparent);
- (d) the batch number;
- (e) the expiry date;
- (f) the words “For animal treatment only” and, if appropriate, “To be supplied only on veterinary prescription”;
- (g) the contents by weight, volume or number of dose units;
- (h) the marketing authorisation number;
- (i) the name and address of the marketing authorisation holder or, if there is a distributor authorised in the marketing authorisation, that distributor;
- (j) a suitably labelled space to record discard date (if relevant);
- (k) the target species;
- (l) the distribution category;
- (m) the words “Keep out of reach of children”;
- (n) storage instructions;
- (o) the in-use shelf-life (if appropriate);
- (p) for food-producing species, the withdrawal period for each species or animal product concerned;
- (q) any warning specified in the marketing authorisation;
- (r) disposal advice;
- (s) full indications;
- (t) dosage instructions;
- (u) contra-indications;
- (v) further information required in the marketing authorisation;
- (w) if the product is one that requires a dose to be specified for the animal being treated, a space for this.

(2) If all this is on the immediate packaging, there is no need for any outer packaging or a package leaflet.

Extent Information

E209 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F180} Labelling of the outer packaging of veterinary medicinal products **E+W+S**]

49.—(1) The following information must be provided on any outer packaging of a veterinary medicinal product—

- (a) the information referred to in paragraph 48(1);
- (b) the contents by weight, volume or number of the immediate packaging units of the veterinary medicinal product;
- (c) a warning that the veterinary medicinal product must be kept out of the sight and reach of children;
- (d) a warning that the veterinary medicinal product is “for animal treatment only”;
- (e) a recommendation to read the package leaflet, if there is one;
- (f) in the case of a veterinary medicinal product not subject to a veterinary prescription, the indication for use;
- (g) the marketing authorisation number.

(2) The information referred to in sub-paragraph (1) must appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms.]

Extent Information

E37 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F180 Sch. 1 para. 49 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 62 (with reg. 200)

Products with immediate and outer packaging **N.I.**

49.—(1) If it is not reasonably practicable to have all the required information on the immediate packaging then this paragraph applies.

(2) The immediate packaging must have at least the following information—

- (a) the name of the veterinary medicinal product, including its strength and pharmaceutical form;
- (b) the name and proportion of each active substance, and of any excipient if knowledge of the excipient is needed for safety reasons;
- (c) the route of administration (if not immediately apparent);
- (d) the batch number;
- (e) the expiry date;
- (f) the words “For animal treatment only” and if appropriate, “To be supplied only on veterinary prescription”;
- (g) the words “Keep the container in the outer carton”.

(3) In addition, the immediate packaging must have as much of the required information as is reasonably practicable.

(4) The outer packaging must contain all the required information if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product in accordance with the following paragraph.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Extent Information

E210 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

^{F181} Labelling of small immediate packaging units of veterinary medicinal products **E+W** **+S**

50.—(1) Where the immediate packaging units of a veterinary medicinal product are too small to include in a legible form all of the information set out in paragraph 48, the immediate packaging must instead provide the following information—

- (a) the name of the veterinary medicinal product;
- (b) the quantitative particulars of the active substances contained in the product;
- (c) the batch number, preceded by the word “Lot”;
- (d) the expiry date, in the form ‘mm/yyyy’, preceded by the abbreviation “Exp”.

(2) The immediate packaging units mentioned in sub-paragraph (1) must be packed within outer packaging which provides the information required by paragraph 49.]

Extent Information

E38 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F181 Sch. 1 para. 50 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **63** (with reg. 200)

Package leaflets **N.I.**

50.—(1) If it is not reasonably practicable to have all the required information on the immediate packaging or all of this information on the outer packaging, there must be a package leaflet supplied with the product, containing all the required information except for the batch number and the expiry date, and including the name of both the marketing authorisation holder and, if different, the name of the distributor named in the marketing authorisation.

(2) If there is a package leaflet, the immediate packaging and the outer packaging must both refer the user to it.

(3) A package leaflet must relate solely to the veterinary medicinal product with which it is included.

(4) It must be written in plain English.

(5) Only a package leaflet approved in the marketing authorisation may be included with the veterinary medicinal product.

Extent Information

E211 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F182}Package leaflet of veterinary medicinal products E+W+S

51.—(1) Subject to sub-paragraphs (5) and (7), a package leaflet must be supplied with each veterinary medicinal product.

(2) The package leaflet must provide the following information—

- (a) the name and address of the marketing authorisation holder and of the manufacturer and, where applicable, the distributor;
- (b) the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;
- (c) the qualitative and quantitative composition of any active substance;
- (d) the target species, the dosage for each species, the method and route of administration and if necessary, advice on the correct administration;
- (e) the indications for use;
- (f) the contra-indications and adverse events;
- (g) if applicable, the withdrawal period for each species, even if such a period is zero;
- (h) special storage precautions, if any;
- (i) information essential for safety or health protection, including any special precautions relating to use and any other warnings;
- (j) the words “use take-back schemes for the disposal of any unused veterinary medicinal product or associated waste materials in accordance with local requirements and with any applicable national collection schemes”;
- (k) the marketing authorisation number;
- (l) contact details for the marketing authorisation holder or its representative, as appropriate, for the reporting of suspected adverse events;
- (m) classification of the veterinary medicinal product as referred to in the summary of product characteristics.

(3) Providing that it complies with the marketing authorisation, the package leaflet may include additional information concerning distribution, possession or any necessary precaution required, provided that this information is not promotional in character.

(4) The package leaflet must be in legible form and designed to be clear and understandable, in terms that are comprehensible to the general public.

(5) Only a package leaflet approved in the marketing authorisation may be published or included with the veterinary medicinal product.

(6) The Secretary of State may require the information set out in sub-paragraph (2) to be made available in written form or electronically, or both.

(7) Where the Secretary of State requires the leaflet to be made available electronically—

- (a) an electronic package information leaflet which includes the information required by this paragraph must be provided in place of a leaflet in written form;
- (b) the packaging of the veterinary medicinal product must include—
 - (i) a statement that the information which must be included on a package leaflet is provided electronically;
 - (ii) any necessary electronic link in order to access the relevant part of the website where the electronic package information leaflet is to be found;
 - (iii) a statement that a copy of the information in written form may be obtained on request;and

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Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

(iv) instructions on how to obtain such a copy.

(8) Any information required by this paragraph to be provided on a package leaflet in written form may be otherwise provided on the packaging of the veterinary medicinal product.]

Extent Information

E39 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F182 Sch. 1 para. 51 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 64 (with reg. 200)

Ampoules **N.I.**

51.—(1) In the case of ampoules or other unit dose forms, where the container cannot bear legibly the required information, only the following information must be shown on the immediate packaging—

- (a) the name of the veterinary medicinal product;
- (b) the name and strength of the active ingredient;
- (c) the route of administration (if not immediately apparent);
- (d) the batch number;
- (e) the expiry date;
- (f) the words “For animal treatment only” and if appropriate, “To be supplied only on veterinary prescription”.

(2) The outer packaging must contain all the required information if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product, except that the ampoule need not refer to the package leaflet.

Extent Information

E212 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Small containers other than ampoules

[^{F183}**52.** As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the required information, all the required information must appear on the outer packaging or outer packaging and package leaflet, but the immediate packaging must be labelled with the batch number and the expiry date and, if there is room, the other information in the preceding paragraph.]

Textual Amendments

F183 Sch. 1 para. 52 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 65 (with reg. 200)

Homeopathic remedies **E+W+S**

53.—(1) A homeopathic remedy registered under these Regulations must be labelled in accordance with this paragraph.

(2) There must be no specific therapeutic indication on the labelling or in any information relating to it.

(3) The labelling (or labelling and package leaflet) must contain the following and no other information—

(a) the words “homeopathic remedy without approved therapeutic indications for veterinary use”;

(b) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used (if the homeopathic remedy is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks);

[^{F184}(c) the name or company name and the permanent address or registered place of business of the registration holder and of the manufacturer]

(d) the method and, if necessary, route of administration;

(e) the expiry date;

(f) the pharmaceutical form;

(g) the contents of the pack;

(h) any special storage precautions;

(i) the target species;

(j) any necessary special warnings;

(k) the batch number; ^{F185}...

(l) the registration number; [^{F186}and]

[^{F187}(m) the withdrawal period, where applicable.]

Extent Information

E40 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F184 Sch. 1 para. 53(3)(c) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **66(a)** (with reg. 200)

F185 Word in Sch. 1 para. 53(3) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **66(b)** (with reg. 200)

F186 Word in Sch. 1 para. 53(3) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **66(c)** (with reg. 200)

F187 Sch. 1 para. 53(3)(m) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **66(d)** (with reg. 200)

Homeopathic remedies **N.I.**

53.—(1) A homeopathic remedy registered under these Regulations must be labelled in accordance with this paragraph.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(2) There must be no specific therapeutic indication on the labelling or in any information relating to it.

(3) The labelling (or labelling and package leaflet) must contain the following and no other information—

- (a) the words “homeopathic remedy without approved therapeutic indications for veterinary use”;
- (b) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used (if the homeopathic remedy is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks);
- (c) the name and address of the registration holder and (on the package leaflet) of the manufacturer;
- (d) the method and, if necessary, route of administration;
- (e) the expiry date;
- (f) the pharmaceutical form;
- (g) the contents of the pack;
- (h) any special storage precautions;
- (i) the target species;
- (j) any necessary special warnings;
- (k) the batch number; and
- (l) the registration number.

Extent Information

E213 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Variations

54. The Secretary of State may permit variations in the above in any individual marketing authorisation if this is necessary for public or animal health purposes or the protection of the environment.

PART 8

Pharmacovigilance

Qualified persons responsible for pharmacovigilance **E+W+S**

^{F188}**55.**

Extent Information

E41 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F188 Sch. 1 para. 55 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 67

Qualified persons responsible for pharmacovigilance **N.I.**

55. A marketing authorisation holder must have permanently and continuously the services of an appropriately qualified person responsible for pharmacovigilance (“a qualified person (pharmacovigilance)”) who resides in a member State [^{F707}or the United Kingdom].

Extent Information

E214 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F707 Words in Sch. 1 para. 55 inserted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(j)(i)**

[^{F189}Duties of marketing authorisation holder in relation to pharmacovigilance **E+W+S**

56.—(1) The marketing authorisation holder is responsible for pharmacovigilance in relation to a veterinary medicinal product for which it holds a marketing authorisation and must continuously evaluate, by appropriate means, the benefit-risk balance of this veterinary medicinal product and, if necessary, take appropriate measures to address any risk presented by the product.

(2) A marketing authorisation holder must carry out the signal management process mentioned in paragraph 56C in relation to any veterinary medicinal product for which it holds an authorisation.

(3) A marketing authorisation holder must comply with best practice in good veterinary pharmacovigilance practice.

(4) A marketing authorisation holder must establish and maintain a system for collecting, collating and evaluating information in relation to suspected adverse events in respect of any veterinary medicinal product for which it holds an authorisation.

(5) Subject to sub-paragraph (6), a marketing authorisation holder must establish and maintain one or more pharmacovigilance system master files describing in detail the pharmacovigilance system with respect to its authorised veterinary medicinal products.

(6) For each veterinary medicinal product, the marketing authorisation holder must not establish and maintain more than one pharmacovigilance system master file.

(7) A marketing authorisation holder must establish and maintain an adequate and effective local system for the purpose of receiving reports of suspected adverse events.

(8) The system mentioned in sub-paragraph (7) must be staffed by personnel trained for this purpose who are able to communicate in English.

(9) A marketing authorisation holder must designate not more than one qualified person responsible for pharmacovigilance (a “qualified person (pharmacovigilance)”) in relation to each pharmacovigilance system master file whose services are available permanently and continuously.

(10) Where the pharmacovigilance functions or the functions of the qualified person for pharmacovigilance are performed by a third party, any such arrangement must be specified in detail in the pharmacovigilance system master file and within appropriate pharmacovigilance agreements.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

(11) A marketing authorisation holder may introduce urgent safety restrictions where evidence comes to the attention of the holder of a risk posed to human or animal health or to the environment from the use of the product.

(12) Where a marketing authorisation holder takes any action under sub-paragraph (11) the holder must inform the Secretary of State no later than the following working day of the reasons for the action.

(13) A marketing authorisation holder must establish and maintain an adequate and effective quality management system for the performance of its pharmacovigilance activities.

(14) The Secretary of State may at any time by notice require a marketing authorisation holder to provide a copy of the pharmacovigilance system master file.

(15) A marketing authorisation holder who is given notice under sub-paragraph (14) must comply with the requirement within seven days of receipt of the notice.]

Extent Information

E42 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F189 [Sch. 1 paras. 56-56C](#) substituted for [Sch. 1 para. 56](#) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **68**

Duties relating to the qualified person **N.I.**

56. The marketing authorisation holder must ensure that the qualified person (pharmacovigilance)—

- (a) establishes and maintains a system that ensures that information about all suspected adverse reactions reported to the marketing authorisation holder is collected and collated in order to be accessible at least at one point in a member State;
- (b) answers any request from the Secretary of State for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a veterinary medicinal product fully and within any time limit imposed by the Secretary of State when the information was requested, including the volume of sales of the veterinary medicinal product concerned and, if available, details of prescriptions;
- (c) provides to the Secretary of State any other information relevant to the evaluation of the benefits and risks afforded by a veterinary medicinal product, including appropriate information on post-marketing surveillance studies; and in this paragraph “post-marketing surveillance studies” means a pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying and investigating a safety hazard relating to an authorised veterinary medicinal product.

Extent Information

E215 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

^[F189] **Duties of marketing authorisation holder in relation to signal management process**

56A.—(1) A marketing authorisation holder must carry out the signal management process mentioned in paragraph 56C on reports received (whether those reports derive from the United Kingdom or any other country) in relation to any veterinary medicinal product for which it holds an authorisation.

(2) The marketing authorisation holder must record on an annual basis the results of the signal management process mentioned in paragraph 56C in relation to the product.

(3) Where, as a result of the carrying out of the signal management process, a new risk or a change in the benefit-risk balance of the product is identified, the marketing authorisation holder must notify the Secretary of State promptly and in any event within 30 days of such identification.

(4) Where the signal management process identifies the necessity for a variation in an authorisation the marketing authorisation holder must submit an application for such a variation to the Secretary of State promptly.

Textual Amendments

F189 Sch. 1 paras. 56-56C substituted for Sch. 1 para. 56 (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **68**

Duties of qualified person (pharmacovigilance)

56B. A qualified person (pharmacovigilance) must—

- (a) establish and maintain a system which ensures that all suspected adverse events which are brought to the attention of the marketing authorisation holder in relation to a veterinary medicinal product are collected and recorded;
- (b) monitor the performance of each product which is the subject of a marketing authorisation, apply the signal management process mentioned in paragraph 56C and ensure that any relevant requirements in accordance with the process are carried out;
- (c) maintain the pharmacovigilance system master file for each such product;
- (d) provide to the Secretary of State any information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product including the results of any study or clinical trial carried out in relation to the product;
- (e) communicate the fact that a regulatory measure has been taken in a country other than the United Kingdom as a consequence of pharmacovigilance data and the nature of such measure to the Secretary of State within 30 days of the receipt of such information, if no equivalent to that regulatory measure has already been taken in the United Kingdom;
- (f) answer fully and promptly any request from the Secretary of State for the provision of additional information necessary for the evaluation of the benefit-risk balance of that product;
- (g) monitor the pharmacovigilance system and ensure that, if required, an appropriate preventative or corrective action plan is prepared and implemented on behalf of the marketing authorisation holder through the use of audits and routine monitoring;
- (h) following any action taken in accordance with paragraph (g), ensure that any relevant amendments are made to the pharmacovigilance system master file;
- (i) liaise with the Secretary of State in relation to any pharmacovigilance inspection carried out under paragraph 60A;

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (j) ensure that any person employed by the marketing authorisation holder who is engaged in pharmacovigilance receives ongoing training which is relevant to that person's duties.

Textual Amendments

F189 Sch. 1 paras. 56-56C substituted for Sch. 1 para. 56 (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **68**

Signal management process

56C.—(1) For the purposes of these Regulations, “signal management process” means a process for performing active surveillance of pharmacovigilance data for veterinary medicinal products in order to assess the pharmacovigilance data and determine whether there is any change to the benefit-risk balance of those veterinary medicinal products, with a view to detecting risks to animal or public health or protection of the environment.

(2) A signal management process must consist of tasks of signal detection, validation, confirmation, analysis and prioritisation, assessment and recommendation for action.

(3) A signal management process must be capable of identifying, at a minimum, in relation to a product—

- (a) a sudden and unexpected increase in the number of adverse events;
- (b) an unexpected increase in the frequency of a known clinical sign;
- (c) a new clinical sign;
- (d) reports in scientific literature of any of the matters mentioned in paragraphs (a) to (c).]

Textual Amendments

F189 Sch. 1 paras. 56-56C substituted for Sch. 1 para. 56 (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **68**

[^{F190} Adverse events following administration of a veterinary medicinal product] **E+W+S**

57.—(1) A marketing authorisation holder must act in accordance with this paragraph on learning of any suspected—

- (a) [^{F191}adverse event in respect of an animal];
- (b) human [^{F192}adverse event]; ^{F193} ...
- (c) unintended transmission of an infectious agent through a veterinary medicinal product,
- [^{F194}(d) occurrence of an adverse environmental event, or
- (e) lack of efficacy,]

following the administration of the product ^{F195}....

[^{F196}(1A) A marketing authorisation holder must also act in accordance with this paragraph where—

- (a) after the end of the withdrawal period a product of animal origin is found to include a pharmacologically active substance or marker residue exceeding the maximum residue limit established in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council; or

- (b) there is evidence in published scientific literature of an adverse event in connection with the product.]
- (2) The holder must make a record of what happened.
- (3) The holder must without delay and in any event within [^{F197}30] days report it (electronically if this is practicable) to the Secretary of State.
- (4) In addition, the holder must supply to the Secretary of State all relevant veterinary pharmacovigilance information that the holder possesses relating to the [^{F198}event], giving a full description of the incident and a list of all the symptoms using internationally recognised veterinary and medical terminology, either with the report or, if the information becomes available after the report has been sent, as soon after it becomes available as is reasonably practicable.
 - [^{F199}(4A) The Secretary of State may require the marketing authorisation holder—
 - (a) to collect specific pharmacovigilance data (in addition to the data mentioned in sub-paragraph (4)) and submit those data to the Secretary of State; and
 - (b) to carry out specific post-marketing surveillance studies.
 - (4B) Where the Secretary of State exercises the power mentioned in sub-paragraph (4A), the Secretary of State must—
 - (a) state the reason for the requirement; and
 - (b) state the time by which, or the period during which, the requirement must be complied with.]
- ^{F200}(5)

Extent Information

E43 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F190** Sch. 1 para. 57 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(g)**
- F191** Words in Sch. 1 para. 57(1)(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(a)(i)**
- F192** Words in Sch. 1 para. 57(1)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(a)(ii)(aa)**
- F193** Word in Sch. 1 para. 57(1)(b) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(a)(ii)(bb)**
- F194** Sch. 1 para. 57(1)(d)(e) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(a)(iii)**
- F195** Words in Sch. 1 para. 57(1) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(a)(iv)**
- F196** Sch. 1 para. 57(1A) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(b)**
- F197** Word in Sch. 1 para. 57(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(c)**
- F198** Word in Sch. 1 para. 57(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(d)**
- F199** Sch. 1 para. 57(4A)(4B) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(e)**

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

F200 Sch. 1 para. 57(5) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **69(f)**

Adverse reactions to a veterinary medicinal product administered in [^{F708}Northern Ireland] **N.I.**

57.—(1) A marketing authorisation holder must act in accordance with this paragraph on learning of any suspected—

- (a) serious adverse reaction;
- (b) human adverse reaction; or
- (c) unintended transmission of an infectious agent through a veterinary medicinal product,

following the administration of the product in [^{F709}Northern Ireland].

(2) The holder must make a record of what happened.

(3) The holder must without delay and in any event within 15 days report it (electronically if this is practicable) to the Secretary of State.

(4) In addition, the holder must supply to the Secretary of State all relevant veterinary pharmacovigilance information that the holder possesses relating to the reaction, giving a full description of the incident and a list of all the symptoms using internationally recognised veterinary and medical terminology, either with the report or, if the information becomes available after the report has been sent, as soon after it becomes available as is reasonably practicable.

(5) In this and the following paragraph—

“human adverse reaction” means a reaction that is noxious and unintended and that occurs in a human being following exposure to a veterinary medicine;

“serious adverse reaction” means an adverse reaction that results in death, is life-threatening, results in significant disability or incapacity, is a congenital anomaly or birth defect, or that results in permanent or prolonged signs in the animals treated.

Extent Information

E216 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F708 Words in Sch. 1 para. 57 heading substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(j)(ii)**

F709 Words in Sch. 1 para. 57(1) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(j)(ii)**

Adverse reactions to a veterinary medicinal product administered in [^{F201}another] country **E+W+S**

^{F202}**58.**

Extent Information

- E44** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F201** Word in Sch. 1 para. 58 heading substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(28)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F202** Sch. 1 para. 58 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024](#) (S.I. 2024/567), regs. 1(1), **70**

Adverse reactions to a veterinary medicinal product administered in a third country **N.I.**

58.—(1) A marketing authorisation holder for a veterinary medicinal product authorised in [^{F710}Northern Ireland] must act in accordance with this paragraph on learning of any suspected—

- (a) serious, unexpected adverse reaction (for these purposes a reaction is unexpected if its nature, severity or outcome is not consistent with the summary of the product characteristics);
- (b) human adverse reaction; or
- (c) unintended transmission of an infectious agent through a veterinary medicinal product,

following the administration of the product in a third country.

(2) The holder must make a record of what happened.

(3) The holder must without delay and in any event within 15 days report the suspected reaction or transmission (electronically if this is practicable) to the Secretary of State, the competent authorities of all member States in which the product is authorised, and the Agency.

(4) In addition to the report, the holder must supply to the Secretary of State, the competent authorities of all ^{F711}... member States where the product is authorised and the Agency, all relevant veterinary pharmacovigilance information in the holder's possession relating to the reaction as in the preceding paragraph.

Extent Information

- E217** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F710** Words in Sch. 1 para. 58(1) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(13)(j)(iii)(aa)**
- F711** Word in Sch. 1 para. 58(4) omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(13)(j)(iii)(bb)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

[^{F203}Annual benefit-risk] reports **E+W+S**

59.—(1) The marketing authorisation holder must submit to the Secretary of State [^{F204}a summary of pharmacovigilance activity] in the form of [^{F205}an annual benefit-risk report] for each marketing authorisation in accordance with this paragraph ^{F206}....

^{F207}(2)

(3) Following the placing on the market in [^{F208}Great Britain], the marketing authorisation holder must submit a [^{F209}benefit-risk report] to the Secretary of State immediately upon [^{F210}request and, in any event, once in the course of every year during the period of validity of the authorisation].

(4) Following the granting of a marketing authorisation, the marketing authorisation holder may apply to the Secretary of State to change the [^{F211}submission dates for the annual benefit-risk reports].

[^{F212}(5) The report must include a statement regarding the benefit-risk balance of the veterinary medicinal product.]

[^{F213}(6) The annual benefit-risk report must include—

- (a) the volume of the product sold in the United Kingdom and in other countries in the period covered by the report, with the volume of the product sold in the United Kingdom in each calendar year identified;
- (b) the notification of signals detected during the reporting period following pharmacovigilance activity in the United Kingdom or a country other than the United Kingdom for which further regulatory actions are required (including a summary of the regular review of adverse events carried out during the year); and
- (c) where it appears from the observed data that there is cause for concern in relation to the safety of the product, recommendations on the need for further intervention by the Secretary of State.]

^{F214}(7)

^{F215}(8)

Extent Information

E45 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F203** Words in Sch. 1 para. 59 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **71(h)**
- F204** Words in Sch. 1 para. 59(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **71(a)(i)**
- F205** Words in Sch. 1 para. 59(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **71(a)(ii)**
- F206** Words in Sch. 1 para. 59(1) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **71(a)(iii)**
- F207** Sch. 1 para. 59(2) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **71(b)**
- F208** Words in Sch. 1 para. 59(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **71(c)(i)**
- F209** Words in Sch. 1 para. 59(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **71(c)(ii)**

- F210** Words in Sch. 1 para. 59(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **71(c)(iii)**
- F211** Words in Sch. 1 para. 59(4) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **71(d)**
- F212** Sch. 1 para. 59(5) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **71(e)**
- F213** Sch. 1 para. 59(6) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **71(f)**
- F214** Sch. 1 para. 59(7) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **71(g)**
- F215** Sch. 1 para. 59(8) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **71(g)**

Periodic safety update reports **N.I.**

59.—(1) The marketing authorisation holder must submit to the Secretary of State records of all adverse reactions (including nil reports) in the form of a periodic safety update report for each marketing authorisation in accordance with this paragraph, including a summary of each incident and a list of all the symptoms using internationally recognised veterinary and medical terminology.

(2) A marketing authorisation holder who has not yet placed a product on the market in [^{F712}Northern Ireland] must submit a periodic safety update report immediately upon request of the Secretary of State and at least every six months after authorisation.

(3) Following the placing on the market in [^{F713}Northern Ireland], the marketing authorisation holder must submit a periodic safety update report to the Secretary of State immediately upon request and—

- (a) at least every six months during the first two years following the initial placing on the market;
- (b) once a year for the following two years; and
- (c) thereafter, at three-yearly intervals.

(4) Following the granting of a marketing authorisation, the marketing authorisation holder may apply to the Secretary of State to change the periods of notification.

(5) The periodic safety update report must include a scientific evaluation of the risk-benefit balance of the veterinary medicinal product.

(6) The periodic safety update report must include—

- (a) the volume of the product sold in each year covered by the report, calculated on an annual basis beginning 1st January;
- (b) the number of adverse reactions for each year of the report;
- (c) the ratio of adverse reactions to volume of product sold for each year of the report, together with an explanation of the basis of the calculation;
- (d) differentiation of data based on—
 - (i) target species (if the product is authorised for use in more than one species);
 - (ii) reaction type (such as serious, non-serious, human, suspected lack of efficacy, unauthorised use or other);
 - (iii) the country of origin of the report.

(7) If the product is indicated for more than one species, the information in sub-paragraph (6)(c) must be based so far as is practicable on the estimated use of the product.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(8) Data relating to different formulations (either different dosage forms or different strengths) must be provided in separate reports.

Extent Information

E218 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F712 Words in Sch. 1 para. 59(2) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(j)(iv)**

F713 Words in Sch. 1 para. 59(3) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(13)(j)(iv)**

Release of information by the marketing authorisation holder

60.—(1) A marketing authorisation holder must not communicate information relating to pharmacovigilance concerns to [^{F216}veterinary surgeons or] the general public in relation to its authorised veterinary medicinal product without giving prior or simultaneous notification to the Secretary of State.

(2) The marketing authorisation holder must ensure that such information is presented objectively and is not misleading.

[^{F217}(3) For the purposes of this paragraph “information” includes any information contained in advertising material.]

Textual Amendments

F216 Words in Sch. 1 para. 60(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **72(a)**

F217 Sch. 1 para. 60(3) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **72(b)**

[^{F218}Pharmacovigilance inspections by Secretary of State

60A.—(1) The Secretary of State must, from time to time, inspect the pharmacovigilance systems of marketing authorisation holders for the purpose of verifying compliance with the provisions of this Schedule in relation to pharmacovigilance.

(2) The frequency of inspections under sub-paragraph (1) must be based on the risks associated with each marketing authorisation holder’s history and the nature of the products included in their pharmacovigilance system.

(3) Within 90 days after an inspection, the Secretary of State must issue an inspection report to the holder of the marketing authorisation if the inspection established compliance with best practice in good veterinary pharmacovigilance practice.]

Textual Amendments

F218 Sch. 1 paras. 60A, 60B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 73

[^{F218}Powers of Secretary of State in relation to signal management process

60B. The Secretary of State may decide to perform a targeted signal management process for a given veterinary medicinal product or a group of veterinary medicinal products.]

Textual Amendments

F218 Sch. 1 paras. 60A, 60B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 73

Action taken on account of pharmacovigilance **E+W+S**

61.—(1) Where, as a result of the evaluation of veterinary pharmacovigilance data, the Secretary of State considers that a marketing authorisation [^{F219}, or a group of marketing authorisations containing the same active substance,] should be—

- (a) suspended;
- (b) revoked; or
- (c) varied so as to—
 - (i) restrict the indications;
 - (ii) change the distribution category;
 - (iii) amend the dose;
 - (iv) add a contraindication; ^{F220} ...
 - (v) add a new precautionary measure, [^{F221} or
 - (vi) implement a risk management plan,]

the Secretary of State must forthwith inform ^{F222} ... and the marketing authorisation holder.

(2) If urgent action is necessary for protecting human or animal health, the Secretary of State may suspend the marketing authorisation of a veterinary medicinal product ^{F223}

^{F224}(3)

^{F225}(4)

Extent Information

E46 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F219 Words in Sch. 1 para. 61(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 74(a)

F220 Word in Sch. 1 para. 61(1)(c) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 74(aa)(b)

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- F221** Sch. 1 para. 61(1)(c)(vi) and word inserted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **74(b)(bb)**
- F222** Words in Sch. 1 para. 61(1) omitted (E.W.S.) (31.12.2020) by virtue of *The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/676), regs. 1(2)(b), **3(29)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F223** Words in Sch. 1 para. 61(2) omitted (E.W.S.) (31.12.2020) by virtue of *The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/676), regs. 1(2)(b), **3(29)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F224** Sch. 1 para. 61(3) omitted (E.W.S.) (31.12.2020) by virtue of *The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/676), regs. 1(2)(b), **3(29)(c)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F225** Sch. 1 para. 61(4) omitted (E.W.S.) (31.12.2020) by virtue of *The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/676), regs. 1(2)(b), **3(29)(c)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Action taken on account of pharmacovigilance **N.I.**

61.—(1) Where, as a result of the evaluation of veterinary pharmacovigilance data, the Secretary of State considers that a marketing authorisation should be—

- (a) suspended;
- (b) revoked; or
- (c) varied so as to—
 - (i) restrict the indications;
 - (ii) change the distribution category;
 - (iii) amend the dose;
 - (iv) add a contraindication; or
 - (v) add a new precautionary measure,

the Secretary of State must forthwith inform the Agency, all ^{F714}... member States (irrespective of whether the product is authorised in [^{F715}a] member State) and the marketing authorisation holder.

(2) If urgent action is necessary for protecting human or animal health, the Secretary of State may suspend the marketing authorisation of a veterinary medicinal product, but must inform the Agency, the Commission and the ^{F716}... member States within one working day.

(3) If, following the opinion of the Agency, the Commission requests the Secretary of State to suspend, withdraw or vary the marketing authorisation, the Secretary of State must comply with that request immediately on a temporary basis.

(4) The Secretary of State must take final measures in accordance with the Decision of the Commission.

Extent Information

E219 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F714** Word in Sch. 1 para. 61(1) omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(13)(j)(v)(aa)**
- F715** Word in Sch. 1 para. 61(1) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(13)(j)(v)(aa)**
- F716** Word in Sch. 1 para. 61(2) omitted (N.I.) (31.12.2020) by virtue of [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(13)(j)(v)(bb)**

PART 9

Homeopathic remedies

Meaning of “homeopathic remedy” **E+W+S**

62. For the purposes of these Regulations, a homeopathic remedy is a veterinary medicinal product (which may contain a number of principles) prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia(30) or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission ^{F226}

Extent Information

- E47** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F226** Words in Sch. 1 para. 62 omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(30)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Meaning of “homeopathic remedy” **N.I.**

62. For the purposes of these Regulations, a homeopathic remedy is a veterinary medicinal product (which may contain a number of principles) prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia(30) or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission or by the competent authority of any member State.

Extent Information

- E220** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

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Status: Point in time view as at 17/05/2024.

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Placing a homeopathic remedy on the market in accordance with a registration **E+W+S**

63.—(1) By way of derogation from the provisions of these Regulations requiring a marketing authorisation for a veterinary medicinal product, a homeopathic remedy may be placed on the market in accordance with a registration by the Secretary of State instead of in accordance with a marketing authorisation if it complies with this paragraph.

(2) It must not be an immunological [^{F227}or, subject to sub-paragraph (2A), a biological] product.

[^{F228}(2A) Sub-paragraph (2) does not apply in relation to a homeopathic remedy which is derived from plants.]

(3) The route of administration must be [^{F229}either topical or oral and must be] as described in the European Pharmacopoeia^{F230}

(4) There must be a sufficient degree of dilution to guarantee the safety of the product, and in any event it must not contain more than one part in 10,000 of the mother tincture.

(5) All other provisions relating to marketing authorisations apply in the same way to registrations of a homeopathic remedy.

Extent Information

E48 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F227 Words in Sch. 1 para. 63(2) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **75(a)**

F228 Sch. 1 para. 63(2A) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **75(b)**

F229 Words in Sch. 1 para. 63(3) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **75(c)**

F230 Words in Sch. 1 para. 63(3) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(31)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Placing a homeopathic remedy on the market in accordance with a registration **N.I.**

63.—(1) By way of derogation from the provisions of these Regulations requiring a marketing authorisation for a veterinary medicinal product, a homeopathic remedy may be placed on the market in accordance with a registration by the Secretary of State instead of in accordance with a marketing authorisation if it complies with this paragraph.

(2) It must not be an immunological product.

(3) The route of administration must be as described in the European Pharmacopoeia or, if it is not described there, by a pharmacopoeia currently used officially in any member State.

(4) There must be a sufficient degree of dilution to guarantee the safety of the product, and in any event it must not contain more than one part in 10,000 of the mother tincture.

(5) All other provisions relating to marketing authorisations apply in the same way to registrations of a homeopathic remedy.

Extent Information

E221 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for registration **E+W+S**

64.—(1) An applicant for registration must submit the following to the Secretary of State—

- (a) the scientific name or other name of the homeopathic stock [^{F231}or stocks] given in a pharmacopoeia, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution;
- (b) a dossier describing how the homeopathic stock is [^{F232}, or stocks are,] obtained and controlled, and justifying [^{F233}their] homeopathic [^{F234}use], on the basis of an adequate bibliography;
- (c) in the case of a product containing biological substances, a description of the measures taken to ensure the absence of pathogens;
- (d) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;
- (e) a copy of the manufacturing authorisation for the product;
- (f) copies of any registrations ^{F235}... obtained for the same homeopathic remedy^{F236}...;
- [^{F237}(g) the text which is to appear on the package leaflet, outer packaging and immediate packaging of the homeopathic remedy;]
- [^{F238}(h) any relevant data concerning the stability of the homeopathic remedy;]
- (i) the proposed withdrawal period necessary to ensure that the provisions of Regulation (EC) No 470/2009 of the European Parliament and of the Council are complied with together with all necessary justification.

(2) These documents must demonstrate the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned.

(3) In the case of a food-producing animal, if the applicant states in the application that the homeopathic remedy contains an active substance, or has been manufactured using an active substance, that substance must be one [^{F239}for which a maximum residue limit has been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council.]

^{F240}(4)

Extent Information

E49 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F231** Words in Sch. 1 para. 64(1)(a) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **76(a)**
- F232** Words in Sch. 1 para. 64(1)(b) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **76(b)(i)**
- F233** Word in Sch. 1 para. 64(1)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **76(b)(ii)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- F234** Word in Sch. 1 para. 64(1)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **76(b)(iii)**
- F235** Words in Sch. 1 para. 64(1)(f) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **76(c)**
- F236** Words in Sch. 1 para. 64(1)(f) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(32)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F237** Sch. 1 para. 64(1)(g) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **76(d)**
- F238** Sch. 1 para. 64(1)(h) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **76(e)**
- F239** Words in Sch. 1 para. 64(3) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(32)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F240** Sch. 1 para. 64(4) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(32)(c)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Application for registration **N.I.**

- 64.—(1) An applicant for registration must submit the following to the Secretary of State—
- (a) the scientific name or other name of the homeopathic stock given in a pharmacopoeia, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution;
 - (b) a dossier describing how the homeopathic stock is obtained and controlled, and justifying its homeopathic nature, on the basis of an adequate bibliography;
 - (c) in the case of a product containing biological substances, a description of the measures taken to ensure the absence of pathogens;
 - (d) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation;
 - (e) a copy of the manufacturing authorisation for the product;
 - (f) copies of any registrations or authorisations obtained for the same homeopathic remedy in other member States;
 - (g) a mock-up of the outer packaging and immediate packaging;
 - (h) stability data;
 - (i) the proposed withdrawal period necessary to ensure that the provisions of Regulation (EC) No 470/2009 of the European Parliament and of the Council are complied with together with all necessary justification.
- (2) These documents must demonstrate the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned.
- (3) In the case of a food-producing animal, if the applicant states in the application that the homeopathic remedy contains an active substance, or has been manufactured using an active substance, that substance must be one that appears in Table 1 in the Annex to Commission Regulation (EU) No 37/2010 and complies with any requirements in that Table relating to that substance.

(4) If a product is registered in [^{F717}a] member State, the Secretary of State may waive some or all of the requirements of this paragraph on being satisfied that it is reasonable to do so.

Extent Information

E222 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F717 Word in Sch. 1 para. 64(4) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(13)(k)**

Procedure for registration

65.—(1) The procedure for registration is the same as the procedure for granting a marketing authorisation in accordance with Part 3, except—

- (a) the applicant is not required to provide proof of efficacy;
- (b) the product is not required to have a summary of product characteristics;
- (c) the Secretary of State is not required to publish an assessment report.

(2) The procedure for variation, suspension and revocation is the same as for a marketing authorisation.

[^{F241}(3) The Secretary of State must ensure that the procedure for granting a registration in relation to a homeopathic remedy is completed within a maximum of 210 days after the submission of the application.]

Textual Amendments

F241 Sch. 1 para. 65(3) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024](#) (S.I. 2024/567), regs. 1(1), **77**

Products on the market before 1994

66. A homeopathic remedy that was on the market before 1st January 1994 may be placed on the market without being registered.

Classification

67. The registration must specify the classification of the homeopathic remedy, which must be one of the classifications specified for a veterinary medicinal product in Schedule 3.

Offences **E+W+S**

68. It is an offence to fail to comply with—

[^{F242}(za) paragraph 22A(1);]

- (a) a requirement made under paragraph 27(1);
- (b) a request made under paragraph 27(2);
- (c) paragraph 28(1) or (2);

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Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (d) a requirement made under paragraph 28(3);
- [^{F243}(da) paragraph 28(4);]
- (e) paragraph 29(3);
- ^{F244}(f)
- (g) paragraph 31(1) or (2);
- (h) a request made under paragraph 31(3);
- ^{F245}(i)
- (j) a prohibition or requirement made under paragraph 41(1);
- [^{F246}(ja) a restriction or requirement made under paragraph 41A;
- (jb) a prohibition made under paragraph 41B;]
- ^{F247}(k)
- (l) paragraph 56;
- [^{F248}(la) paragraph 56A;
- (lb) paragraph 56B;
- (lc) paragraph 56C;]
- (m) paragraph 57;
- ^{F249}(n)
- (o) paragraph 59; or
- (p) paragraph 60.

Extent Information

E50 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F242 Sch. 1 para. 68(za) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **78(a)**

F243 Sch. 1 para. 68(da) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **78(b)**

F244 Sch. 1 para. 68(f) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **78(c)**

F245 Sch. 1 para. 68(i) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **78(d)**

F246 Sch. 1 para. 68(ja)(jb) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **78(e)**

F247 Sch. 1 para. 68(k) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **78(f)**

F248 Sch. 1 paras. 68(la)-(lc) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **78(g)**

F249 Sch. 1 para. 68(n) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **78(h)**

Offences **N.I.**

68. It is an offence to fail to comply with—
- (a) a requirement made under paragraph 27(1);
 - (b) a request made under paragraph 27(2);
 - (c) paragraph 28(1) or (2);
 - (d) a requirement made under paragraph 28(3);
 - (e) paragraph 29(3);
 - (f) paragraph 30;
 - (g) paragraph 31(1) or (2);
 - (h) a request made under paragraph 31(3);
 - (i) a prohibition or requirement made under paragraph 39(4);
 - (j) a prohibition or requirement made under paragraph 41(1);
 - (k) paragraph 55;
 - (l) paragraph 56;
 - (m) paragraph 57;
 - (n) paragraph 58;
 - (o) paragraph 59; or
 - (p) paragraph 60.

Extent Information

E223 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F250}SCHEDULE 1A

Regulation 4(4)

Converted EU marketing authorisations

Textual Amendments

F250 Sch. 1A inserted (E.W.S.) (31.12.2020) by [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), 17(3), **Sch. 8 Pt. 1**; 2020 c. 1, Sch. 5 para. 1(1)

1. In this Schedule—

“converted EU marketing authorisation” means an EU marketing authorisation to which paragraph 2 applies;

“EU marketing authorisation” means a marketing authorisation for a veterinary medicinal product granted by the European Commission in accordance with Title 3 of Regulation [\(EC\) No 726/2004](#) of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

2. This paragraph applies to an EU marketing authorisation which—
 - (a) was granted before exit day, and
 - (b) remains in force immediately before exit day.
3. A converted EU marketing authorisation has effect on and after exit day for the purposes of these regulations as if it were a marketing authorisation granted by the Secretary of State under these Regulations on the date it was originally granted—
 - (a) on the terms which were in force immediately before exit day,
 - (b) with the benefit of any periods of data marketing exclusivity from which the holder benefited immediately before exit day, and
 - (c) subject to any suspension or post-authorisation obligations which were in force immediately before exit day.
4. Without prejudice to the generality of paragraph 3—
 - (a) the holder of a converted EU marketing authorisation is subject to the annual fee as set out in paragraph 26 of Schedule 7;
 - (b) a converted EU marketing authorisation is to be treated as having been granted in accordance with regulation 4(3) and Schedule 1 for the purposes of Regulation (EC) No 469/2009.]

[^{F251}SCHEDULE 1B

Regulation 4(5)

Qualifying Northern Ireland good (QNIG) certificates

Textual Amendments

F251 Sch. 1B inserted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(b), **4(8)**

1. In this Schedule—

“QNIG certificate” means a certificate issued under paragraph 3;

“QNIG certificate holder”, in relation to a QNIG certificate, means the person to whom that certificate was issued under paragraph 3;

“qualifying Northern Ireland goods” has the meaning given to it from time to time in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

“Northern Ireland VMRs” means the Veterinary Medicines Regulations 2013 as they have effect in Northern Ireland.
2. This Schedule applies to a veterinary medicinal product which is—
 - (a) a qualifying Northern Ireland good in respect of which there is a marketing authorisation valid in Northern Ireland under the Northern Ireland VMRs,
 - (b) not a product in respect of which there is a marketing authorisation which is valid in Great Britain (including any marketing authorisation which has effect under paragraph 3 of Schedule 1A),
 - (c) not a product in respect of which a QNIG certificate issued under this Schedule already applies, and
 - (d) not a product to which Article 41(1) of the EU withdrawal agreement applies.

3. If the condition in paragraph 4 is met in respect of the veterinary medicinal product, the Secretary of State must issue a QNIG certificate in respect of that product to the person who holds a marketing authorisation in respect of the product which is valid in Northern Ireland under the Northern Ireland VMRs.

4. The condition is that the person who holds a marketing authorisation in respect of the product which is valid in Northern Ireland under the Northern Ireland VMRs, who must be a person established in Northern Ireland, has provided the Secretary of State with the following information—

- (a) the Northern Ireland address of that person;
- (b) all necessary administrative information, and all scientific documentation necessary for demonstrating the safety, quality and efficacy of the veterinary medicinal product, equivalent to that which would need to be provided under Schedule 1 if an application for a marketing authorisation was to be made in respect of that product under paragraph 1 of that Schedule (allowing for any relevant derogations provided for in Part 2 of that Schedule);
- (c) the name and address of a person who resides in the United Kingdom or in a member State who is to provide in respect of the veterinary medicinal product, permanently and continuously, the services of a qualified person (pharmacovigilance) for the purposes of Part 8 of Schedule 1.

5. A QNIG certificate has effect as if it were a marketing authorisation granted by the Secretary of State under these Regulations subject to the modification that the qualified person (pharmacovigilance) for the purposes of Part 8 of Schedule 1 is the person identified under paragraph 4(c).

6. The QNIG certificate holder must provide to the Secretary of State from time to time such further information as is appropriate to ensure that the information provided under paragraph 4 remains accurate and complete.

7. Without prejudice to any other power to suspend a marketing authorisation under Schedule 1, if the Secretary of State considers that a QNIG certificate holder is in breach of these Regulations as modified by paragraph 5, or that the information provided in respect of the matters specified in paragraph 4 is no longer accurate or complete, the Secretary of State may by notice suspend the QNIG certificate.

8. The Secretary of State must publish any notice given under paragraph 7 in such manner as the Secretary of State considers appropriate from time to time.

9. Paragraphs 39 and 40 of Schedule 1 apply to the suspension of a QNIG certificate under paragraph 7 as they would to the suspension of such a certificate under paragraph 38 of that Schedule as read with paragraph 5.]

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

SCHEDULE 2

Regulation 5(2)

The manufacture of veterinary medicinal products

PART 1

Manufacturing authorisations

[^{F252}Manufacturing authorisation E+W+S]

1.—(1) No person may carry out any activity mentioned in sub-paragraph (2) otherwise than in accordance with an authorisation granted under this Schedule (a “manufacturing authorisation”).

(2) For the purposes of sub-paragraph (1) the activities are—

- (a) the manufacture of veterinary medicinal products (whether for use in Great Britain or another country);
- (b) the carrying out of any part of the manufacturing process or of bringing a veterinary medicinal product to its final state, including the processing, assembling, packaging or repackaging, labelling or relabelling, storing, sterilising or releasing for supply of a veterinary medicinal product;
- (c) the importation of any veterinary medicinal product for use in Great Britain.]

Extent Information

E51 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F252 Sch. 2 para. 1 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **80**

Application N.I.

1. An application for a manufacturing authorisation must be made to the Secretary of State.

Extent Information

E224 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F253}Application for authorisation E+W+S]

2.—(1) An application for a manufacturing authorisation must be submitted to the Secretary of State electronically and must include the matters mentioned in sub-paragraph (2).

(2) For the purposes of sub-paragraph (1) the matters are—

- (a) the name of the person who will hold the manufacturing authorisation and that person’s address or registered place of business;
- (b) the names and addresses of the sites (including any site where work is undertaken on behalf of the proposed holder under contract) where—

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (i) each stage of the manufacturing process or of bringing a veterinary medicinal product to its final state, including processing, assembling, packaging or repackaging, labelling or relabelling, storing or sterilising, is carried out;
- (ii) any imported products are held; or
- (iii) any control or batch release is carried out;
- (c) a description of the veterinary medicinal products or pharmaceutical forms proposed to be manufactured or imported under the authorisation;
- (d) the name of the proposed qualified person (manufacture) for the purposes of paragraph 9;
- (e) the name of the person proposed to have responsibility for quality control;
- (f) the qualifications and a description of the relevant experience of the person proposed to have responsibility for quality control;
- (g) the name of the person proposed to have responsibility for production;
- (h) the qualifications and a description of the relevant experience of the person proposed to have responsibility for production;
- (i) a declaration that the applicant complies with good manufacturing practice and any relevant legislation; and
- (j) a declaration that any site mentioned in paragraph (b) is ready for inspection.]

Extent Information

E52 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F253 Sch. 2 para. 2 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **81**

Time limits **N.I.**

2.—(1) The Secretary of State must process an application for a manufacturing authorisation within 90 days of receiving it.

(2) The Secretary of State must process an application for a variation of a manufacturing authorisation within 30 days unless the Secretary of State notifies the applicant in writing that the time has been extended to 90 days.

Extent Information

E225 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F254} Procedure for grant of authorisations and time limits **E+W+S**

3.—(1) The Secretary of State must process an application mentioned in paragraph 2 within 90 days of validating the application.

(2) The Secretary of State must inspect the sites mentioned in paragraph 2(2)(b) within 90 days of validating the application.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

(3) The Secretary of State must grant the manufacturing authorisation if satisfied, following the inspection mentioned in sub-paragraph (2), that—

- (a) the sites are suitable for the intended purposes;
- (b) the applicant has—
 - (i) suitable and sufficient staff, technical equipment and facilities for the proposed activities; and
 - (ii) a documented quality management system in place.

(4) Where the Secretary of State is not satisfied in relation to one or more of the matters mentioned in sub-paragraph (3), the Secretary of State may—

- (a) reject the application; or
- (b) grant a conditional manufacturing authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

(5) The Secretary of State may extend the period for which a conditional manufacturing authorisation is granted under sub-paragraph (4)(b).

(6) Where a conditional manufacturing authorisation is granted under sub-paragraph (4)(b) and the deficiency is addressed within the specified period to the satisfaction of the Secretary of State, the authorisation continues to have effect without those conditions.]

Extent Information

E53 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F254 Sch. 2 para. 3 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **82**

Granting the authorisation **N.I.**

3. The Secretary of State must grant a manufacturing authorisation on being satisfied that the applicant has suitable and sufficient premises, staff, technical equipment and facilities for the manufacture, control and storage of the products, and will comply with these Regulations.

Extent Information

E226 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

The authorisation **E+W+S**

4.—(1) The manufacturing authorisation must specify—

- (a) the types of veterinary medicinal products and pharmaceutical forms that may be manufactured [^{F255}, controlled] or imported;
- [^{F256}(b) the name and address of the site where the products are to be manufactured or controlled, or to which they are to be imported;]
- (c) the name and address of the person holding the authorisation;
- (d) the address of the premises to which it relates;

(e) the names of all qualified persons nominated to act under this Schedule.

(2) It may specify that different activities must be carried out in different premises or parts of premises, and may require the holder of the manufacturing authorisation to restrict access to premises or parts of premises to persons carrying out activities there.

(3) The holder of a manufacturing authorisation must notify the Secretary of State, and if necessary apply for a variation of the authorisation, before making a material alteration to the premises or facilities used under the authorisation, or to the operations for which they are used.

Extent Information

E54 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F255 Word in Sch. 2 para. 4(1)(a) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **83(a)**

F256 Sch. 2 para. 4(1)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **83(b)**

The authorisation **N.I.**

4.—(1) The manufacturing authorisation must specify—

- (a) the types of veterinary medicinal products and pharmaceutical forms that may be manufactured or imported;
- (b) the place where they are to be manufactured or controlled;
- (c) the name and address of the person holding the authorisation;
- (d) the address of the premises to which it relates;
- (e) the names of all qualified persons nominated to act under this Schedule.

(2) It may specify that different activities must be carried out in different premises or parts of premises, and may require the holder of the manufacturing authorisation to restrict access to premises or parts of premises to persons carrying out activities there.

(3) The holder of a manufacturing authorisation must notify the Secretary of State, and if necessary apply for a variation of the authorisation, before making a material alteration to the premises or facilities used under the authorisation, or to the operations for which they are used.

Extent Information

E227 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F257} Application for variation to the authorisation

4A.—(1) The holder of a manufacturing authorisation must notify the Secretary of State, and apply for a variation of the authorisation, before—

- (a) making a material alteration to the premises or facilities used under the authorisation, or to the operations for which they are used;
- (b) changing the qualified person (manufacture), the person with responsibility for quality control or the person with responsibility for production.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(2) The Secretary of State must process an application under sub-paragraph (1) within 30 days of receiving it unless the Secretary of State notifies the applicant in writing that the time has been extended to 90 days.

(3) The Secretary of State must grant the application under sub-paragraph (1) if satisfied in respect of the matters in paragraph 3(3) as regards the proposed variation.

(4) The Secretary of State may inspect any site to which the manufacturing authorisation or proposed variation relates in connection with the application.

(5) Where the Secretary of State is not satisfied for the purposes of sub-paragraph (3), the Secretary of State may—

- (a) reject the application; or
- (b) grant a conditional variation to the manufacturing authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

(6) The Secretary of State may extend the period for which a conditional variation to the marketing authorisation is granted under sub-paragraph (5)(b).

(7) Where a conditional variation to the manufacturing authorisation is granted under sub-paragraph (5)(b) and the deficiency is addressed within the specified period to the satisfaction of the Secretary of State, the authorisation continues to have effect as so varied without those conditions.]

Textual Amendments

F257 Sch. 2 para. 4A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **84**

[^{F258}**Suspension, revocation etc] of the authorisation **E+W+S****

5.—(1) The Secretary of State may suspend, vary or revoke a manufacturing authorisation if the holder—

- (a) has not complied with these Regulations;
- (b) has manufactured a veterinary medicinal product not authorised by the manufacturing authorisation;
- (c) has produced a veterinary medicinal product outside the terms of a marketing authorisation; ^{F259} ...
- (d) no longer has suitable premises or equipment.

[^{F260}(e) has failed to carry out the activity specified in the authorisation for a period of five years or more; or

- (f) has not paid any fee required under these Regulations]

[^{F261}(2) The Secretary of State may also suspend, vary or revoke the authorisation on being satisfied that the qualified person (manufacture), the person responsible for quality control or the person with responsibility for production is not fulfilling that person's duties under these Regulations.

(3) In particular, the Secretary of State may—

- (a) suspend the manufacture or import of veterinary medicinal products;
- (b) suspend, revoke or vary the manufacturing authorisation for one or more pharmaceutical forms;
- (c) suspend, revoke or vary the manufacturing authorisation for one or more activities in one or more manufacturing sites.]

Extent Information

E55 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F258 Words in Sch. 2 para. 5 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **85(c)**

F259 Word in Sch. 2 para. 5(1) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **85(a)(i)**

F260 Sch. 2 para. 5(1)(e)(f) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **85(a)(ii)**

F261 Sch. 2 para. 5(2)(3) substituted for Sch. 2 para. 5(2) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **85(b)**

Suspension, variation or revocation of the authorisation **N.I.**

5.—(1) The Secretary of State may suspend, vary or revoke a manufacturing authorisation if the holder—

- (a) has not complied with these Regulations;
- (b) has manufactured a veterinary medicinal product not authorised by the manufacturing authorisation;
- (c) has produced a veterinary medicinal product outside the terms of a marketing authorisation; or
- (d) no longer has suitable premises or equipment.

(2) The Secretary of State may also suspend, vary or revoke it on being satisfied that the qualified person (manufacture) is not fulfilling their duties under these Regulations.

Extent Information

E228 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F262}Good manufacturing practice certificates and inspection of sites] **E+W+S**

6.—(1) The Secretary of State must, from time to time, inspect [^{F263}sites][^{F264}authorised] under paragraph 3, basing the frequency of the inspection on the risks associated with each [^{F265}site's history] and the nature of the products handled at the [^{F263}sites].

[^{F266}(2) Within 90 days after an inspection, the Secretary of State must issue a certificate of good manufacturing practice to the manufacturer if the inspection establishes that the manufacturer has complied with the requirements of these Regulations in respect of the site to which the inspection relates.

(2A) Where the Secretary of State does not consider that compliance is established after inspection in accordance with sub-paragraph (2), the Secretary of State must enter that fact in the register mentioned in paragraph 12(a).

(2B) The Secretary of State may carry out an inspection on a site occupied by a manufacturer established in a country other than the United Kingdom notwithstanding any arrangements that may have been entered into between the United Kingdom and that country.

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

(2C) The importer of a veterinary medicinal product must ensure before importation that the manufacturer of that product has—

- (a) a valid certificate of good manufacturing practice issued by the Secretary of State; or
- (b) an equivalent certificate issued by a regulatory authority—
 - (i) with which the Secretary of State has an agreement or arrangement for such purposes; or
 - (ii) which the Secretary of State considers to have demonstrated equivalent standards to those in the United Kingdom.]

- F267(3)
- F267(4)
- F267(5)

Extent Information

E56 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F262 Sch. 2 para. 6 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **86(c)**

F263 Word in Sch. 2 para. 6(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **86(a)(i)**

F264 Word in Sch. 2 para. 6(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **86(a)(ii)**

F265 Words in Sch. 2 para. 6(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **86(a)(iii)**

F266 Sch. 2 para. 6(2)-(2C) substituted for Sch. 2 para. 6(2) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **86(b)**

F267 Sch. 2 para. 6(3)-(5) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(33)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Inspection of premises N.I.

6.—(1) The Secretary of State must, from time to time, inspect premises registered under paragraph 3, basing the frequency of the inspection on the risks associated with each premises’ history and the nature of the products handled at the premises.

(2) Within 90 days after an inspection, the Secretary of State must issue a certificate of good manufacturing practice to the manufacturer if the inspection established compliance with the principles and guidelines on good manufacturing practice in accordance with Commission [Directive 91/412/EEC](#) laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products**(31)**.

(3) If an inspection is carried out at the request of the European Pharmacopoeia to establish compliance with a monograph, the Secretary of State must issue a certificate of compliance with the monograph, if appropriate.

(31) OJ No L 228, 17.8.91, p. 70.

(4) The Secretary of State must provide details of each certificate of good manufacturing practice issued to the Agency for entry into a database.

(5) If the outcome of the inspection is that the manufacturer does not comply with the principles and guidelines of good manufacturing practice, the Secretary of State must provide details to the Agency for entry into the database.

Extent Information

E229 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Report following inspection

7.—(1) After each inspection of manufacturing premises, the inspector must make a written report to the Secretary of State on whether the principles and guidelines on good manufacturing practice and the conditions of these Regulations are being complied with.

(2) The Secretary of State must inform the inspected manufacturer of the content of such reports.

Duties on the holder of a manufacturing authorisation **E+W+S**

8.—(1) A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with the marketing authorisation.

[^{F268}(2) The holder must have permanently at the holder's disposal the services of—

- (a) staff complying with any legal requirements in relation to manufacture of veterinary medicinal products; and
- (b) at least one qualified person (manufacture).

(2A) The holder must place at the disposal of any qualified person (manufacture) all necessary documents, premises and technical and other facilities in order to enable that person to discharge their duties as the qualified person.

(2B) Where any qualified person (manufacture) ceases to be available to provide services to the holder, the holder must give notice of the fact to the Secretary of State—

- (a) at least 30 days in advance of the person's ceasing to be so available; or
- (b) where such notice is not possible, at the earliest opportunity.]

[^{F269}(3) The holder must—

- (a) comply with good manufacturing practice and have a valid certificate of good manufacturing practice;
- (b) use as starting materials only active substances which have been manufactured in accordance with good manufacturing practice and distributed in accordance with good distribution practice for active substances;
- (c) verify that each manufacturer, distributor or importer from whom the holder obtains active substances and to which paragraph 26 applies is registered with the Secretary of State under that paragraph;
- (d) carry out audits based on a risk assessment in relation to the manufacturers, distributors and importers from which the holder obtains active substances;
- (e) have in place a system of quality assurance and quality control; and
- (f) give to the Secretary of State, on request, proof of any control test specified by the Secretary of State which has been carried out on the veterinary medicinal product or the

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Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

constituents and intermediate products of the manufacturing process in accordance with the data submitted in support of the application for the marketing authorisation.

(3A) The holder of a manufacturing authorisation must inform the Secretary of State and the holder of any relevant marketing authorisation where the holder obtains information that veterinary medicinal products which fall within the scope of its manufacturing authorisation are falsified, or are suspected of being falsified, irrespective of whether those products were distributed within the legal supply chain or by illegal means.]

(4) A holder who makes up a bulk package of veterinary medicinal products must ensure that the package is labelled, in a way that the label is clearly visible and legible, with—

- (a) the name of the veterinary medicinal product, its strength as shown in the summary of product characteristics and its pharmaceutical form;
- (b) the batch number;
- (c) the expiry date;
- (d) any storage requirements; and
- (e) any other warning necessary for the safe handling of the package.

(5) A holder must keep an adequate number of representative samples of each batch of a veterinary medicinal product in stock at least until the expiry date of the batch, and must submit any such sample to the Secretary of State if required in writing to do so.

[^{F270}(6) A holder must keep detailed records of all veterinary medicinal products which the holder supplies.]

Extent Information

E57 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F268 Sch. 2 para. 8(2)-(2B) substituted for Sch. 2 para. 8(2) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **87(a)**

F269 Sch. 2 para. 8(3)(3A) substituted for Sch. 2 para. 8(3) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **87(b)**

F270 Sch. 2 para. 8(6) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **87(c)**

Duties on the holder of a manufacturing authorisation **N.I.**

8.—(1) A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with the marketing authorisation.

(2) The holder must have permanently at their disposal the services of at least one qualified person (manufacture) who is on the register of qualified persons (manufacture) maintained by the Secretary of State and must place all necessary facilities at the qualified person's disposal.

(3) The holder must—

- (a) have a current Certificate of Good Manufacturing Practice;
- (b) have in place a system of Quality Assurance and Quality Control; and
- (c) give to the Secretary of State on request proof of all control tests carried out on the veterinary medicinal product or the constituents and intermediate products of the

manufacturing process in accordance with the data submitted in support of the application for the marketing authorisation.

(4) A holder who makes up a bulk package of veterinary medicinal products must ensure that the package is labelled, in a way that the label is clearly visible and legible, with—

- (a) the name of the veterinary medicinal product, its strength as shown in the summary of product characteristics and its pharmaceutical form;
- (b) the batch number;
- (c) the expiry date;
- (d) any storage requirements; and
- (e) any other warning necessary for the safe handling of the package.

(5) A holder must keep an adequate number of representative samples of each batch of a veterinary medicinal product in stock at least until the expiry date of the batch, and must submit any such sample to the Secretary of State if required in writing to do so.

Extent Information

E230 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F271}Good manufacturing practice

8A.—(1) A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with this paragraph, whether the manufacturing is performed by the holder or another person.

(2) The manufacturing operations must be conducted in accordance with a written methodology, to be known as the “pharmaceutical quality system” or “PQS”.

(3) The PQS must be—

- (a) clear;
- (b) systematically reviewed from time to time in the light of experience; and
- (c) capable of consistently manufacturing veterinary medicinal products which are of the required quality and which meet the requirements of the relevant marketing authorisation.

(4) The critical steps of the manufacturing process set out in the PQS must be validated.

(5) Any significant amendments to the PQS must be validated.

(6) The PQS must provide for—

- (a) appropriately qualified and trained personnel;
- (b) adequate premises and space;
- (c) suitable equipment and access to services;
- (d) suitable materials, containers and labelling;
- (e) relevant procedures and instructions;
- (f) suitable storage and transport;
- (g) investigation into complaints and defects.

(7) The PQS must provide for any significant deviations from its provisions to be—

- (a) fully recorded, and
- (b) investigated, with appropriate corrective and preventative action implemented.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (8) The holder of a manufacturing authorisation must ensure that records of the manufacturing process, including distribution, are kept in a comprehensible and accessible form until the later of—
- (a) the date which is five years after the date on which the veterinary medicinal product is placed on the market;
 - (b) the date which is one year after the expiry date of the batch of veterinary medicinal product.
- (9) In this paragraph, a process (or part of a process) is “validated” if scientific evidence is assembled which demonstrates that it is capable of consistently delivering expected results.]

Textual Amendments

F271 Sch. 2 paras. 8A, 8B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **88**

[^{F271}Recalled and counterfeit products

8B.—(1) The holder of a manufacturing authorisation must comply with any requirement by the Secretary of State to recall a veterinary medicinal product and must record the details of the recall operation.

(2) The holder of a manufacturing authorisation must record any veterinary medicinal product which is—

- (a) recalled (whether or not the holder physically receives the recalled product); or
- (b) discovered to be counterfeit.

(3) Where any veterinary medicinal product is recalled and physically received, the qualified person (manufacture) must assess the recalled product in order to determine whether—

- (a) the product has been stored (including during transport) in accordance with the summary of product characteristics;
- (b) the product is a genuine product and not counterfeit.

(4) Where the qualified person (manufacture) determines that a recalled veterinary medicinal product does not satisfy sub-paragraph (3)(a) or (b), or where it is not possible for the qualified person (manufacture) to determine whether the product does so, the product may not be re-sold.

(5) The qualified person (manufacture) must record any assessment and determination made under sub-paragraphs (3) and (4).

(6) Any veterinary medicinal products which may not be re-sold must be identified, held separately and destroyed and the holder of a manufacturing authorisation must develop a suitable procedure to set out the steps to be taken in accordance with this sub-paragraph.

(7) The holder of a manufacturing authorisation must keep any information recorded under this paragraph for five years.]

Textual Amendments

F271 Sch. 2 paras. 8A, 8B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **88**

Qualified persons for manufacture

9.—(1) The Secretary of State may appoint as a qualified person (manufacture) any person [^{F272}(including the manufacturer of a veterinary medicinal product)] who is—

- (a) a member of the Royal Pharmaceutical Society or registered with the Pharmaceutical Society of Northern Ireland;
- (b) a Chartered Chemist or a Fellow, Member or Associate Member of the Royal Society of Chemistry; or
- (c) a Chartered Biologist or a Fellow, Member or Associate Member of the Society of Biology;

^{F273}(1A) For the purposes of sub-paragraph (1), a person has sufficient practical experience if they have been engaged in one or more of the activities mentioned in sub-paragraph (1B) for at least two years in the provision of services to the holder of a manufacturing authorisation.

(1B) For the purposes of sub-paragraph (1A) the activities are—

- (a) quality assurance of medicinal products;
- (b) qualitative analysis of medicinal products;
- (c) quantitative analysis of active substances.

(1C) The Secretary of State may treat the reference in sub-paragraph (1A) to two years of practical experience as a reference to—

- (a) one year, where the person's formal course of study lasted for at least five years;
- (b) six months, where the person's formal course of study lasted for at least six years.]

who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent and who has sufficient practical experience to carry out the duties under this Schedule.

(2) The Secretary of State may exceptionally appoint a person who is not a member of one of those institutions to act as a qualified person (manufacture) on being satisfied that that person has the educational qualifications or practical experience to carry out the duties under this Schedule.

Textual Amendments

F272 Words in Sch. 2 para. 9(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **89(a)**

F273 Sch. 2 para. 9(1A)-(1C) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **89(b)**

^{F274}**Refusal, revocation, suspension or variation of appointment** **E+W+S**

10. The Secretary of State may refuse [^{F275}, revoke, suspend or vary] an appointment if the Secretary of State is not satisfied that a person has fulfilled or will fulfil duties under these Regulations.

Extent Information

E58 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F274 Sch. 2 para. 10 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **90(b)**

F275 Words in Sch. 2 para. 10 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **90(a)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Refusal or revocation of appointment **N.I.**

10. The Secretary of State may refuse or revoke an appointment if the Secretary of State is not satisfied that a person has fulfilled or will fulfil duties under these Regulations.

Extent Information

E231 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Duties on a qualified person **E+W+S**

11.—(1) The qualified person (manufacture) must ensure that each batch of veterinary medicinal product manufactured under that person's responsibility is manufactured and checked in compliance with these Regulations and in accordance with the data submitted in support of the application for the marketing authorisation.

(2) If a manufacturer imports a veterinary medicinal product from [^{F276}another] country,^{F277} ..., the qualified person (manufacture) must ensure that, following importation, each production batch imported is fully tested^{F278} ..., including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or controls necessary to ensure the quality of a veterinary medicinal product is in accordance with the requirements of the marketing authorisation.

(3) Sub-paragraph (2) does not apply [^{F279}where the exporting country has demonstrated equivalent standards to those of the United Kingdom or] where appropriate arrangements have been made^{F280} ...with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission [Directive 91/412/EEC](#) and to ensure that the controls in sub-paragraph (2) have been carried out in the exporting country.

(4) At each stage of manufacture, including release for sale, the qualified person (manufacture) must certify in writing that all control tests required under the marketing authorisation have been carried out, and that the production batch complies with the marketing authorisation.

Extent Information

E59 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F276 Word in Sch. 2 para. 11(2) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(33)(b)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F277 Words in Sch. 2 para. 11(2) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(33)(b)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F278 Words in Sch. 2 para. 11(2) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(33)(b)(iii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F279 Words in Sch. 2 para. 11(3) inserted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU](#)

Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(c)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F280 Words in Sch. 2 para. 11(3) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(c)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Duties on a qualified person **N.I.**

11.—(1) The qualified person (manufacture) must ensure that each batch of veterinary medicinal product manufactured under that person's responsibility is manufactured and checked in compliance with these Regulations and in accordance with the data submitted in support of the application for the marketing authorisation.

(2) If a manufacturer imports a veterinary medicinal product from a third country, including a product manufactured in a member State, the qualified person (manufacture) must ensure that, following importation, each production batch imported is fully tested in a member State, including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or controls necessary to ensure the quality of a veterinary medicinal product is in accordance with the requirements of the marketing authorisation.

(3) Sub-paragraph (2) does not apply where appropriate arrangements have been made by the European Union with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission [Directive 91/412/EEC](#) and to ensure that the controls in sub-paragraph (2) have been carried out in the exporting country.

(4) At each stage of manufacture, including release for sale, the qualified person (manufacture) must certify in writing that all control tests required under the marketing authorisation have been carried out, and that the production batch complies with the marketing authorisation.

Extent Information

E232 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Register

12. The Secretary of State must maintain and publish a register of—

- (a) holders of manufacturing authorisations; and
- (b) qualified persons (manufacture) appointed under paragraph 9(2).

Test sites **E+W+S**

13.—(1) The Secretary of State may authorise [^{F281}a site] to act as a test site to carry out contract testing for a holder of a manufacturing authorisation.

(2) The [^{F282}site] must have a current certificate of good manufacturing practice.

[^{F283}(2A) The site must be specified in an existing manufacturing authorisation.]

(3) [^{F284}Inspection of the site is] the same as for a manufacturing authorisation.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Extent Information

E60 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F281 Words in Sch. 2 para. 13(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **91(a)**

F282 Word in Sch. 2 para. 13(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **91(b)**

F283 Sch. 2 para. 13(2A) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **91(c)**

F284 Words in Sch. 2 para. 13(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **91(d)**

Test sites **N.I.**

13.—(1) The Secretary of State may authorise premises to act as a test site to carry out contract testing for a holder of a manufacturing authorisation.

(2) The premises must have a current certificate of good manufacturing practice.

(3) Authorisation and inspection of the premises are the same as for a manufacturing authorisation.

Extent Information

E233 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F285}PART 2

Authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade]

Textual Amendments

F285 [Sch. 2 Pt. 2](#) (paras. 14-25 entitled "Authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade") substituted for Sch. 2 Pt. 2 (paras. 14-19 entitled "Authorisation of manufacturers of autogenous vaccines"), Pt. 3 (paras. 20-24 entitled "Authorisation of blood banks"), Pt. 4 (paras. 25-29 entitled "Authorisation of manufacturers of products for administration under the cascade") and Pt. 5 (paras. 30-35 entitled "Authorisation of equine stem cell centres") (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **92**

[^{F285}Authorisation to manufacture specific veterinary medicinal products **E+W+S**

14.—(1) The Secretary of State may authorise a person to—

(a) manufacture—

- (i) autogenous vaccines; or
- (ii) an unauthorised veterinary medicinal product for administration under the cascade;
- (b) collect, store and supply blood in connection with the treatment of non-food animals;
- (c) collect, store and supply blood constituents obtained by the physical separation of donor blood into different fractions within a closed bag system, for the treatment of non-food animals; or
- (d) collect, process and store stem cells for use as an autologous treatment in non-food animals,

and may authorise sites for the purpose of carrying out those activities by that person.

(2) A single authorisation under sub-paragraph (1) may confer permission to carry out the activities mentioned in both paragraph (b) and (c) of that sub-paragraph.

(3) In this paragraph, a “closed bag system” means a system in which the blood pack assembly is manufactured under clean conditions, sealed to the external environment and sterilised.]

Extent Information

E61 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Authorisation to manufacture autogenous vaccines **N.I.**

14.—(1) The Secretary of State may authorise a person to manufacture autogenous vaccines and may authorise premises for the purpose of such manufacture by that person.

(2) In order to be authorised the premises must be under the supervision of—

- (a) a veterinary surgeon; or
- (b) a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.

(3) Before authorising the premises, the Secretary of State must be satisfied that the production process will produce a consistent, safe product.

(4) No person may manufacture an autogenous vaccine other than in accordance with an authorisation under sub-paragraph (1).

Extent Information

E234 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F285}Prohibition **E+W+S**

15. No person may carry out any activity mentioned in paragraph 14 otherwise than—

- (a) in accordance with an authorisation mentioned in that paragraph; or
- (b) pursuant to paragraph 1(2) of Schedule 4 (administration under the cascade).]

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Extent Information

E62 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Types of authorisation **N.I.**

15.—(1) The authorisation must specify the products that may be manufactured.

(2) It may either be for the production of a single batch of product or for ongoing production of the products specified in the authorisation.

(3) If it is for a single batch it must be time limited.

(4) Only the products specified in the authorisation may be manufactured, and in the case of an authorisation for a single batch the product may only be manufactured before the expiry of the authorisation.

Extent Information

E235 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

^{F285} Personnel **E+W+S**

16. In order to be authorised the site mentioned in paragraph 14(1) must be under the supervision of a named person responsible for release (a “PRR”) who in the opinion of the Secretary of State has sufficient qualifications and experience to manufacture the product safely.]

Extent Information

E63 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Labelling **N.I.**

16. The operator of the premises must ensure that every container containing autogenous vaccine is labelled with—

- (a) the name of the veterinary surgeon who ordered the vaccine;
- (b) a precise description of the vaccine;
- (c) the date the vaccine was produced;
- (d) the name of the authorisation holder and address of the authorised premises;
- (e) the expiry date;
- (f) any necessary warnings; and
- (g) instructions for use.

Extent Information

E236 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F285} **Process of authorisation** **E+W+S**

17.—(1) An applicant for authorisation under paragraph 14 must, at least two months before commencing an activity mentioned in that paragraph, submit the following to the Secretary of State—

- (a) the name and address of the proposed holder of the authorisation;
- (b) a description of the activity in which the applicant for authorisation proposes to be engaged;
- (c) particulars (including the name and address) in relation to the site at which the relevant activity is to be carried out (whether in the occupation of the proposed holder or otherwise) and a description of the technical equipment on the site;
- (d) particulars in relation to the qualifications and experience of the proposed PRR who will supervise the activities at the site.

(2) The application must include a declaration that the applicant will comply with the requirements of these Regulations and confirmation that the site is ready for inspection.

(3) Before granting an authorisation in relation to a site, the Secretary of State must be satisfied that the production process carried out there will produce a consistent, safe product and, in the case of a blood bank or a stem cell centre, that the welfare of the animals involved in the processes will be respected.]

Extent Information

E64 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Records **N.I.**

17. The operator of the premises must, as soon as is reasonably practicable, record—

- (a) the name and address of the veterinary surgeon who ordered the vaccine;
- (b) the identification of the source animal;
- (c) the expiry date;
- (d) the date of supply to the veterinary surgeon,

and must keep the records for at least five years.

Extent Information

E237 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

[^{F285} **Authorisation in relation to blood banks** **E+W+S**]

18.—(1) No person may collect blood for the purposes of a non-food animal blood bank other than a veterinary surgeon or a person acting under the responsibility of a veterinary surgeon.

(2) The holder of an authorisation to carry out an activity under paragraph 14(1)(b) or (c) may only supply blood or blood constituents to a veterinary surgeon.

(3) No person other than a veterinary surgeon or someone acting under a veterinary surgeon's responsibility may administer blood to a non-food producing animal.

(4) No person may administer blood to a food-producing animal.]

Extent Information

E65 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Adverse reactions **N.I.**

18. The authorised person must notify the Secretary of State of any adverse reactions to an autogenous vaccine within 15 days of learning of the reaction.

Extent Information

E238 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F285} **Authorisation in relation to stem cells** **E+W+S**]

19.—(1) No person may collect stem cells for the purposes of treating animals other than a veterinary surgeon or a person acting under the responsibility of a veterinary surgeon.

(2) No person may collect stem cells from embryonic tissues.

(3) No person may administer any product grown from stem cells to a food-producing animal.]

Extent Information

E66 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Inspection of premises **N.I.**

19. The Secretary of State must inspect the authorised premises, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

Extent Information

E239 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F285} **Authorisation in relation to products for administration under the cascade** **E+W+S**]

20.—(1) Subject to sub-paragraph (2), no person may manufacture a product for administration under the cascade that is the pharmaceutical equivalent of an authorised veterinary medicinal product.

(2) The Secretary of State may authorise the manufacture of a product notwithstanding sub-paragraph (1) where there is difficulty in relation to the supply of the authorised veterinary medicinal product.

(3) The holder of an authorisation under paragraph 14(1)(a)(ii) may not supply a product manufactured in accordance with that sub-paragraph other than to a veterinary surgeon who has prescribed the product under the cascade.

(4) The holder of an authorisation under paragraph 14(1)(a)(ii) must—

- (a) provide a list of products manufactured in accordance with that sub-paragraph to the Secretary of State annually or at the request of the Secretary of State;
- (b) provide sales data for products supplied under sub-paragraph (3) at the request of the Secretary of State.

(5) For the purposes of this paragraph, a product is the pharmaceutical equivalent of an authorised veterinary medicinal product if—

- (a) it has the same qualitative and quantitative composition in active substances; and
- (b) it has the same pharmaceutical form.]

Extent Information

E67 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Authorisation of blood banks **N.I.**

20.—(1) The Secretary of State may authorise blood banks for—

- (a) the collection, storage and supply of blood, or
- (b) the storage and supply of blood constituents obtained by the physical separation of donor blood into different fractions within a closed-bag system,

for the treatment of non-food-producing animals.

(2) The authorisation may be for either or both of these activities.

(3) In order to be authorised a blood bank must be under the supervision of—

- (a) a veterinary surgeon named in the authorisation; or
- (b) a person named in the authorisation who the Secretary of State is satisfied is suitably qualified to operate the blood bank.

(4) Before authorising a blood bank, the Secretary of State must be satisfied—

- (a) that the welfare of animals used in the collection of blood will be respected; and
- (b) that the production process will produce a consistent, safe product.

(5) The Secretary of State may suspend, vary or revoke an authorisation of a blood bank if—

- (a) the holder no longer uses fit and proper processes;
- (b) the premises in which the blood bank is being or is to be operated are not suitable;
- (c) the equipment is not suitable; or

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (d) the holder has not complied with these Regulations.
- (6) Blood may only be collected under the responsibility of a veterinary surgeon.
- (7) No person may operate a blood bank for treatment of animals other than in accordance with such an authorisation.

Extent Information

E240 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F285}Suspension, compulsory variation or revocation of authorisation **E+W+S**]

21. The Secretary of State may by notice suspend, vary or revoke an authorisation under paragraph 14 if the Secretary of State is satisfied that—

- (a) the holder of the authorisation no longer uses fit and proper processes;
- (b) the site at which the activity takes place is not suitable;
- (c) the equipment is not suitable;
- (d) the PRR has not carried out adequately the PRR’s responsibilities under these Regulations;
- (e) in the case of a person authorised under paragraph 14(1), that person has manufactured a veterinary medicinal product pursuant to that authorisation that is not within its scope;
- (f) the holder has not conducted an activity relating to the authorisation for five years or more;
- (g) the holder has not paid any fee required under these Regulations; or
- (h) the holder has not complied with any other provision in these Regulations.]

Extent Information

E68 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Supply and administration of blood from a blood bank **N.I.**

- 21.—(1)** The operator of a blood bank may only supply blood to a veterinary surgeon.
- (2) No person other than a veterinary surgeon or someone acting under a veterinary surgeon’s responsibility may administer blood.
- (3) No person may administer blood to a food-producing animal.

Extent Information

E241 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F285}Labelling **E+W+S**]

22.—(1) The holder of an authorisation under paragraph 14 must ensure that every container used is labelled with—

- (a) a precise description of the product;

- (b) the date on which the product was produced;
- (c) the name and address of the authorisation holder;
- (d) the address of the site named under the authorisation and its authorisation number;
- (e) the instructions for use;
- (f) the expiry date;
- (g) any necessary warnings;
- (h) in the case of an autogenous vaccine or an unauthorised veterinary medicinal product for administration under the cascade, the name of the veterinary surgeon who ordered the product;
- (i) in the case of blood or a stem cell product—
 - (i) the identification of the donor animal; and
 - (ii) the date of collection.

(2) In the case of blood or blood constituents there must be no specific therapeutic indication on the label or on any information related to the product.

(3) In the case of an unauthorised veterinary medicinal product for administration under the cascade the words “this veterinary medicinal product does not hold a marketing authorisation” must appear on the label.]

Extent Information

E69 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Labelling **N.I.**

22.—(1) The operator of a blood bank must ensure that every container used for the blood is labelled with—

- (a) the identification of the donor animal;
- (b) the date of collection;
- (c) the authorisation number of the blood bank;
- (d) any necessary warnings;
- (e) the expiry date.

(2) There must be no specific therapeutic indication on the label or on any information relating to the product.

Extent Information

E242 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F285}Records **E+W+S**

23. The holder of an authorisation under paragraph 14 must, as soon as is reasonably practicable after the product is supplied, in addition to the expiry date of the product, record the following—

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (a) in the case of an unauthorised veterinary medicinal product for administration under the cascade—
 - (i) the name and address of the veterinary surgeon who ordered the veterinary medicinal product;
 - (ii) a precise description of the product;
 - (iii) the date of production;
 - (iv) the date of supply to the veterinary surgeon;
- (b) in the case of stem cells or blood—
 - (i) the identification of the source animal;
 - (ii) the name of the veterinary surgeon who collected the product (or under whose responsibility it was collected);
 - (iii) the date of collection of the product;
 - (iv) the date that the product was used or if the product was supplied to another veterinary surgeon, the name and address of that veterinary surgeon and the date the product was supplied;
- (c) in the case of an autogenous vaccine—
 - (i) the name and address of the veterinary surgeon who ordered the vaccine;
 - (ii) the identification of the source animal;
 - (iii) the date of supply to the veterinary surgeon,

and must keep the records for at least five years.]

Extent Information

E70 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Records **N.I.**

- 23.** The operator of a blood bank must, as soon as is reasonably practicable, record—
- (a) the date of collection;
 - (b) the identification of the donor animal;
 - (c) the veterinary surgeon who collected it;
 - (d) the expiry date;
 - (e) the date the blood was used or, if it was supplied to another veterinary surgeon, the name of that veterinary surgeon and the date it was supplied;

and must keep the records for at least five years.

Extent Information

E243 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F285} **Adverse events** **E+W+S**]

24. The holder of an authorisation under paragraph 14 must notify the Secretary of State of any adverse event in relation to a product produced by that person under that authorisation within 30 days of learning of the event.]

Extent Information

E71 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Inspection of premises **N.I.**

24. The Secretary of State must inspect the authorised premises, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

Extent Information

E244 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F285} **Inspection of sites** **E+W+S**]

25. The Secretary of State must inspect any site authorised under paragraph 14, basing the frequency of the inspection on the risks associated with each site's history and the nature of the products handled at the site.]

Extent Information

E72 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Authorisation to manufacture products for administration under the cascade **N.I.**

25.—(1) The Secretary of State may authorise a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade.

(2) In order to be authorised the premises must be under the supervision of a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.

(3) Before authorising the premises, the Secretary of State must be satisfied that the production process will produce a safe product.

(4) The authorisation must specify what types of product it covers.

(5) No person may manufacture an unauthorised veterinary medicinal product other than in accordance with an authorisation under sub-paragraph (1).

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Extent Information

E245 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F286}PART 2A Active Substances]

Textual Amendments

F286 Sch. 2 Pts. 2A (paras. 26-31), 2B (para. 32) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **93**

[^{F286}Prohibition on manufacture, importation or distribution of active substances unless registered **E+W+S**

26.—(1) No person may manufacture, import or distribute an active substance unless the person is registered in the register maintained under sub-paragraph (2).

(2) The Secretary of State must establish and maintain a register of manufacturers, importers and distributors of active substances and the sites occupied by them for the purposes of manufacturing or holding active substances.]

Extent Information

E73 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Labelling **N.I.**

26. The authorised person must ensure that, before a veterinary medicinal product is supplied, every container is labelled with—

- (a) the name of the veterinary surgeon who ordered the veterinary medicinal product;
- (b) a precise description of the veterinary medicinal product;
- (c) the date of production;
- (d) the name of the authorisation holder and the address of the authorised premises;
- (e) the expiry date;
- (f) any necessary warnings; and
- (g) instructions for use.

Extent Information

E246 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F286} **Application for registration** **E+W+S**]

27.—(1) An applicant for registration under paragraph 26 must, at least two months before commencing an activity mentioned in paragraph 26(1) or, in the case of an existing manufacturer, within two months of the date on which this provision comes into force, submit the following to the Secretary of State—

- (a) the name and address of the proposed registration holder;
- (b) the name of the relevant active substance;
- (c) a description of the activity proposed to be engaged in in relation to the relevant active substance; and
- (d) particulars in relation to the site at which the relevant active substance is to be manufactured or held (as the case may be).

(2) Information may be submitted to the Secretary of State pursuant to sub-paragraph (1) prior to the date on which this provision comes into force, and in such a case—

- (a) as regards an applicant for registration who is not an existing manufacturer, the relevant period of two months is to be treated as having started on the date of submission;
- (b) as regards an applicant for registration who is an existing manufacturer, the information is to be treated as having been submitted within the relevant period of two months.]

Extent Information

E74 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Records **N.I.**

27. The authorised person must, as soon as is reasonably practicable, record—

- (a) the name and address of the veterinary surgeon who ordered the veterinary medicinal product;
- (b) a precise description of the veterinary medicinal product;
- (c) the date of production;
- (d) the expiry date; and
- (e) the date of supply to the veterinary surgeon,

and must keep the record for at least five years.

Extent Information

E247 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F286} **Good manufacturing or distribution practice** **E+W+S**]

28. A manufacturer, importer or distributor of active substances must comply with good manufacturing practice or good distribution practice, as applicable.]

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the
The Veterinary Medicines Regulations 2013. (See end of Document for details)

Extent Information

E75 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Adverse reactions **N.I.**

28. The authorised person must notify the Secretary of State of any adverse reactions to a product manufactured by that person within 15 days of learning of the reaction.

Extent Information

E248 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F286}Supply of information **E+W+S**

29.—(1) A person registered under paragraph 26 must immediately inform the Secretary of State on receipt of any new information that might adversely affect the quality and safety of the active substance.

(2) A person registered under paragraph 26 must immediately inform the Secretary of State of any prohibition or restriction in relation to the active substance imposed by the competent authorities of any country other than the United Kingdom in which the active substance is authorised.]

Extent Information

E76 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Inspection of premises **N.I.**

29. The Secretary of State must inspect the authorised premises, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

Extent Information

E249 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F286}Inspection of sites **E+W+S**

30. The Secretary of State may, from time to time, inspect sites registered under paragraph 26, basing the frequency of the inspections on the risks associated with each site's history and the nature of the substances handled at the site.]

Extent Information

E77 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Authorisation of stem cell centres **N.I.**

30.—(1) The Secretary of State may authorise equine stem cell centres for the collection, storage, processing, production and administration of equine stem cells for use as an autologous treatment for horses.

(2) In order to be authorised a centre must be under the supervision of—

- (a) a veterinary surgeon named in the authorisation; or
- (b) a person named in the authorisation who the Secretary of State is satisfied is suitably qualified to operate the centre.

(3) Before authorising a centre, the Secretary of State must be satisfied—

- (a) that the welfare of animals used in the collection of equine stem cells will be respected; and
- (b) that the production process will produce a consistent, safe product.

(4) Equine stem cells may only be collected under the responsibility of a veterinary surgeon.

(5) The Secretary of State may suspend, vary or revoke an authorisation of an equine stem cell centre if—

- (a) the holder no longer uses fit and proper processes;
- (b) the premises in which the centre is being or is to be operated are not suitable;
- (c) the equipment of the centre is not suitable; or
- (d) the holder has not complied with these Regulations.

(6) No person may operate an equine stem cell centre other than in accordance with such an authorisation.

Extent Information

E250 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F286}Report following inspection **E+W+S**

31.—(1) After each inspection of a site for the purposes of this Part, the inspector must make a written report to the Secretary of State on whether the requirements in this Part are being complied with.

(2) The Secretary of State must inform the inspected registered person of the content of such reports.]

Extent Information

E78 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Supply and administration of stem cells **N.I.**

- 31.**—(1) The operator of an equine stem cell centre may only collect equine stem cells.
- (2) The operator of an equine stem cell centre may not collect stem cells from embryonic tissues.
- (3) No person other than a veterinary surgeon or someone acting under a veterinary surgeon's responsibility may administer any product grown from collected equine stem cells.
- (4) No person may administer any product grown from collected equine stem cells to a food-producing horse.

Extent Information

E251 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F286}PART 2B Schedule 2 Offences]

[^{F286}Offences **E+W+S**

- 32.** It is an offence to fail to comply with—
- (a) paragraph 1;
 - (b) paragraph 4(3);
 - (c) paragraph 8;
 - (d) paragraph 11;
 - (e) paragraph 15;
 - (f) paragraph 18;
 - (g) paragraph 19;
 - (h) paragraph 20(1), (3) or (4);
 - (i) paragraph 22;
 - (j) paragraph 23;
 - (k) paragraph 24;
 - (l) paragraph 26;
 - (m) paragraph 28;
 - (n) paragraph 29.]

Extent Information

E79 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Labelling **N.I.**

- 32.**—(1) The operator of an equine stem cell centre must ensure that every container used for the stem cell product is labelled with—

- (a) the identification of the donor animal;
- (b) the date of collection;
- (c) the authorisation number of the equine stem cell centre;
- (d) any necessary warnings;
- (e) the expiry date.

(2) The operator of an equine stem cell centre must ensure that no specific therapeutic indication is included on the label or on any information relating to the product.

Extent Information

E252 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Records **E+W+S**

33. ^{F285}

Extent Information

E80 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F285 [Sch. 2 Pt. 2](#) (paras. 14-25 entitled "Authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade") substituted for [Sch. 2 Pt. 2](#) (paras. 14-19 entitled "Authorisation of manufacturers of autogenous vaccines"), [Pt. 3](#) (paras. 20-24 entitled "Authorisation of blood banks"), [Pt. 4](#) (paras. 25-29 entitled "Authorisation of manufacturers of products for administration under the cascade") and [Pt. 5](#) (paras. 30-35 entitled "Authorisation of equine stem cell centres") (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\), 92](#)

Records **N.I.**

33. The operator of an equine stem cell centre must, as soon as is reasonably practicable, record for each stem cell product—

- (a) the identification of the donor animal;
- (b) the date of collection;
- (c) the veterinary surgeon under whose responsibility the stem cells were collected;
- (d) the expiry date;
- (e) the date the product was used or, if it was supplied to another veterinary surgeon, the name of that veterinary surgeon and the date it was supplied,

and must keep the records for at least five years.

Extent Information

E253 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Inspection of premises **E+W+S**

34. ^{F285}

Extent Information

E81 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F285 [Sch. 2 Pt. 2](#) (paras. 14-25 entitled "Authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade") substituted for [Sch. 2 Pt. 2](#) (paras. 14-19 entitled "Authorisation of manufacturers of autogenous vaccines"), [Pt. 3](#) (paras. 20-24 entitled "Authorisation of blood banks"), [Pt. 4](#) (paras. 25-29 entitled "Authorisation of manufacturers of products for administration under the cascade") and [Pt. 5](#) (paras. 30-35 entitled "Authorisation of equine stem cell centres") (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\), 92](#)

Inspection of premises **N.I.**

34. The Secretary of State must inspect the authorised premises, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

Offences **E+W+S**

35. ^{F285}

Extent Information

E82 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F285 [Sch. 2 Pt. 2](#) (paras. 14-25 entitled "Authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade") substituted for [Sch. 2 Pt. 2](#) (paras. 14-19 entitled "Authorisation of manufacturers of autogenous vaccines"), [Pt. 3](#) (paras. 20-24 entitled "Authorisation of blood banks"), [Pt. 4](#) (paras. 25-29 entitled "Authorisation of manufacturers of products for administration under the cascade") and [Pt. 5](#) (paras. 30-35 entitled "Authorisation of equine stem cell centres") (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), [regs. 1\(1\), 92](#)

Offences **N.I.**

35. It is an offence to fail to comply with—
- (a) paragraph 4(3);
 - (b) paragraph 11;
 - (c) paragraph 14(4);
 - (d) paragraph 16;
 - (e) paragraph 17;

- (f) paragraph 18;
- (g) paragraph 20(6) or (7);
- (h) paragraph 21;
- (i) paragraph 22;
- (j) paragraph 23;
- (k) paragraph 25(5);
- (l) paragraph 26;
- (m) paragraph 27;
- (n) paragraph 28;
- (o) paragraph 30(4) or (6);
- (p) paragraph 31;
- (q) paragraph 32; or
- (r) paragraph 33.

Extent Information

E254 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

SCHEDULE 3

Regulation 7

Classification and supply, wholesale dealers and sheep dip

PART 1

Classification and supply of authorised veterinary medicinal products

Classification of veterinary medicinal products **E+W+S**

1.—(1) There shall be the following categories of authorised veterinary medicinal products—

- (a) Prescription Only Medicine–Veterinarian (abbreviated to POM-V);
- (b) Prescription Only Medicine–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to POM-VPS);
- (c) Non-Food Animal–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS);
- (d) Authorised Veterinary Medicine–General Sales List (abbreviated to AVM-GSL).

(2) The Secretary of State must specify the classification of the veterinary medicinal product when granting the initial marketing authorisation.

(3) The Secretary of State may change the classification after the marketing authorisation has been granted, either at the request of the marketing authorisation holder or in accordance with paragraph 37 of Schedule 1 (compulsory variation).

(4) When granting the marketing authorisation the Secretary of State must classify the following as POM-V—

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (a) products containing narcotic or psychotropic substances;
 - (b) products intended for administration following a diagnosis or clinical assessment by a veterinary surgeon;
 - [^{F287}(c) products containing an antimicrobial;
 - (d) products for the purpose of euthanasia;
 - (e) products with a hormonal or thyrostatic function;
 - (f) products containing beta-agonists].
- (5) When granting the marketing authorisation the Secretary of State must classify the following as POM-V or POM-VPS—
- (a) products for food-producing animals;
 - (b) products in respect of which special precautions must be taken in order to avoid any unnecessary risk to—
 - (i) the target species;
 - (ii) the person administering the products to the animal; and
 - (iii) the environment;
 - (c) products that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures; ^{F288} ...
 - (d) [^{F289}immunological veterinary medicinal products.]
- (6) The requirement in sub-paragraph (5)(a) relating to veterinary medicinal products for food-producing animals does not apply if all the following criteria are met—
- (a) the administration of the veterinary medicinal product is restricted to formulations requiring no particular knowledge or skill in using the product;
 - (b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;
 - (c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;
 - (d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious [^{F290}adverse event] reporting;
 - (e) the summary of product characteristics does not refer to contra-indications related to other veterinary medicinal products commonly used without prescription;
 - (f) the veterinary medicinal product is not subject to special storage conditions;
 - (g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly; and
 - (h) there is no risk to human or animal health as regards the development of resistance to [^{F291}antibiotics] or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

Extent Information

E83 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F287** Sch. 3 para. 1(4)(c)-(f) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **95(a)**
- F288** Word in Sch. 3 para. 1(5)(c) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **95(b)(i)**
- F289** Sch. 3 para. 1(5)(e) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **95(b)(ii)**
- F290** Words in Sch. 3 para. 1(6)(d) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **95(c)(i)**
- F291** Word in Sch. 3 para. 1(6)(h) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **95(c)(ii)**

Classification of veterinary medicinal products **N.I.**

- 1.—(1) There shall be the following categories of authorised veterinary medicinal products—
- Prescription Only Medicine–Veterinarian (abbreviated to POM-V);
 - Prescription Only Medicine–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to POM-VPS);
 - Non-Food Animal–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS);
 - Authorised Veterinary Medicine–General Sales List (abbreviated to AVM-GSL).
- (2) The Secretary of State must specify the classification of the veterinary medicinal product when granting the initial marketing authorisation.
- (3) The Secretary of State may change the classification after the marketing authorisation has been granted, either at the request of the marketing authorisation holder or in accordance with paragraph 37 of Schedule 1 (compulsory variation).
- (4) When granting the marketing authorisation the Secretary of State must classify the following as POM-V—
- products containing narcotic or psychotropic substances;
 - products intended for administration following a diagnosis or clinical assessment by a veterinary surgeon.
- (5) When granting the marketing authorisation the Secretary of State must classify the following as POM-V or POM-VPS—
- products for food-producing animals;
 - products in respect of which special precautions must be taken in order to avoid any unnecessary risk to—
 - the target species;
 - the person administering the products to the animal; and
 - the environment;
 - products that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures; and
 - new veterinary medicinal products containing an active substance that has not been included in an authorised veterinary medicinal product for five years.
- (6) The requirement in sub-paragraph (5)(a) relating to veterinary medicinal products for food-producing animals does not apply if all the following criteria are met—

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (a) the administration of the veterinary medicinal product is restricted to formulations requiring no particular knowledge or skill in using the product;
- (b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;
- (c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;
- (d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious adverse reaction reporting;
- (e) the summary of product characteristics does not refer to contra-indications related to other veterinary medicinal products commonly used without prescription;
- (f) the veterinary medicinal product is not subject to special storage conditions;
- (g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly; and
- (h) there is no risk to human or animal health as regards the development of resistance to antimicrobials or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

Extent Information

E255 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Wholesale supply of veterinary medicinal products **E+W+S**

2.—(1) Only a holder^{F292}... of a manufacturing authorisation or the holder of a wholesale dealer's authorisation granted by the Secretary of State may supply a veterinary medicinal product wholesale, or be in possession of it for that purpose.

(2) A person mentioned in sub-paragraph (1) may only supply a veterinary medicinal product if—

- (a) the authorisation in question relates to that product, and
- (b) the supply [^{F293}is to the holder of a manufacturing authorisation or] is to another person who is entitled to supply that product under these Regulations, either wholesale or retail.

[^{F294}(3) If the supply is to a veterinary surgeon, a pharmacist or a suitably qualified person, it must be to premises registered (or authorised as the case may be) in accordance with paragraph 8(1), paragraph 10(1) or paragraph 14(4).]

(4) It is immaterial whether or not the supply is for profit.

(5) This paragraph does not apply in relation to a retailer of veterinary medicinal products who supplies another retailer with such products for the purpose of alleviating a temporary supply shortage that could be detrimental to animal welfare.

(6) A wholesale dealer may break open any package (other than the immediate packaging) of a veterinary medicinal product.

Extent Information

E84 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F292 Words in Sch. 3 para. 2(1) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **96(a)** (with reg. 202)

F293 Words in Sch. 3 para. 2(2)(b) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **96(b)**

F294 Sch. 3 para. 2(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **96(c)**

Wholesale supply of veterinary medicinal products **N.I.**

2.—(1) Only a holder of a marketing authorisation, the holder of a manufacturing authorisation or the holder of a wholesale dealer's authorisation granted by the Secretary of State may supply a veterinary medicinal product wholesale, or be in possession of it for that purpose.

(2) A person mentioned in sub-paragraph (1) may only supply a veterinary medicinal product if—

- (a) the authorisation in question relates to that product, and
- (b) the supply is to another person who is entitled to supply that product under these Regulations, either wholesale or retail.

(3) If the supply is to a suitably qualified person, it must be to the premises approved in accordance with paragraph 14.

(4) It is immaterial whether or not the supply is for profit.

(5) This paragraph does not apply in relation to a retailer of veterinary medicinal products who supplies another retailer with such products for the purpose of alleviating a temporary supply shortage that could be detrimental to animal welfare.

(6) A wholesale dealer may break open any package (other than the immediate packaging) of a veterinary medicinal product.

Extent Information

E256 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Retail supply of veterinary medicinal products **E+W+S**

3.—(1) This paragraph applies in relation to retail supply of veterinary medicinal products.

(2) A veterinary medicinal product classified as POM-V may only be supplied by a veterinary surgeon or a pharmacist and must be supplied in accordance with a prescription from a veterinary surgeon.

(3) A veterinary medicinal product classified as POM-VPS may only be supplied by—

- (a) a veterinary surgeon;
- (b) a pharmacist; or
- (c) a suitably qualified person in accordance with paragraph 14,

and must be in accordance with a prescription from one of those persons.

(4) A veterinary medicinal product classified as NFA-VPS may be supplied without prescription, but may only be supplied by—

- (a) a veterinary surgeon;
- (b) a pharmacist; or

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (c) a suitably qualified person in accordance with paragraph 14.
- (5) There are no restrictions on the supply of AVM-GSL products.
- (6) In this paragraph—
 - [^{F295}(a) “retail supply” means a supply whether or not for payment to the owner or keeper of an animal for administration to that animal; and]
 - (b) a person may supply a product irrespective of who owns it.

Extent Information

E85 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F295 Sch. 3 para. 3(6)(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 97

Retail supply of veterinary medicinal products **N.I.**

- 3.—(1) This paragraph applies in relation to retail supply of veterinary medicinal products.
- (2) A veterinary medicinal product classified as POM-V may only be supplied by a veterinary surgeon or a pharmacist and must be supplied in accordance with a prescription from a veterinary surgeon.
- (3) A veterinary medicinal product classified as POM-VPS may only be supplied by—
- (a) a veterinary surgeon;
 - (b) a pharmacist; or
 - (c) a suitably qualified person in accordance with paragraph 14,
- and must be in accordance with a prescription from one of those persons.
- (4) A veterinary medicinal product classified as NFA-VPS may be supplied without prescription, but may only be supplied by—
- (a) a veterinary surgeon;
 - (b) a pharmacist; or
 - (c) a suitably qualified person in accordance with paragraph 14.
- (5) There are no restrictions on the supply of AVM-GSL products.
- (6) In this paragraph—
- (a) “retail supply” means any supply other than to or from the holder of a wholesale dealer’s authorisation, and whether or not for payment; and
 - (b) a person may supply a product irrespective of who owns it.

Extent Information

E257 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F296}Supply of samples

3A.—(1) Subject to sub-paragraph (2) a person mentioned in paragraph 2(1) or 3(2) may not supply a veterinary medicinal product for promotional purposes.

(2) Subject to sub-paragraph (3), the person may supply samples of product labelled in a way that clearly identifies them as such to—

- (a) sales representatives who are responsible for promoting the product; or
- (b) those entitled to supply the product during sponsored events.

(3) Sub-paragraph (2) does not apply in relation to a product containing an antimicrobial substance.]

Textual Amendments

F296 Sch. 3 paras. 3A-3E inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **98**

[^{F296}Register of online suppliers of veterinary medicinal products

3B.—(1) No person may supply or offer to supply a veterinary medicinal product classified as POM-V, POM-VPS or NFA-VPS by means of the internet to persons in Great Britain unless the person—

- (a) is established within Great Britain;
- (b) has an address within Great Britain; and
- (c) appears on the register maintained under sub-paragraph (2).

(2) The Secretary of State must establish, maintain and publish on a website a register of persons who supply veterinary medicinal products by means of the internet.]

Textual Amendments

F296 Sch. 3 paras. 3A-3E inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **98**

[^{F296}Application for registration

3C.—(1) An applicant for registration under paragraph 3B must, at least two months before commencing the activity mentioned in paragraph 3B(1) (or in the case of an existing supplier of veterinary medicinal products by means of the internet within two months of the date on which this provision comes into force), submit to the Secretary of State the name and the address within Great Britain of the proposed registration holder.

(2) Information may be submitted to the Secretary of State pursuant to sub-paragraph (1) prior to the date on which this provision comes into force, and in such a case—

- (a) as regards an applicant for registration who is not an existing supplier of veterinary medicinal products by means of the internet, the relevant period of two months is to be treated as having started on the date of submission;
- (b) as regards an applicant for registration who is an existing supplier of veterinary medicinal products by means of the internet, the information is to be treated as having been submitted within the relevant period of two months.]

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

F296 Sch. 3 paras. 3A-3E inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **98**

[^{F296}Duties in relation to online supply

3D. Where a person offers to supply a veterinary medicinal product by means of the internet, that person must make available on each part of the website where the product is offered—

- (a) the statement “registered internet retailer of veterinary medicines”;
- (b) the contact details of the Secretary of State; and
- (c) a link to the published register.]

Textual Amendments

F296 Sch. 3 paras. 3A-3E inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **98**

[^{F296}Retail storage of veterinary medicinal products

3E. A retailer of veterinary medicinal products must store (including during transport) a veterinary medicinal product in accordance with the terms of any specific instructions on the label of the product and in accordance with the relevant summary of product characteristics.]

Textual Amendments

F296 Sch. 3 paras. 3A-3E inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **98**

Prescriptions by a veterinary surgeon

4.—(1) A veterinary surgeon who prescribes a veterinary medicinal product classified as POM-V [^{F297}or a veterinary medicinal product under the cascade] must first carry out a clinical assessment of the animal, and the animal must be under that veterinary surgeon’s care.

(2) This does not apply in relation to the administration of such a product to a wild animal where the administration is authorised by the Secretary of State.

Textual Amendments

F297 Words in Sch. 3 para. 4(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **99**

Prescriptions **E+W+S**

5.—(1) A prescription may be [^{F298}verbal] or written, but a veterinary medicinal product classified as POM-V or POM-VPS [^{F299}or a veterinary medicinal product prescribed under the cascade] may only be supplied—

- (a) by the person who prescribed it;
- (b) under a written prescription that complies with paragraph 6; or
- (c) (in the case of POM-VPS) by a suitably qualified person in accordance with paragraph 14(5).

[^{F300}(1A) Where a veterinary medicinal product is supplied in accordance with a prescription which is not a written prescription, the person who prescribes the product must make a record of the reason for prescribing the product.

(1B) A record made in accordance with sub-paragraph (1A) must be kept by the person mentioned in that sub-paragraph for a period of five years from the date on which the product is prescribed]

- (2) A person supplying such a product under a written prescription—
 - (a) may only supply the product specified in that prescription;
 - (b) must take all reasonable steps to be satisfied that the prescription has been written and signed by a person entitled to prescribe the product; and
 - (c) must take all reasonable steps to ensure that it is supplied to the person named in the prescription.

(3) No person may alter a written prescription unless authorised to do so by the person who signed it.

[^{F301}(4) No person may submit a written prescription to a retailer on more than one occasion where the prescription is not repeatable.]

Extent Information

E86 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F298 Word in Sch. 3 para. 5(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **100(a)(i)** (with reg. 203)

F299 Words in Sch. 3 para. 5(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **100(a)(ii)** (with reg. 203)

F300 Sch. 3 para. 5(1A)(1B) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **100(b)** (with reg. 203)

F301 Sch. 3 para. 5(4) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **100(c)** (with reg. 203)

Prescriptions **N.I.**

5.—(1) A prescription may be oral or written, but a veterinary medicinal product classified as POM-V or POM-VPS may only be supplied—

- (a) by the person who prescribed it;
 - (b) under a written prescription that complies with paragraph 6; or
 - (c) (in the case of POM-VPS) by a suitably qualified person in accordance with paragraph 14(5).
- (2) A person supplying such a product under a written prescription—
- (a) may only supply the product specified in that prescription;

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (b) must take all reasonable steps to be satisfied that the prescription has been written and signed by a person entitled to prescribe the product; and
 - (c) must take all reasonable steps to ensure that it is supplied to the person named in the prescription.
- (3) No person may alter a written prescription unless authorised to do so by the person who signed it.

Extent Information

E258 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Written prescriptions **E+W+S**

- 6.—^{F302}(1) A written prescription must include—
- (a) the full name, address and contact details of the person prescribing the product, including that person's professional registration number (if available);
 - (b) the full name, address and contact details of the animal owner or keeper;
 - (c) the identification (including the species) of the animal or group of animals to be treated;
 - (d) the premises at which the animals are kept if this is different from the address of the owner or keeper;
 - (e) the issue date;
 - (f) the signature or electronic signature of the prescriber;
 - (g) the name and amount of the product prescribed;
 - (h) the pharmaceutical form and strength of the product;
 - (i) as regards veterinary medicinal products that are antibiotics which are prescribed for prophylactic purposes or metaphylactic purposes (as the case may be), a statement to that effect;
 - (j) the dosage regimen;
 - (k) any warnings necessary to ensure the proper use, including, where relevant, to ensure prudent use of antimicrobials;
 - (l) the words “It is an offence under the Veterinary Medicines Regulations 2013 for a person to alter a written prescription unless authorised to do so by the person who signed it”;
 - (m) for food-producing animal species, the withdrawal period or a statement that the withdrawal period is equal to zero days; and
 - (n) if the prescription relates to a product prescribed under the cascade, a statement to that effect.

(1A) Subject to the professional obligations of a veterinary surgeon to ensure the health and welfare of animals under their care, a veterinary surgeon may only prescribe a veterinary medicinal product that is an antibiotic where satisfied that the circumstances set out in sub-paragraph (1B) apply.

- (1B) For the purposes of sub-paragraph (1A) the circumstances are that the product is not—
- (a) used routinely;
 - (b) used to compensate for poor hygiene, inadequate animal husbandry, or poor farm management practices; or

(c) used to promote growth or increase yield.]

(2) A written prescription for a controlled drug as specified in Schedules 2 to 4 of the Misuse of Drugs Regulations 2001(32) is valid for 28 days.

(3) A written prescription for any other drug is valid for six months or such shorter period as may be specified in the prescription.

(4) If the prescription is repeatable it must specify the number of times the veterinary medicinal product may be supplied.

Extent Information

E87 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F302 Sch. 3 para. 6(1)-(1B) substituted for Sch. 3 para. 6(1) (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), 101 (with reg. 204)

Written prescriptions **N.I.**

6.—(1) A written prescription must include—

- (a) the name, address and telephone number of the person prescribing the product;
- (b) the qualifications enabling the person to prescribe the product;
- (c) the name and address of the owner or keeper;
- (d) the identification (including the species) of the animal or group of animals to be treated;
- (e) the premises at which the animals are kept if this is different from the address of the owner or keeper;
- (f) the date of the prescription;
- (g) the signature or other authentication of the person prescribing the product;
- (h) the name and amount of the product prescribed;
- (i) the dosage and administration instructions;
- (j) any necessary warnings;
- (k) the withdrawal period if relevant; and
- (l) if it is prescribed under the cascade, a statement to that effect.

(2) A written prescription for a controlled drug as specified in Schedules 2 to 4 of the Misuse of Drugs Regulations 2001(32) is valid for 28 days.

(3) A written prescription for any other drug is valid for six months or such shorter period as may be specified in the prescription.

(4) If the prescription is repeatable it must specify the number of times the veterinary medicinal product may be supplied.

(32) S. I. 2001/3998; relevant amending instruments are S. I. 2003/1432 and 2005/1653.

(32) S. I. 2001/3998; relevant amending instruments are S. I. 2003/1432 and 2005/1653.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Extent Information

E259 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Duties when a product is prescribed or supplied

7.—^[F303](1) A person who prescribes ^[F304]a veterinary medicinal product under the cascade or] a product classified as POM-V or POM-VPS, or supplies a product classified as NFA-VPS—

- (a) before doing so, must be satisfied that the person who will use the product is competent to do so safely, and intends to use it for a purpose for which it is authorised;
- (b) when doing so, must advise on its safe administration and on any warnings or contra-indications on the label or package leaflet; and
- (c) must not prescribe (or, in the case of a NFA-VPS product, supply) more than the minimum amount required for the treatment; but it is a defence to a charge of failing to comply with this paragraph to show that—
 - (i) the product prescribed or supplied was in a container specified in the marketing authorisation;
 - (ii) the manufacturer does not supply that veterinary medicinal product in a smaller container; and
 - (iii) the person prescribing or supplying is not a person authorised to break open the package before supply.

^[F305](2) A person who prescribes antimicrobials must ensure that the product is prescribed for the most limited period that is consistent with the risk to be addressed.]

Textual Amendments

F303 Sch. 3 para. 7 renumbered as Sch. 3 para. 7(1) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **102(a)**

F304 Words in Sch. 3 para. 7(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **102(b)**

F305 Sch. 3 para. 7(2) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **102(c)**

^[F306]Duties in relation to prescribing of antibiotic veterinary medicinal products

7A.—(1) Subject to sub-paragraphs (2) and (3) a veterinary surgeon may not prescribe a veterinary medicinal product which is an antibiotic for prophylactic purposes.

(2) Without prejudice to paragraph 6(1A), a veterinary surgeon may only prescribe a veterinary medicinal product which is an antibiotic for administration to an animal for prophylactic purposes in exceptional circumstances where the risk of an infection or of an infectious disease is very high and where the consequences of not prescribing the product are likely to be severe.

(3) Subject to sub-paragraph (2), a veterinary surgeon may only prescribe a veterinary medicinal product which is an antibiotic for administration to a group of animals for prophylactic purposes where the circumstances set out in sub-paragraph (4) apply.

(4) For the purposes of sub-paragraph (3) the circumstances are that—

- (a) the rationale for prescribing the product to the group of animals is clearly recorded by the veterinary surgeon prescribing it; and
 - (b) a management review is carried out by a veterinary surgeon at, or as soon as reasonably practicable after, administration of the product in order to identify factors and implement measures for the purpose of eliminating the need for any future such administration.
- (5) A veterinary surgeon who prescribes a veterinary medicinal product which is an antibiotic must make a record of the satisfaction of the relevant conditions for the purposes of its use in accordance with this paragraph and keep that documentation for at least five years.]

Textual Amendments

F306 Sch. 3 para. 7A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **103**

Supply by a veterinary surgeon from registered premises

8.—(1) A veterinary surgeon may only supply a veterinary medicinal product from practice premises registered with the Royal College of Veterinary Surgeons as veterinary practice premises at which veterinary medicinal products are stored or supplied.

(2) This paragraph does not apply in relation to a veterinary medicinal product classified as AVM-GSL.

(3) The Royal College of Veterinary Surgeons must, on request, supply the Secretary of State with a copy of the register of veterinary practice premises.

(4) The Secretary of State must, from time to time, inspect premises registered under sub-paragraph (1), basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

(5) Where an inspection under sub-paragraph (4) reveals significant breaches of these Regulations the Secretary of State may require the Royal College of Veterinary Surgeons to remove the premises from the register maintained under sub-paragraph (1).

(6) Where the Secretary of State requires the removal of premises from the register the veterinary surgeon concerned may appeal using the procedure in regulation 30.

(7) Where premises have been removed from the register under sub-paragraph (5) they may not be re-registered without the approval of the Secretary of State.

(8) The Secretary of State may only grant approval under sub-paragraph (7) after a further inspection of the premises.

Supply by a veterinary surgeon

9.—(1) A veterinary surgeon supplying a veterinary medicinal product (other than one classified as AVM-GSL) must be present when it is handed over unless the veterinary surgeon—

- (a) authorises each transaction individually before the product is supplied; and
- (b) is satisfied that the person handing it over is competent to do so.

(2) A veterinary surgeon or a person acting under a veterinary surgeon's responsibility may open any package containing a veterinary medicinal product.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Supply by a pharmacist **E+W+S**

10.—(1) A pharmacist may only supply a veterinary medicinal product classified as POM-V, POM-VPS or NFA-VPS [^{F307}, or prescribed under the cascade,] from—

- (a) premises registered as a pharmacy with the General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland;
- (b) premises registered with the Royal College of Veterinary Surgeons as being premises from which a veterinary surgeon supplies veterinary medicinal products; or
- (c) (in the case of a veterinary medicinal product classified as POM-VPS or NFA-VPS) from premises [^{F308} authorised] under paragraph 14.

(2) A pharmacist supplying a veterinary medicinal product (other than one classified as AVM-GSL) must be present when it is handed over unless the pharmacist—

- (a) authorises each transaction individually before the product is supplied; and
- (b) is satisfied that the person handing it over is competent to do so.

(3) A pharmacist may supply any veterinary medicinal product prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the end-user.

(4) A pharmacist may supply a homeopathic remedy prepared extemporaneously by a pharmacist in a registered pharmacy (as well as any other homeopathic remedy permitted to be supplied by a pharmacist under these Regulations) provided that it is prepared in accordance with paragraph 63 of Schedule 1 and intended to be supplied directly to the end user.

(5) A pharmacist may break open any package containing a veterinary medicinal product for the purposes of supply other than the immediate packaging of an injectable product.

Extent Information

E88 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F307 Words in Sch. 3 para. 10(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **104(a)**

F308 Word in Sch. 3 para. 10(1)(c) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **104(b)**

Supply by a pharmacist **N.I.**

10.—(1) A pharmacist may only supply a veterinary medicinal product classified as POM-V, POM-VPS or NFA-VPS from—

- (a) premises registered as a pharmacy with the General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland;
- (b) premises registered with the Royal College of Veterinary Surgeons as being premises from which a veterinary surgeon supplies veterinary medicinal products; or
- (c) (in the case of a veterinary medicinal product classified as POM-VPS or NFA-VPS) from premises approved under paragraph 14.

(2) A pharmacist supplying a veterinary medicinal product (other than one classified as AVM-GSL) must be present when it is handed over unless the pharmacist—

- (a) authorises each transaction individually before the product is supplied; and

(b) is satisfied that the person handing it over is competent to do so.

(3) A pharmacist may supply any veterinary medicinal product prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the end-user.

(4) A pharmacist may supply a homeopathic remedy prepared extemporaneously by a pharmacist in a registered pharmacy (as well as any other homeopathic remedy permitted to be supplied by a pharmacist under these Regulations) provided that it is prepared in accordance with paragraph 63 of Schedule 1 and intended to be supplied directly to the end user.

(5) A pharmacist may break open any package containing a veterinary medicinal product for the purposes of supply other than the immediate packaging of an injectable product.

Extent Information

E260 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply of a ^{F309} medicinal premix] **E+W+S**

11.—(1) This paragraph applies in relation to the supply of a ^{F310} medicinal premix].

(2) ^{F311}... An authorised manufacturer of the product or an authorised wholesale dealer may only supply such a ^{F312} medicinal premix] to—

- (a) a veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person;
- (b) an [^{F313} authorised][^{F314} intermediate feedingstuffs] manufacturer; or
- (c) an [^{F313} authorised] feedingstuffs manufacturer if the approval permits the rate of incorporation specified on the label of that [^{F312} medicinal premix] (if the manufacturer is the end-user the supply must be in accordance with a [^{F315} medicated feedingstuffs prescription]).

(3) A veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person may only supply such a ^{F316} medicinal premix] to—

- (a) an [^{F313} authorised][^{F317} intermediate feedingstuffs] manufacturer; or
- (b) an [^{F313} authorised] feedingstuffs manufacturer if the [^{F318} authorisation] permits the rate of incorporation specified on the label of that [^{F316} medicinal premix] (if the manufacturer is the end user the supply must be in accordance with a prescription [^{F319} for medicated feedingstuffs]).

^{F320}(4) This paragraph does not apply in relation to a feedingstuffs manufacturer approved to incorporate a medicinal premix who supplies another such feedingstuffs manufacturer with medicinal premix where the purpose of that supply is to alleviate a temporary supply shortage that could be detrimental to animal welfare.]

Extent Information

E89 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

- F309** Words in Sch. 3 para. 11 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(f)**
- F310** Words in Sch. 3 para. 11(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(b)**
- F311** Words in Sch. 3 para. 11(2) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(c)(ii)**
- F312** Words in Sch. 3 para. 11(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(c)(i)**
- F313** Word in Sch. 3 para. 11 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(a)**
- F314** Words in Sch. 3 para. 11(2)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(c)(iii)**
- F315** Words in Sch. 3 para. 11(2)(c) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(c)(iv)**
- F316** Words in Sch. 3 para. 11(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(d)(i)**
- F317** Words in Sch. 3 para. 11(3)(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(d)(ii)**
- F318** Word in Sch. 3 Sch. 3 para. 11(3)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(d)(iii)(aa)**
- F319** Words in Sch. 3 para. 11(3)(b) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(d)(iii)(bb)**
- F320** Sch. 3 para. 11(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **105(e)**

Supply of a veterinary medicinal product for incorporation into feedingstuffs **N.I.**

11.—(1) This paragraph applies in relation to the supply of a veterinary medicinal product intended for incorporation into feedingstuffs.

(2) The marketing authorisation holder, an authorised manufacturer of the product or an authorised wholesale dealer may only supply such a veterinary medicinal product to—

- (a) a veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person;
- (b) an approved premixture manufacturer; or
- (c) an approved feedingstuffs manufacturer if the approval permits the rate of incorporation specified on the label of that veterinary medicinal product (if the manufacturer is the end-user the supply must be in accordance with a prescription).

(3) A veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person may only supply such a veterinary medicinal product to—

- (a) an approved premixture manufacturer; or
- (b) an approved feedingstuffs manufacturer if the approval permits the rate of incorporation specified on the label of that veterinary medicinal product (if the manufacturer is the end user the supply must be in accordance with a prescription).

(4) An approved premixture manufacturer or an approved feedingstuffs manufacturer may only supply such a veterinary medicinal product to another approved premixture manufacturer or approved feedingstuff manufacturer if the amount supplied does not exceed five per cent in terms of value of veterinary medicinal product incorporated annually by the person supplying the veterinary medicinal product.

Extent Information

E261 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Labelling at the time of retail supply

12.—(1) If a veterinary medicinal product is supplied in a container specified in the marketing authorisation, it must not be supplied if any information on the outer packaging (or, if there is no outer packaging, the immediate packaging) is not clearly visible at the time of supply or has been changed in any way.

(2) Sub-paragraph (1) does not apply to a veterinary surgeon who amends a label, or a pharmacist who amends it in accordance with a prescription from a veterinary surgeon, provided that the unamended information remains clearly visible.

(3) If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the person supplying the veterinary medicinal product must ensure that the container is suitably labelled and must supply sufficient written information (which may include a copy of the summary of product characteristics or the package leaflet) to enable the product to be used safely.

Supply of veterinary medicinal products for use under the cascade **E+W+S**

13.—(1) A veterinary medicinal product supplied for administration under the cascade may only be supplied in accordance with a prescription from a veterinary surgeon.

(2) Unless the veterinary surgeon who prescribed the veterinary medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information—

- (a) the name and address of the pharmacy, [^{F321}veterinary practice premises] or [^{F322}authorised] premises supplying the veterinary medicinal product;
- (b) the name of the veterinary surgeon who has prescribed the product;
- (c) the name and address of the animal owner;
- (d) the identification (including the species) of the animal or group of animals;
- (e) the date of supply;
- (f) the expiry date of the product, if applicable;
- (g) the name or description of the product, which should include at least the name and quantity of active ingredients;
- (h) dosage and administration instructions;
- (i) any special storage precautions;
- (j) any necessary warnings for the user, target species, administration or disposal of the product;
- (k) the withdrawal period, if relevant; and
- (l) the words “Keep out of reach of children” and “For animal treatment only”.

Extent Information

E90 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

F321 Words in Sch. 3 para. 13(2)(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **106(a)**

F322 Word in Sch. 3 para. 13(2)(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **106(b)**

Supply of veterinary medicinal products for use under the cascade **N.I.**

13.—(1) A veterinary medicinal product supplied for administration under the cascade may only be supplied in accordance with a prescription from a veterinary surgeon.

(2) Unless the veterinary surgeon who prescribed the veterinary medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information—

- (a) the name and address of the pharmacy, veterinary surgery or approved premises supplying the veterinary medicinal product;
- (b) the name of the veterinary surgeon who has prescribed the product;
- (c) the name and address of the animal owner;
- (d) the identification (including the species) of the animal or group of animals;
- (e) the date of supply;
- (f) the expiry date of the product, if applicable;
- (g) the name or description of the product, which should include at least the name and quantity of active ingredients;
- (h) dosage and administration instructions;
- (i) any special storage precautions;
- (j) any necessary warnings for the user, target species, administration or disposal of the product;
- (k) the withdrawal period, if relevant; and
- (l) the words “Keep out of reach of children” and “For animal treatment only”.

Extent Information

E262 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply by a suitably qualified person **E+W+S**

14.—(1) The Secretary of State may recognise bodies that are suitable to maintain a register for suitably qualified persons to prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS.

- (2) In order to recognise such a body, the Secretary of State must be satisfied that the body—
- (a) has in place a system for ensuring that persons applying for registration have adequate training to act as a suitably qualified person under these Regulations;
 - (b) has adequate standards in deciding whether or not to register someone as a suitably qualified person;
 - (c) maintains a programme of continuing professional development for persons registered with it;

- (d) operates an adequate appeal system if it intends to refuse to register anyone with appropriate qualifications or to remove anyone from the register.
- (3) For the purposes of these Regulations, a suitably qualified person is a person who has passed examinations specified by such a body, and is registered with such a body as a suitably qualified person.
- (4) A suitably qualified person may only supply a veterinary medicinal product classified as POM-VPS, NFA-VPS or AVM-GSL, and may only supply it from—
- (a) premises [^{F323}authorised] by the Secretary of State as being suitable for the storage and supply of veterinary medicinal products by a suitably qualified person;
 - (b) premises registered as a pharmacy with the General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland; or
 - (c) practice premises registered under these Regulations as being premises from which a veterinary surgeon supplies veterinary medicinal products.
- [^{F324}(5) A suitably qualified person who supplies a product classified as POM-VPS or NFA-VPS must be present when it is handed over unless the suitably qualified person—
- (a) authorises each transaction individually before the product is supplied; and
 - (b) is satisfied that the person handing it over is competent to do so.]
- (6) A suitably qualified person supplying products from premises [^{F323}authorised] under this regulation by the Secretary of State who considers that the premises no longer comply with the [^{F325}authorisation] must notify the Secretary of State without unreasonable delay.
- (7) The Secretary of State may issue a Code of Practice for suitably qualified persons [^{F326}and bodies recognised under this paragraph], and a body recognised under this paragraph must take appropriate action in accordance with any disciplinary code that applies to that body if a suitably qualified person registered with it does not comply with the Code of Practice.
- (8) The Secretary of State must publish a list of—
- (a) suitably qualified persons; and
 - (b) the trading names and the addresses of premises [^{F323}authorised] under this paragraph(33).
- (9) A suitably qualified person may break open any package (other than the immediate packaging) of a veterinary medicinal product.
- (10) The Secretary of State may suspend or revoke the [^{F325}authorisation] of [^{F323}authorised] premises on being satisfied that they are no longer suitable for the storage and supply of veterinary medicinal products.
- [^{F327}(11) The Secretary of State must, from time to time, inspect premises authorised under sub-paragraph (4)(a) basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.
- (12) The Secretary of State may suspend or revoke recognition of a body mentioned in sub-paragraph (1) where the body fails to comply with a provision of any Code of Practice issued under this paragraph.]

Extent Information

E91 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

- F323** Word in Sch. 3 para. 14 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **107(a)**
- F324** Sch. 3 para. 14(5) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **107(c)**
- F325** Word in Sch. 3 para. 14 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **107(b)**
- F326** Words in Sch. 3 para. 14(7) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **107(d)**
- F327** Sch. 3 para. 14(11)(12) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **107(e)**

Supply by a suitably qualified person **N.I.**

14.—(1) The Secretary of State may recognise bodies that are suitable to maintain a register for suitably qualified persons to prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS.

(2) In order to recognise such a body, the Secretary of State must be satisfied that the body—

- (a) has in place a system for ensuring that persons applying for registration have adequate training to act as a suitably qualified person under these Regulations;
- (b) has adequate standards in deciding whether or not to register someone as a suitably qualified person;
- (c) maintains a programme of continuing professional development for persons registered with it;
- (d) operates an adequate appeal system if it intends to refuse to register anyone with appropriate qualifications or to remove anyone from the register.

(3) For the purposes of these Regulations, a suitably qualified person is a person who has passed examinations specified by such a body, and is registered with such a body as a suitably qualified person.

(4) A suitably qualified person may only supply a veterinary medicinal product classified as POM-VPS, NFA-VPS or AVM-GSL, and may only supply it from—

- (a) premises approved by the Secretary of State as being suitable for the storage and supply of veterinary medicinal products by a suitably qualified person;
- (b) premises registered as a pharmacy with the General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland; or
- (c) practice premises registered under these Regulations as being premises from which a veterinary surgeon supplies veterinary medicinal products.

(5) A suitably qualified person who supplies a product classified as POM-VPS or NFA-VPS must either—

- (a) hand over or despatch the product personally;
- (b) ensure that, when the product is handed over or despatched, the suitably qualified person is in a position to intervene if necessary; or
- (c) check the product after it has been allocated for supply to a customer, and be satisfied that the person handing over or dispatching it is competent to do so.

(6) A suitably qualified person supplying products from premises approved under this regulation by the Secretary of State who considers that the premises no longer comply with the approval must notify the Secretary of State without unreasonable delay.

(7) The Secretary of State may issue a Code of Practice for suitably qualified persons, and a body recognised under this paragraph must take appropriate action in accordance with any disciplinary code that applies to that body if a suitably qualified person registered with it does not comply with the Code of Practice.

(8) The Secretary of State must publish a list of—

- (a) suitably qualified persons; and
- (b) the trading names and the addresses of premises approved under this paragraph⁽³³⁾.

(9) A suitably qualified person may break open any package (other than the immediate packaging) of a veterinary medicinal product.

(10) The Secretary of State may suspend or revoke the approval of approved premises on being satisfied that they are no longer suitable for the storage and supply of veterinary medicinal products.

Extent Information

E263 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

^{F328} Audit **E+W+S**

15.—(1) At least once a year, a retailer of prescription only veterinary medicinal products must carry out a detailed audit of stock and compare the incoming and outgoing veterinary medicinal products recorded with products currently held and make a record of this audit.

(2) Where, as a result of the audit mentioned in sub-paragraph (1), the retailer identifies a discrepancy the retailer must make a record of the fact.

(3) The retailer must keep the records mentioned in sub-paragraphs (1) and (2) for a period of five years from the date of the audit and the Secretary of State may require the retailer to provide a copy of them at any time within that period.]

Extent Information

E92 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F328 Sch. 3 para. 15 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **108**

Annual audit **N.I.**

15. At least once a year every person entitled to supply a veterinary medicinal product on prescription must carry out a detailed audit, and incoming and outgoing veterinary medicinal products must be reconciled with products currently held in stock, any discrepancies being recorded.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Extent Information

E264 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

PART 2

Requirements for a wholesale dealer's authorisation

[^{F329} Wholesale dealer's authorisation **E+W+S**]

16. No person may carry out any wholesale dealing in veterinary medicinal products otherwise than in accordance with an authorisation granted under paragraph 18(2) (a “wholesale dealer's authorisation”).]

Extent Information

E93 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F329 Sch. 3 para. 16 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **109**

Application **N.I.**

16. An application for a wholesale dealer's authorisation must be made to the Secretary of State.

Extent Information

E265 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F330} Application for authorisation **E+W+S**]

17.—(1) An application for a wholesale dealer's authorisation (which must be submitted to the Secretary of State electronically) must include the matters mentioned in sub-paragraph (2).

(2) For the purposes of sub-paragraph (1) the matters are—

- (a) the name of the person who will hold the wholesale dealer's authorisation and that person's address or registered place of business;
- (b) the names and addresses of the sites from which wholesale dealing of veterinary medicinal products is to take place;
- (c) evidence that the sites mentioned in paragraph (b) are—
 - (i) weatherproof;
 - (ii) secure and lockable;
 - (iii) clean;

- (iv) free from contaminants;
- (v) designed with designated areas for the receipt of veterinary medicinal products; and
- (vi) where the veterinary medicinal products for which the authorisation is sought are subject to specific storage requirements, capable of fulfilling those requirements;
- (d) the name of the person nominated to act in accordance with good distribution practice (the “wholesale qualified person”);
- (e) the qualifications and a description of the relevant experience of the wholesale qualified person;
- (f) a description of the veterinary medicinal products proposed to be dealt in under the authorisation;
- (g) evidence that the proposed holder of the authorisation has available to it the services of technically competent staff;
- (h) evidence that the proposed holder of the authorisation has in place—
 - (i) an effective emergency recall plan; and
 - (ii) a quality system;
- (i) a declaration that the applicant complies with good distribution practice and any relevant legislation;
- (j) a declaration that any site mentioned in paragraph (b) is ready for inspection.]

Extent Information

E94 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F330 Sch. 3 para. 17 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **110**

Time limits **N.I.**

17. The Secretary of State must process an application for a wholesale dealer’s authorisation within 90 days of receiving it.

Extent Information

E266 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F331} Procedure and time limits for authorisations **E+W+S**

18.—(1) The Secretary of State must inspect the sites mentioned in paragraph 17(2)(b) within 90 days of validating the application.

(2) Where the Secretary of State is satisfied, following the inspection mentioned in subparagraph (1) that—

- (a) the sites are suitable for the intended purposes; and
- (b) the applicant has—

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (i) suitable and sufficient staff and facilities for the storage of veterinary medicinal products; and
- (ii) a documented quality system in place,

the Secretary of State must grant the wholesale dealer's authorisation.

(3) Where the Secretary of State is not satisfied in relation to one or more of the matters mentioned in sub-paragraph (2), the Secretary of State may—

- (a) reject the application; or
- (b) grant a conditional wholesale dealer's authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

(4) The Secretary of State may extend the period for which a conditional wholesale dealer's authorisation is granted under sub-paragraph (3)(b).

(5) Where a conditional wholesale dealer's authorisation is granted under sub-paragraph (3)(b) and the deficiency is addressed within the specified period to the satisfaction of the Secretary of State, the authorisation continues to have effect without those conditions.]

Extent Information

E95 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F331 Sch. 3 para. 18 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **111**

Granting the authorisation **N.I.**

18.—(1) The Secretary of State must grant a wholesale dealer's authorisation on being satisfied that this paragraph is complied with.

(2) The authorised site must be—

- (a) weatherproof;
- (b) secure and lockable;
- (c) clean; and
- (d) free from contaminants.

(3) If the veterinary medicinal products covered by the authorisation are subject to specific storage conditions, the site must be capable of fulfilling those requirements.

(4) The authorisation holder must—

- (a) have the services of technically competent staff; and
- (b) have an effective emergency recall plan.

Extent Information

E267 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F332} Periodic inspections and suspension etc. for lack of use E+W+S

19.—(1) The Secretary of State must, from time to time, inspect the sites from which wholesale dealing of veterinary medicinal products takes place pursuant to a wholesale dealer's authorisation basing the frequency of the inspection on the risks associated with each site's history and the nature of the products handled at the site.

(2) The Secretary of State may suspend, vary or revoke a wholesale dealer's authorisation if, in respect of any one of the sites covered by that authorisation, the holder does not deal in veterinary medicinal products from that site for five years.]

Extent Information

E96 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F332 Sch. 3 para. 19 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **112**

The authorisation N.I.

19.—(1) The wholesale dealer's authorisation must specify—

- (a) the types of veterinary medicinal products and pharmaceutical forms that may be dealt in;
- (b) the place where they are to be stored;
- (c) the name and address of the person holding the authorisation;
- (d) the address of the premises to which it relates;
- (e) the name of the qualified person nominated to act under the Guidelines on Good Distribution Practice for Human Use⁽³⁴⁾.

(2) It may cover more than one site.

(3) It lapses if the holder does not deal in veterinary medicinal products for five years.

(4) The holder of a wholesale dealer's authorisation must notify the Secretary of State, and if necessary apply for a variation of the authorisation, before making a material alteration to the premises or facilities used under the authorisation, or in the operations for which they are used.

Extent Information

E268 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F333} Application for variation to the authorisation

19A.—(1) The holder of a wholesale dealer's authorisation must notify the Secretary of State, and apply for a variation of the authorisation, before making a material alteration to the premises or facilities used under the authorisation or the operations for which the premises or facilities are used or where there is a change in the personnel carrying out the role of wholesale qualified person.

⁽³⁴⁾ OJ No C 63, 1.3.94, p. 4.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(2) The Secretary of State must process an application under sub-paragraph (1) within 30 days of receiving it unless the Secretary of State notifies the applicant in writing that the time has been extended to 90 days.

(3) The Secretary of State must grant the application under sub-paragraph (1) if satisfied in respect of the matters in paragraph 18(2) as regards the proposed variation.

(4) The Secretary of State may inspect any site to which the wholesale dealer's authorisation or proposed variation relates in connection with the application.

(5) Where the Secretary of State is not satisfied for the purposes of sub-paragraph (3), the Secretary of State may—

- (a) reject the application; or
- (b) grant a conditional variation to the wholesale dealer's authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

(6) The Secretary of State may extend the period for which a conditional variation to the wholesale dealer's authorisation is granted under sub-paragraph (5)(b).

(7) Where a conditional variation to the wholesale dealer's authorisation is granted under sub-paragraph (5)(b) and the deficiency is addressed within the specified period to the satisfaction of the Secretary of State, the authorisation continues to have effect as so varied without those conditions.]

Textual Amendments

F333 Sch. 3 para. 19A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **113**

Suspension, variation or revocation of the authorisation **E+W+S**

20. The Secretary of State may suspend, vary or revoke a wholesale dealer's authorisation if the holder—

- (a) has not complied with these Regulations; or
- [^{F334}(b) no longer has suitable premises, equipment or technically competent staff]

Extent Information

E97 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F334 Sch. 3 para. 20(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **114**

Suspension, variation or revocation of the authorisation **N.I.**

20. The Secretary of State may suspend, vary or revoke a wholesale dealer's authorisation if the holder—

- (a) has not complied with these Regulations; or
- (b) no longer has suitable premises or equipment.

Extent Information

E269 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Duties on the holder of a wholesale dealer’s authorisation **E+W+S**

- 21.** The holder of a wholesale dealer’s authorisation must—
- (a) store veterinary medicinal products in accordance with the terms of the marketing authorisation for each product;
 - ^{F335}(b) comply with good distribution practice;]
 - ^{F336}(c)
 - (d) supply information and samples to the Secretary of State on demand [^{F337}; and
 - (e) notify the Secretary of State (and in relation to paragraph (ii), the holder of the relevant marketing authorisation) where it has reason to suspect—
 - (i) a threat to the continued supply of a veterinary medicinal product;
 - (ii) that it has been offered veterinary medicinal products which are counterfeit].

Extent Information

E98 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F335** Sch. 3 para. 21(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **115(a)**
- F336** Sch. 3 para. 21(c) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **115(b)**
- F337** Sch. 3 para. 21(e) and word inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **115(c)**

Duties on the holder of a wholesale dealer’s authorisation **N.I.**

- 21.** The holder of a wholesale dealer’s authorisation must—
- (a) store veterinary medicinal products in accordance with the terms of the marketing authorisation for each product;
 - (b) comply with the Guidelines on Good Distribution Practice of Medicinal Products for Human Use as if the veterinary medicinal products were authorised human medicinal products;
 - (c) carry out a detailed stock audit at least once a year; and
 - (d) supply information and samples to the Secretary of State on demand.

Extent Information

E270 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

^{F338}Register of authorised wholesale dealers

21A. The Secretary of State must establish, maintain and publish on a website a register of authorised wholesale dealers and their sites.]

Textual Amendments

F338 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **116**

^{F338}Documentation accompanying veterinary medicinal products supplied wholesale

21B.—(1) This paragraph applies in relation to wholesale supply of veterinary medicinal products.

(2) The holder of a wholesale dealer’s authorisation must ensure that a document accompanies each consignment of veterinary medicinal products specifying—

- (a) the name of the veterinary medicinal product;
- (b) the strength and pharmaceutical form;
- (c) the date on which the veterinary medicinal product was supplied;
- (d) the quantity of product supplied;
- (e) the batch number;
- (f) the expiry date;
- (g) the name and address of the wholesale dealer supplying the product;
- (h) the means by which the product was transported and the required conditions of storage;
- (i) the name of the person to whom the product was supplied and the address to which it is to be delivered.

(3) The holder of a wholesale dealer’s authorisation must make a record of the information mentioned in sub-paragraph (2) and must keep it for at least five years.]

Textual Amendments

F338 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **116**

^{F338}Recalled, counterfeit or returned products

21C.—(1) The holder of a wholesale dealer’s authorisation must comply with any requirement by the Secretary of State to recall a veterinary medicinal product and must record the details of the recall operation.

(2) The holder of a wholesale dealer’s authorisation must record any veterinary medicinal product which is—

- (a) recalled (whether or not the holder physically receives the recalled product);
- (b) discovered to be counterfeit; or
- (c) returned.

(3) Where any veterinary medicinal product is recalled or returned and physically received, the wholesale qualified person must assess the product received in order to determine whether the

product has been stored (including during transport) in accordance with the summary of product characteristics.

(4) Where a recalled or returned veterinary medicinal product has not been stored (including during transport) in accordance with the summary of product characteristics or where it is not possible for the wholesale qualified person to determine whether the product has been stored in accordance with the summary of product characteristics, the product may not be re-sold.

(5) Any veterinary medicinal products which may not be re-sold must be identified, held separately and destroyed and the holder of a wholesale dealer's authorisation must develop a suitable procedure to set out the steps to be taken in accordance with this sub-paragraph.

(6) The holder of a wholesale dealer's authorisation must keep any information recorded under this paragraph for five years.]

Textual Amendments

F338 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **116**

[^{F338}Audit

21D.—(1) At least once a year, the holder of a wholesale dealer's authorisation must carry out a detailed audit of stock and compare the incoming and outgoing veterinary medicinal products recorded with products currently held and record the results of the audit in written form.

(2) Where, as a result of the audit mentioned in sub-paragraph (1), the holder identifies a discrepancy the holder must—

- (a) make a record of that fact,
- (b) conduct an investigation for the purpose of discovering the cause of the discrepancy, and
- (c) maintain records of that investigation.

(3) The holder must keep the records mentioned in sub-paragraphs (1) and (2) for a period of five years from the date of the audit and the Secretary of State may require the holder to provide a copy of them at any time within that period.]

Textual Amendments

F338 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **116**

[^{F338}Contractual arrangements between holders of wholesale dealer's authorisations

21E. Where the holder of a wholesale dealer's authorisation contracts out any wholesale dealing activities to another such holder, the arrangement must record in writing the responsibilities of each party in relation to their respective roles in the supply process and, in particular, in connection with the recall of a veterinary medicinal product under paragraph 21C.]

Textual Amendments

F338 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **116**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

[^{F338}Self-inspection programme

21F.—(1) The holder of a wholesale dealer’s authorisation must have in place a self-inspection programme which ensures that every aspect of its business is inspected at least once a year in order to ensure that it is complying with good distribution practice.

(2) Where, as a result of the self-inspection mentioned in sub-paragraph (1), the holder identifies any non-compliance the holder must—

- (a) make a record of that fact,
- (b) conduct an investigation for the purpose of discovering the cause of the non-compliance, and
- (c) maintain records of that investigation.

(3) The holder must keep the records mentioned in sub-paragraph (2) for a period of five years from the date of the audit and the Secretary of State may require the holder to provide a copy of them at any time within that period.]

Textual Amendments

F338 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **116**

PART 3

Sheep dip

Supply of sheep dip

22.—(1) A person who supplies by retail sheep dip which contains a veterinary medicinal product must supply it in accordance with this paragraph.

(2) The supply must be to a person (or a person acting on that person’s behalf) who is qualified to use it in accordance with paragraph 23.

(3) The supplier must make a record of that person’s certificate or award number as soon as is reasonably practicable, and keep it for at least three years.

(4) If the active ingredient of the veterinary medicinal product is an organophosphorus compound, the supplier must give to the buyer—

- (a) a double-sided laminated notice meeting the specifications in the following sub-paragraph (unless the notice has been provided to the buyer within the previous twelve months and the supplier knows or has reasonable cause to believe that the buyer still has it available for use); and
- (b) two pairs of gloves either as described in the notice or providing demonstrably superior protection to the proposed user against exposure to the dip than would be provided by gloves as so described.

(5) The notice must be at least A4 size with a laminated transparent cover and must tell the user of the sheep dip—

- (a) to read and act in accordance with the label, including instructions on measuring and diluting concentrate;
- (b) that sheep dip is absorbed through the skin;

- (c) always to wear the recommended protective clothing, including gloves, and have spare protective clothing available;
 - (d) always to wash protective clothing before taking it off; and
 - (e) to direct any questions to the supplier or manufacturer.
- (6) The notice must contain a diagram showing recommended protective clothing.

Use of sheep dip **E+W+S**

23.—(1) ^{F339}No person may use sheep dip which contains a veterinary medicinal product unless they hold, or they are acting under the supervision and in the presence of a person who holds, either]—

- (a) a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed; or
 - (b) NPTC Level 2 Award in the Safe Use of Sheep Dip (QCF).
- (2) The certificate must be issued—
- (a) in England, Wales and Northern Ireland; by—
 - (i) the National Proficiency Tests Council;
 - (ii) NPTC Part of the City & Guilds Group; or
 - (iii) City and Guilds NPTC;
 - (b) in Scotland, by one of those organisations or the Scottish Skills Testing Service.

Extent Information

E99 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F339 Words in [Sch. 3 para. 23\(1\)](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **117**

Use of sheep dip **N.I.**

23.—(1) No person may use sheep dip which contains a veterinary medicinal product unless the person is acting under the supervision and in the presence of, a person who holds either—

- (a) a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed; or
 - (b) NPTC Level 2 Award in the Safe Use of Sheep Dip (QCF).
- (2) The certificate must be issued—
- (a) in England, Wales and Northern Ireland; by—
 - (i) the National Proficiency Tests Council;
 - (ii) NPTC Part of the City & Guilds Group; or
 - (iii) City and Guilds NPTC;
 - (b) in Scotland, by one of those organisations or the Scottish Skills Testing Service.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Extent Information

E271 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Offences **E+W+S**

24. It is an offence to fail to comply with—

- (a) paragraph 2;
- (b) paragraph 3;
- [^{F340}(ba) paragraph 3A;
- (bb) paragraph 3B;
- (bc) paragraph 3C;
- (bd) paragraph 3D;
- (be) paragraph 3E;]
- (c) paragraph 4(1);
- (d) paragraph 5;
- [^{F341}(da) paragraph 6;]
- (e) paragraph 7;
- [^{F342}(ea) paragraph 7A;]
- (f) paragraph 8(1);
- (g) paragraph 9(1);
- (h) paragraph 10;
- (i) paragraph 11;
- (j) paragraph 12(1) or (3);
- (k) paragraph 13;
- (l) paragraph 14(4), (5) or (6);
- (m) paragraph 15;
- [^{F343}(ma) paragraph 16;]
- ^{F344}(n)
- (o) paragraph 21;
- [^{F345}(oa) paragraph 21B;
- (ob) paragraph 21C;
- (oc) paragraph 21D;
- (od) paragraph 21E;
- (oe) paragraph 21F;]
- (p) paragraph 22; or
- (q) paragraph 23(1).

Extent Information

E100 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F340** Sch. 3 paras. 24(ba)-(be) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **118(a)**
- F341** Sch. 3 para. 24(da) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **118(b)**
- F342** Sch. 3 para. 24(ea) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **118(c)**
- F343** Sch. 3 para. 24(ma) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **118(d)**
- F344** Sch. 3 para. 24(n) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **118(e)**
- F345** Sch. 3 paras. 24(oa)-(oe) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **118(f)**

Offences **N.I.**

24. It is an offence to fail to comply with—

- (a) paragraph 2;
- (b) paragraph 3;
- (c) paragraph 4(1);
- (d) paragraph 5;
- (e) paragraph 7;
- (f) paragraph 8(1);
- (g) paragraph 9(1);
- (h) paragraph 10;
- (i) paragraph 11;
- (j) paragraph 12(1) or (3);
- (k) paragraph 13;
- (l) paragraph 14(4), (5) or (6);
- (m) paragraph 15;
- (n) paragraph 19(4);
- (o) paragraph 21;
- (p) paragraph 22; or
- (q) paragraph 23(1).

Extent Information

E272 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

SCHEDULE 4

Regulation 8

Administration of a veterinary medicinal product outside the terms of a marketing authorisation

Administration under the cascade **E+W+S**

1.—(1) A veterinary surgeon acting under this paragraph who prescribes a veterinary medicinal product may either administer it personally or may direct another person to do so under the responsibility of the veterinary surgeon.

(2) If there is no authorised veterinary medicinal product in the United Kingdom for a condition the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following (“the cascade”), cascaded in the following order—

- (a) a veterinary medicinal product authorised in the United Kingdom for use with another animal species, or for another condition in the same species; or
- (b) if there is no such product that is suitable, either—
 - (i) a human medicinal product authorised in the United Kingdom; or
 - (ii) a veterinary medicinal product not authorised in the United Kingdom but authorised in another ^[F346]country for use with any animal species (in the case of a food-producing animal, it must be a food-producing species); or
- (c) if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

(3) In the case of a veterinary medicinal product imported from another ^[F347]country, if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting importation, the veterinary surgeon must obtain a certificate from the Secretary of State before administration.

(4) ^[F348]All substances included in a medicinal product administered to a food-producing animal under the cascade must ^[F349]be substances for which a maximum residue limit has been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council^[F350] or substances which do not fall within the scope of Regulation (EC) No 470/2009 of the European Parliament and of the Council].

^[F351](5) Where a substance mentioned in sub-paragraph (4) is administered, the maximum residue limits established in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council must be complied with.]

Extent Information

E101 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F346 Word in Sch. 4 para. 1(2)(b)(ii) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(34)(a)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F347 Word in Sch. 4 para. 1(3) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(34)(a)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

- F348** Words in Sch. 4 para. 1(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **120(a)(i)**
- F349** Words in Sch. 4 para. 1(4) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(34)(a)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F350** Words in Sch. 4 para. 1(4) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **120(a)(ii)**
- F351** Sch. 4 para. 1(5) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **120(b)**

Administration under the cascade **N.I.**

1.—(1) A veterinary surgeon acting under this paragraph who prescribes a veterinary medicinal product may either administer it personally or may direct another person to do so under the responsibility of the veterinary surgeon.

(2) If there is no authorised veterinary medicinal product in [^{F718}Northern Ireland] for a condition the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following (“the cascade”), cascaded in the following order—

- (a) a veterinary medicinal product authorised in [^{F718}Northern Ireland] for use with another animal species, or for another condition in the same species; or
- (b) if there is no such product that is suitable, either—
 - (i) a human medicinal product authorised in the United Kingdom; or
 - (ii) a veterinary medicinal product not authorised in [^{F718}Northern Ireland] but authorised in another member State for use with any animal species (in the case of a food-producing animal, it must be a food-producing species); or
- (c) if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

(3) In the case of a veterinary medicinal product imported from another member State, if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting importation, the veterinary surgeon must obtain a certificate from the Secretary of State before administration.

(4) Any pharmacologically active substances included in a medicinal product administered to a food-producing animal under the cascade must be listed in Table 1 in the Annex to Commission Regulation (EU) No 37/2010.

Extent Information

- E273** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F718** Words in [Sch. 4 para. 1](#) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(14)(a)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Withdrawal periods **E+W+S**

2.—(1) A veterinary surgeon prescribing or administering a veterinary medicinal product to a food-producing animal under the cascade must specify an appropriate withdrawal period.

[^{F352}(2) The withdrawal period must ensure that—

- (a) where there is a maximum residue limit established for the active substance for the treated species under Regulation (EC) No 470/2009 of the European Parliament and of the Council, the level of residue of the active substance does not exceed that limit; and
- (b) where there is no maximum residue limit for the treated species established under Regulation (EC) No 470/2009 of the European Parliament and of the Council but one is established for the substance itself, the level of residue of the active substance does not exceed the level determined by reference to Commission Implementing Regulation (EU) 2018/470 on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC.]

(3) In any event, unless the Secretary of State has specified in writing a different withdrawal period for a particular veterinary medicinal product, the withdrawal period (irrespective of whether or not a maximum residue limit [^{F353}has been established]) must not be less than—

[^{F354}(a) for eggs—

- (i) the longest withdrawal period in the summary of product characteristics for any species multiplied by a factor of 1.5; or
- (ii) 14 days, if the product is not authorised for animals producing eggs for human consumption;]

[^{F355}(b) for milk—

- (i) the longest withdrawal period in the summary of product characteristics for any species multiplied by a factor of 1.5;
- (ii) 7 days, if the veterinary medicinal product is not authorised for animals producing milk for human consumption; or
- (iii) 1 day, if the medicinal product has a zero-hour withdrawal period;]

[^{F356}(c) for meat and offal from food-producing mammals, poultry and farmed game-birds—

- (i) the longest withdrawal period provided in its summary of product characteristics for meat and offal, multiplied by a factor of 1.5;
- (ii) 28 days if the veterinary medicinal product is not authorised for food-producing animals; or
- (iii) 1 day, if the veterinary medicinal product has a zero-day withdrawal period;]

[^{F357}(d) for aquatic species producing meat for human consumption—

- (i) the longest withdrawal period for any of the aquatic species in the summary of product characteristics multiplied by a factor of 1.5 and expressed as degree-days;
- (ii) if the medicinal product is authorised for food-producing terrestrial animal species, the longest withdrawal period for any of the food-producing animal species in the summary of product characteristics multiplied by a factor of 50 and expressed as degree-days; or
- (iii) 25 degree-days if the highest withdrawal period for any animal species is zero.]

[^{F358}(4) For the purposes of sub-paragraph (3)—

- (a) if the calculation of a withdrawal period results in a fraction of days, the withdrawal period must be rounded to the nearest number of days, with any half of a day being rounded upwards;
- (b) in relation to the calculation of the withdrawal period for milk, if the calculation of the period results in a milk withdrawal period not divisible by 12, the withdrawal period must be rounded up to the nearest multiple of 12 hours.]

Extent Information

E102 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F352** Sch. 4 para. 2(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **121(a)**
- F353** Words in Sch. 4 para. 2(3) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(34)(b)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F354** Sch. 4 para. 2(3)(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **121(b)(i)**
- F355** Sch. 4 para. 2(3)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **121(b)(ii)**
- F356** Sch. 4 para. 2(3)(c) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **121(b)(iii)**
- F357** Sch. 4 para. 2(3)(d) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **121(b)(iv)**
- F358** Sch. 4 para. 2(4) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **121(c)**

Withdrawal periods **N.I.**

2.—(1) A veterinary surgeon prescribing or administering a veterinary medicinal product to a food-producing animal under the cascade must specify an appropriate withdrawal period.

(2) The withdrawal period must ensure that, if there is a maximum residue limit specified for the active substance in Table 1 in the Annex to Commission Regulation (EU) No 37/2010, the level of residue of the active substance does not exceed that limit.

(3) In any event, unless the Secretary of State has specified in writing a different withdrawal period for a particular veterinary medicinal product, the withdrawal period (irrespective of whether or not a maximum residue limit is specified in Table 1 in the Annex to Commission Regulation (EU) No 37/2010) must not be less than—

- (a) 7 days for eggs;
- (b) 7 days for milk;
- (c) 28 days for meat from poultry and mammals including fat and offal;
- (d) 500 degree days**(35)** for fish meat.

(35) The number of days of the withdrawal period is calculated by dividing 500 by the mean temperature of the water in degrees Celsius.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Extent Information

E274 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Administration to food-producing horses

3.—(1) If there is no authorised veterinary medicinal product for a food-producing horse (as shown on its horse passport) and treatment under the cascade is unsuitable, substances may be administered in accordance with [Commission Regulation \(EC\) No 122/2013](#) (establishing, in accordance with [Directive 2001/82/EC](#) of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae (**36**)).

(2) The person administering the substance must comply with Article 3(2) of [Commission Regulation \(EC\) No 122/2013](#) (recording the details of the treatment in the animal's passport).

Immunological products for serious epizootic disease [^{F359}or emerging disease] **E+W+S**

4. In the event of serious epizootic diseases [^{F360}or emerging diseases], the Secretary of State may permit in writing the administration of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product ^{F361}... and may publicise any permit as the Secretary of State sees fit.

Extent Information

E103 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F359 Words in Sch. 4 para. 4 heading inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **122(b)**

F360 Words in Sch. 4 para. 4 inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **122(a)**

F361 Words in Sch. 4 para. 4 omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(34)(c)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Immunological products for serious epizootic disease **N.I.**

4. In the event of serious epizootic diseases, the Secretary of State may permit in writing the administration of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use and may publicise any permit as the Secretary of State sees fit.

Extent Information

E275 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Immunological products for an imported or exported animal **E+W+S**

5. If an animal is imported from, or exported to, [^{F362}another] country, the Secretary of State may permit the administration to that animal of an immunological veterinary medicinal product that is not covered by a marketing authorisation in the United Kingdom but is authorised under the legislation of [^{F363}that other] country.

Extent Information

E104 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F362 Word in Sch. 4 para. 5 substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(34)(d)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F363 Words in Sch. 4 para. 5 substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(34)(d)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Immunological products for an imported or exported animal **N.I.**

5. If an animal is imported from, or exported to, a third country, the Secretary of State may permit the administration to that animal of an immunological veterinary medicinal product that is not covered by a marketing authorisation in [^{F719}Northern Ireland] but is authorised under the legislation of the third country.

Extent Information

E276 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F719 Words in Sch. 4 para. 5 substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(14)(b)**

Administration by veterinary surgeons from other [^{F364}countries] **E+W+S**

6.—(1) Veterinary surgeons practising in another [^{F365}country with equivalent medicines regulation standards to those of the United Kingdom] may bring into the United Kingdom and administer to animals small quantities of veterinary medicinal products that are not authorised for use in the United Kingdom if—

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (a) the quantity does not exceed the requirements for the treatment of specific animals;
 - (b) the product is authorised in the [^{F366}country] in which the veterinary surgeon is established;
 - (c) the product is transported by the veterinary surgeon in the original manufacturer's packaging;
 - (d) in the case of administration to food-producing animals, there is a veterinary medicinal product authorised in the United Kingdom that has the same qualitative and quantitative composition in terms of active substances;
 - (e) the veterinary surgeon is acquainted with the Code of Professional Conduct for veterinary surgeons issued by the Royal College of Veterinary Surgeons⁽³⁷⁾.
- (2) The veterinary surgeon must only supply to the owner or keeper enough veterinary medicinal product to complete the treatment of animals concerned.
- (3) The veterinary surgeon must—
- (a) ensure that the withdrawal period specified on the label of the product is complied with, or the United Kingdom withdrawal period for the equivalent product authorised in the United Kingdom if this is longer than the one on the label; and
 - (b) keep detailed records of the animals treated, the diagnosis or clinical assessment, the products administered, the dosage administered, the duration of treatment and the withdrawal period applied, and must keep them in the United Kingdom for at least three years.
- (4) The overall range and quantity of veterinary medicinal products carried by the veterinary surgeon must not exceed that generally required for the daily needs of good veterinary practice.
- (5) This paragraph does not apply in relation to immunological veterinary medicinal products.

Extent Information

E105 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F364 Word in Sch. 4 para. 6 heading substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(34)(e)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F365 Words in Sch. 4 para. 6(1) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(34)(e)(ii)(aa)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F366 Word in Sch. 4 para. 6(1)(b) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(b), **3(34)(e)(ii)(bb)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Administration by veterinary surgeons from ^{F720}... member States **N.I.**

6.—(1) Veterinary surgeons practising in [^{F721}a] member State may bring into [^{F722}Northern Ireland] and administer to animals small quantities of veterinary medicinal products that are not authorised for use in [^{F722}Northern Ireland] if—

- (a) the quantity does not exceed the requirements for the treatment of specific animals;
- (b) the product is authorised in the member State in which the veterinary surgeon is established;
- (c) the product is transported by the veterinary surgeon in the original manufacturer's packaging;
- (d) in the case of administration to food-producing animals, there is a veterinary medicinal product authorised in [^{F723}Northern Ireland] that has the same qualitative and quantitative composition in terms of active substances;
- (e) the veterinary surgeon is acquainted with the Code of Professional Conduct for veterinary surgeons issued by the Royal College of Veterinary Surgeons(37).

(2) The veterinary surgeon must only supply to the owner or keeper enough veterinary medicinal product to complete the treatment of animals concerned.

(3) The veterinary surgeon must—

- ^{F724}(a) ensure that the withdrawal period specified on the label of the product is complied with, or the Northern Ireland withdrawal period for the equivalent product authorised in Northern Ireland if this is longer than the one on the label; and]
- (b) keep detailed records of the animals treated, the diagnosis or clinical assessment, the products administered, the dosage administered, the duration of treatment and the withdrawal period applied, and must keep them in [^{F725}Northern Ireland] for at least three years.

(4) The overall range and quantity of veterinary medicinal products carried by the veterinary surgeon must not exceed that generally required for the daily needs of good veterinary practice.

(5) This paragraph does not apply in relation to immunological veterinary medicinal products.

Extent Information

E277 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F720 Word in Sch. 4 para. 6 heading omitted (N.I.) (31.12.2020) by virtue of *The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020* (S.R. 2020/353), regs. 1(3), **10(14)(c)(i)**

F721 Word in Sch. 4 para. 6(1) substituted (N.I.) (31.12.2020) by *The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020* (S.R. 2020/353), regs. 1(3), **10(14)(c)(ii)**

F722 Words in Sch. 4 para. 6(1) substituted (N.I.) (31.12.2020) by *The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020* (S.R. 2020/353), regs. 1(3), **10(14)(c)(iii)**

F723 Words in Sch. 4 para. 6(1)(d) substituted (N.I.) (31.12.2020) by *The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020* (S.R. 2020/353), regs. 1(3), **10(14)(c)(iii)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

F724 Sch. 4 para. 6(3)(a) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(14)(c)(iv)**

F725 Words in Sch. 4 para. 6(3)(b) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(14)(c)(iii)**

^{F367} Administration of autogenous vaccines

6A.—(1) An autogenous vaccine may only be administered to animals in exceptional circumstances where no suitable immunological veterinary medicinal product has been authorised in relation to the target species and indication.

(2) Where a vaccine is used in accordance with sub-paragraph (1) it must be administered in accordance with a prescription under the cascade.]

Textual Amendments

F367 Sch. 4 para. 6A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **123**

Treatment in exceptional circumstances **E+W+S**

7.—(1) Where the health situation so requires, and where there is no suitable veterinary medicinal product available either as an authorised product or under the cascade, a veterinary surgeon may treat an animal with a medicinal product authorised in [^{F368}another] country; but a veterinary surgeon who has not obtained a certificate from the Secretary of State under regulation 25(5) permitting importation must obtain a certificate from the Secretary of State before treating the animal.

(2) The certificate may be granted subject to any condition the Secretary of State thinks fit.

Extent Information

E106 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F368 Word in Sch. 4 para. 7(1) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(34)(f)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Treatment in exceptional circumstances **N.I.**

7.—(1) Where the health situation so requires, and where there is no suitable veterinary medicinal product available either as an authorised product or under the cascade, a veterinary surgeon may treat an animal with a medicinal product authorised in a third country; but a veterinary surgeon who has not obtained a certificate from the Secretary of State under regulation 25(5) permitting importation must obtain a certificate from the Secretary of State before treating the animal.

(2) The certificate may be granted subject to any condition the Secretary of State thinks fit.

Extent Information

E278 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Administration of a homeopathic remedy

8.—(1) A registered homeopathic remedy or a homeopathic remedy prepared and supplied by a pharmacist under paragraph 10 of Schedule 3 may be administered to an animal by anyone, subject to any restrictions specified in its registration.

(2) A homeopathic remedy that was on the market before 1st January 1994 may be administered by anyone.

(3) A veterinary surgeon may administer, either personally or under the veterinary surgeon's responsibility—

- (a) a homeopathic remedy authorised for human use, or
- (b) a homeopathic remedy prepared extemporaneously by a veterinary surgeon, a pharmacist or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

Administration under an animal test certificate **E+W+S**

9.—(1) A medicinal product may be administered in accordance with an animal test certificate granted for [^{F369}clinical trials] by the Secretary of State.

(2) An application for an animal test certificate may be refused if this is necessary for the protection of animal or public health or the environment, and the animal test certificate may be varied, suspended or revoked in the same way as a marketing authorisation.

(3) The holder of an animal test certificate may not supply a product for administration that is not within the terms of the animal test certificate.

(4) The holder of an animal test certificate test who becomes aware of any [^{F370}adverse event] following the administration of a product under an animal test certificate must report the reaction to the Secretary of State within [^{F371}30 days] of learning of it.

Extent Information

E107 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F369 Words in Sch. 4 para. 9(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **124(a)**

F370 Words in Sch. 4 para. 9(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **124(b)(i)**

F371 Words in Sch. 4 para. 9(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **124(b)(ii)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Administration under an animal test certificate **N.I.**

9.—(1) A medicinal product may be administered in accordance with an animal test certificate granted for research purposes by the Secretary of State.

(2) An application for an animal test certificate may be refused if this is necessary for the protection of animal or public health or the environment, and the animal test certificate may be varied, suspended or revoked in the same way as a marketing authorisation.

(3) The holder of an animal test certificate may not supply a product for administration that is not within the terms of the animal test certificate.

(4) The holder of an animal test certificate test who becomes aware of any serious adverse reaction following the administration of a product under an animal test certificate must report the reaction to the Secretary of State within 15 days of learning of it.

Extent Information

E279 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F372}Misuse of the cascade

9A. A person must not promote or facilitate any purported use of the cascade which is not in accordance with this Schedule.]

Textual Amendments

F372 Sch. 4 para. 9A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **125**

Offences **E+W+S**

10. It is an offence to fail to comply with—

[^{F373}(za) paragraph 2;]

(a) paragraph 3(2);

(b) paragraph 6; ^{F374}...

[^{F375}(ba) paragraph 6A;]

(c) paragraph 9(3) or [^{F376}(4); or]

[^{F377}(d) paragraph 9A.]

Extent Information

E108 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F373 Sch. 4 para. 10(za) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **126(a)**

F374 Word in Sch. 4 para. 10(b) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **126(b)**

- F375** Sch. 4 para. 10(ba) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **126(c)**
- F376** Words in Sch. 4 para. 10(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **126(d)**
- F377** Sch. 4 para. 10(d) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **126(e)**

Offences **N.I.**

- 10.** It is an offence to fail to comply with—
- (a) paragraph 3(2);
 - (b) paragraph 6; or
 - (c) paragraph 9(3) or (4).

Extent Information

- E280** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

SCHEDULE 5

Regulation 14

Medicated feedingstuffs and specified feed additives

Scope and interpretation

1.—(1) This Schedule applies in relation to the following (referred to in this Schedule as “specified feed additives”) when used as feed additives—

- (a) coccidiostats;
- (b) histomonostats; and
- (c) all other zootechnical additives except—
 - (i) digestibility enhancers;
 - (ii) gut flora stabilisers; and
 - (iii) substances incorporated with the intention of favourably affecting the environment.

(2) It also applies in relation to the manufacture and placing on the market of feedingstuffs containing a veterinary medicinal product.

(3) In this Schedule—

[^{F378}“animal keeper” means any natural or legal person responsible for animals, whether on a permanent or a temporary basis;

“batch” means an identifiable quantity of feed determined to have common characteristics whether in relation to origin, variety, type of packaging, packer, consignor or labelling and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units when produced in continuous order and stored together;

“cross-contamination” means contamination of a non-target feed with an active substance originating from the previous use of the relevant facilities or equipment;

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

“distributor” means a feed business operator distributing specified feed additives, intermediate feedingstuff or complete feed containing specified feed additives, or intermediate feedingstuff or complete feed containing medicinal premixes;

“feed business” means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on their own holding;

“feed business operator” means any person responsible for ensuring that the requirements of this Schedule are met within the feed business under that person’s control;

“non-target feed” means feed, whether medicated or not which is not intended to contain a specific active substance;

“premises” means any unit of a feed business;]

“zootechnical additive” means any additive used to maintain animals in good health or favourably affect their performance.

Textual Amendments

F378 Words in Sch. 5 para. 1(3) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **128(b)**

F379 Words in Sch. 5 para. 1(3) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **128(a)**

Enforcement of Regulation (EC) No 178/2002

2.—(1) For the purposes of [^{F380}Regulation (EC) No 178/2002] the competent authority is the Secretary of State.

(2) No person may fail to comply with any of the following provisions of that Regulation—

- (a) Article 11 (requirements relating to imports);
- (b) Article 12 (requirements relating to exports);
- (c) Article 15(1) (prohibition on the placing on the market or feeding unsafe feedingstuffs);
- (d) Article 16 so far as it prohibits misleading labelling, advertising or presentation of feedingstuffs;
- (e) Article 18(2) and (3) (requirements of traceability) in so far as it relates to feed business operators; and
- (f) Article 20 (responsibilities of feed business operators).

Textual Amendments

F380 Words in Sch. 5 para. 2(1) substituted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(a), **2(4)(a)**

Enforcement of Regulation (EC) No 1831/2003 **E+W+S**

3.—(1) For the purposes of [^{F381}Regulation (EC) No 1831/2003] the competent authority is the Secretary of State.

(2) An authorisation under Article 3(2) of that Regulation must be in writing.

(3) No person may possess a specified feed additive, or [^{F382}an intermediate feedingstuff] or feedingstuffs containing a specified feed additive, unless the specified feed additive has been authorised under Regulation (EC) No 1831/2003 or is for export to [^{F383}another] country.

(4) No person may fail to comply with any of the following provisions of that Regulation—

- (a) Article 3(1) or Article 3(3) (the authorisation, conditions of use and labelling of specified feed additives);
- (b) Article 12(1) or (2) (conditions relating to specified feed additives);
- (c) Article 16(1) (labelling);
- (d) Article 16(3) (additional labelling requirement);
- (e) Article 16(4) (premixtures containing specified feed additives);
- (f) Article 16(5) (packaging).

Extent Information

E109 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F381 Words in Sch. 5 para. 3(1) substituted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(a), **2(4)(b)**

F382 Words in Sch. 5 para. 3(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **129**

F383 Word in Sch. 5 para. 3(3) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(35)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Enforcement of Regulation (EC) No 1831/2003 **N.I.**

3.—(1) For the purposes of [^{F726}Regulation (EC) No 1831/2003] the competent authority is the Secretary of State.

(2) An authorisation under Article 3(2) of that Regulation must be in writing.

(3) No person may possess a specified feed additive, or a premixture or feedingstuffs containing a specified feed additive, unless the specified feed additive has been authorised under Regulation (EC) No 1831/2003 or is for export to a third country.

(4) No person may fail to comply with any of the following provisions of that Regulation—

- (a) Article 3(1) or Article 3(3) (the authorisation, conditions of use and labelling of specified feed additives);
- (b) Article 12(1) or (2) (conditions relating to specified feed additives);
- (c) Article 16(1) (labelling);
- (d) Article 16(3) (additional labelling requirement);
- (e) Article 16(4) (premixtures containing specified feed additives);
- (f) Article 16(5) (packaging).

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Extent Information

E281 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F726 Words in Sch. 5 para. 3(1) substituted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/676), regs. 1(2)(a), **2(4)(b)**

Enforcement of [^{F384}Regulation (EU) 2017/625] **E+W+S**

4. For the purposes of [^{F385} Regulation (EU) 2017/625] the competent authority is the Secretary of State.

Extent Information

E110 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F384 Words in Sch. 5 para. 4 heading substituted (E.) (14.12.2019) by [The Official Controls \(Animals, Feed and Food, Plant Health Fees etc.\) Regulations 2019](#) (S.I. 2019/1488), regs. 1(1), 27(d)(ii); and said words substituted (W.) (31.1.2020) by [The Official Controls \(Animals, Feed and Food, Plant Health Fees etc.\) \(Wales\) Regulations 2020](#) (S.I. 2020/44), regs. 1(2), **24(1)(d)(ii)**; and said words substituted (S.N.I.) (31.12.2020) by [The Official Controls \(Animals, Feed and Food, Plant Health etc.\) \(Amendment\) \(EU Exit\) \(No. 2\) Regulations 2020](#) (S.I. 2020/1631), regs. 1(2), **3(4)(b)**

F385 Words in Sch. 5 para. 4 substituted (E.) (14.12.2019) by [The Official Controls \(Animals, Feed and Food, Plant Health Fees etc.\) Regulations 2019](#) (S.I. 2019/1488), regs. 1(1), 27(d)(ii); and said words substituted (W.) (31.1.2020) by [The Official Controls \(Animals, Feed and Food, Plant Health Fees etc.\) \(Wales\) Regulations 2020](#) (S.I. 2020/44), regs. 1(2), **24(1)(d)(i)**; and said words substituted (S.N.I.) (31.12.2020) by [The Official Controls \(Animals, Feed and Food, Plant Health etc.\) \(Amendment\) \(EU Exit\) \(No. 2\) Regulations 2020](#) (S.I. 2020/1631), regs. 1(2), **3(4)(b)**

[^{F727}Enforcement of Regulation (EU) 2017/625] **N.I.**

4. For the purposes of Regulation (EU) 2017/625 the competent authority is the Secretary of State.]

Extent Information

E282 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F727 Sch. 5 para. 4 substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020](#) (S.R. 2020/353), regs. 1(3), **10(15)(b)**

Enforcement of Regulation (EC) No 183/2005

5.—(1) For the purposes of [^{F386}Regulation (EC) No 183/2005] the competent authority is the Secretary of State.

(2) No person may fail to comply with any of the following provisions of that Regulation—

- (a) Article 5(2), (5) or (6) (specific obligations);
- (b) Article 6(1) as read with (2) and (3) (HACCP system);
- (c) Article 7(1) (documents concerning the HACCP system);
- (d) Article 9(2) (official controls, notification and registration);
- (e) Article 10(1) (approval of feed business establishments);
- (f) Article 11 (prohibition on operating without approval or registration);
- (g) Article 17(2) (exemption from on-site visits);
- (h) Article 18(3) (declaration of compliance);
- (i) Article 23(1) (conditions relating to imports from third countries);
- (j) Article 25 (feedingstuffs produced for export to third countries).

(3) A manufacturer must ensure that, so far as is reasonably practicable, the active ingredient is evenly incorporated throughout the feedingstuffs.

(4) In the case of the refusal, suspension or revocation of an approval under the Regulation the appeals procedure relating to a manufacturing authorisation in regulation 30 applies.

Textual Amendments

F386 Words in Sch. 5 para. 5(1) substituted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(a), **2(4)(d)**

Enforcement of Regulation (EC) No 767/2009

6. No person may contravene Article 8 of Regulation (EC) No 767/2009 of the European Parliament and of the Council in relation to feedingstuffs containing specified feed additives.

[^{F387}Authorisation] of manufacturers and distributors of feedingstuffs containing [^{F388}medicinal premixes] **E+W+S**

7.—(1) For the purposes of [Directive 90/167/EEC](#) laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community(**38**) the competent authority is the Secretary of State.

(2) No person may incorporate a [^{F389}medicinal premix] into [^{F390}an intermediate feedingstuff] or feedingstuff, or act as a distributor of [^{F391}intermediate feedingstuffs] or feedingstuffs containing a [^{F389}medicinal premix], without being [^{F392}authorised] to do so by the Secretary of State.

(3) The conditions which govern [^{F393}authorisation] of feed business [^{F394}premises] under Regulation (EC) No 183/2005 laying down requirements for feed hygiene(**39**) also govern [^{F393}authorisation] of manufacturers and distributors under sub-paragraph (2).

(38) OJ No L 92, 7.4.1990, p. 42.

(39) OJ No L 35, 8.2.2005, p. 1.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

(4) The Secretary of State shall conduct inspections of manufacturers and distributors [^{F395}authorised] under sub-paragraph (2) basing the frequency of inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

[^{F396}(5) A manufacturer must ensure that, so far as is reasonably practical the medicinal premix is evenly incorporated and homogeneously dispersed throughout the feedingstuffs, taking into account the specific properties of the medicinal premix and the mixing technology employed.]

(6) The provisions of this paragraph do not apply in relation to any person breeding or selling ornamental fish not intended for human consumption provided that the person does not use more than a total of 1kg of [^{F397}medicinal premix] annually for that purpose.

(7) In the case of the refusal, suspension or revocation of an [^{F398}authorisation] under this paragraph the appeals procedure relating to a manufacturing authorisation in regulation 30 applies.

Extent Information

E111 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F387 Word in Sch. 5 para. 7 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(g)(i)**

F388 Words in Sch. 5 para. 7 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(g)(ii)**

F389 Words in Sch. 5 para. 7(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(a)(i)**

F390 Words in Sch. 5 para. 7(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(a)(ii)**

F391 Words in Sch. 5 para. 7(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(a)(iii)**

F392 Word in Sch. 5 para. 7(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(a)(iv)**

F393 Word in Sch. 5 para. 7(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(b)(i)**

F394 Word in Sch. 5 para. 7(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(b)(ii)**

F395 Word in Sch. 5 para. 7(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(c)**

F396 Sch. 5 para. 7(5) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(d)**

F397 Words in Sch. 5 para. 7(6) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(e)**

F398 Word in Sch. 5 para. 7(7) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **130(f)**

Approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products **N.I.**

7.—(1) For the purposes of [Directive 90/167/EEC](#) laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community(**38**) the competent authority is the Secretary of State.

(38) OJ No L 92, 7.4.1990, p. 42.

(2) No person may incorporate a veterinary medicinal product into a premixture or feedingstuff, or act as a distributor of premixtures or feedingstuffs containing a veterinary medicinal product, without being approved to do so by the Secretary of State.

(3) The conditions which govern approval of feed business establishments under Regulation (EC) No 183/2005 laying down requirements for feed hygiene⁽³⁹⁾ also govern approval of manufacturers and distributors under sub-paragraph (2).

(4) The Secretary of State shall conduct inspections of manufacturers and distributors approved under sub-paragraph (2) basing the frequency of inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

(5) A manufacturer must ensure that, so far as is reasonably practical, the veterinary medicinal product is evenly incorporated throughout the feedingstuffs.

(6) The provisions of this paragraph do not apply in relation to any person breeding or selling ornamental fish not intended for human consumption provided that the person does not use more than a total of 1kg of veterinary medicinal product annually for that purpose.

(7) In the case of the refusal, suspension or revocation of an approval under this paragraph the appeals procedure relating to a manufacturing authorisation in regulation 30 applies.

Extent Information

E283 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Incorporation of a ^{F399} medicinal premix into an intermediate feedingstuff **E+W+S**

8. Any person who incorporates a ^{F400} medicinal premix] into ^{F401} an intermediate feedingstuff]—
- (a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there; and
 - (b) must ensure that the ^{F400} medicinal premix] does not contain the same active substance as any other additive.

Extent Information

E112 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F399 Words in Sch. 5 para. 8 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **131(c)**

F400 Words in Sch. 5 para. 8 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **131(a)**

F401 Words in Sch. 5 para. 8 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **131(b)**

Incorporation of a veterinary medicinal product into a premixture **N.I.**

8. Any person who incorporates a veterinary medicinal product into a premixture—

⁽³⁹⁾ OJ No L 35, 8.2.2005, p. 1.

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Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there; and
- (b) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive.

Extent Information

E284 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Top dressing

9. No person may promote or label any veterinary medicinal product, or anything containing a veterinary medicinal product, as being suitable for top dressing (that is, sprinkling it on to feedingstuffs without thoroughly incorporating it) unless the summary of product characteristics specifically permits this use.

Incorporation of a [^{F402}medicinal premix] into feedingstuffs **E+W+S**

10. Any person who incorporates a [^{F403}medicinal premix] (or [^{F404}an intermediate feedingstuff]) into feedingstuffs—

- (a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there;
- (b) must ensure that the [^{F403}medicinal premix] does not contain the same active substance as any other additive;
- (c) must ensure that the [^{F403}medicinal premix] is incorporated in accordance with its marketing authorisation (unless it has been prescribed under the cascade) and the [^{F405}medicated feedingstuff prescription];
- (d) must ensure that the daily dose of the [^{F403}medicinal premix] is contained in a quantity of medicated feedingstuffs corresponding to at least half the daily feedingstuffs ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirements of non-mineral complementary feedingstuffs.

Extent Information

E113 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F402 Words in *Sch. 5 para. 10* heading substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **132(d)**

F403 Words in *Sch. 5 para. 10* substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **132(a)**

F404 Words in *Sch. 5 para. 10* substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **132(b)**

F405 Words in *Sch. 5 para. 10(c)* substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **132(c)**

Incorporation of a veterinary medicinal product into feedingstuffs **N.I.**

10. Any person who incorporates a veterinary medicinal product (or a premixture containing a veterinary medicinal product) into feedingstuffs—

- (a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there;
- (b) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive;
- (c) must ensure that the veterinary medicinal product is incorporated in accordance with its marketing authorisation (unless it has been prescribed under the cascade) and the prescription;
- (d) must ensure that the daily dose of the veterinary medicinal product is contained in a quantity of medicated feedingstuffs corresponding to at least half the daily feedingstuffs ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirements of non-mineral complementary feedingstuffs.

Extent Information

E285 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Additional record keeping requirements relating to **[^{F406}medicinal premixes]** **E+W+S**

11.—(1) Any person who—

- (a) incorporates a [^{F407}medicinal premix] into [^{F408}an intermediate feedingstuff];
- (b) incorporates [^{F409}an intermediate feedingstuff] containing a [^{F410}medicinal premix] into feedingstuffs; or
- (c) incorporates a [^{F411}medicinal premix] into feedingstuffs,

must make a daily record of—

- (d) the types and quantities of all [^{F412}medicinal premixes] (and specified feed additives, if any) and [^{F413}intermediate feedingstuffs] used in the manufacturing process; and
- (e) the quantity of feedingstuffs and [^{F414}intermediate feedingstuffs] containing [^{F415}medicinal premix] manufactured that day.

(2) An [^{F416}authorised] distributor must make a daily record of—

- (a) the types and quantities of all [^{F417}intermediate feedingstuffs] and feedingstuffs containing [^{F418}medicinal premixes] bought and sold that day; and
- (b) the quantity held.

(3) A manufacturer and distributor must also record, as soon as reasonably practicable, for each consignment supplied—

- (a) the date of delivery;
- (b) the name and address of each consignee (or, in the case of a manufacturer supplying to a distributor, the name and address of the distributor);
- (c) the type of feedingstuffs or [^{F419}intermediate feedingstuffs] supplied;
- (d) the quantity;

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (e) the type of [^{F420} medicinal premix] incorporated into the feedingstuffs; ^{F421} ...
 - (f) the expiry date [^{F422}; and
 - (g) the batch number.]
- (4) Records must be kept for five years.

Textual Amendments

- F406** Words in Sch. 5 para. 11 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(d)**
- F407** Words in Sch. 5 para. 11(1)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(i)(aa)**
- F408** Words in Sch. 5 para. 11(1)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(i)(bb)**
- F409** Words in Sch. 5 para. 11(1)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(ii)(aa)**
- F410** Words in Sch. 5 para. 11(1)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(ii)(bb)**
- F411** Words in Sch. 5 para. 11(1)(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(iii)**
- F412** Words in Sch. 5 para. 11(1)(d) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(iv)(aa)**
- F413** Words in Sch. 5 para. 11(1)(d) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(iv)(bb)**
- F414** Words in Sch. 5 para. 11(1)(e) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(v)(aa)**
- F415** Words in Sch. 5 para. 11(1)(e) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(a)(v)(bb)**
- F416** Word in Sch. 5 para. 11(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(b)(i)**
- F417** Words in Sch. 5 para. 11(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(b)(ii)**
- F418** Words in Sch. 5 para. 11(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(b)(iii)**
- F419** Words in Sch. 5 para. 11(3)(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(c)(i)**
- F420** Words in Sch. 5 para. 11(3)(e) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(c)(ii)**
- F421** Word in Sch. 5 para. 11(3) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(c)(iii)**
- F422** Sch. 5 para. 11(3)(g) and word inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **133(c)(iv)**

Additional record keeping requirements relating to veterinary medicinal products **N.I.**

- 11.—(1) Any person who—
- (a) incorporates a veterinary medicinal product into a premixture;
 - (b) incorporates a premixture containing a veterinary medicinal product into feedingstuffs; or
 - (c) incorporates a veterinary medicinal product into feedingstuffs,
- must make a daily record of—

- (d) the types and quantities of all veterinary medicinal products (and specified feed additives, if any) and premixture used in the manufacturing process; and
 - (e) the quantity of feedingstuffs and premixture containing veterinary medicinal product manufactured that day.
- (2) An approved distributor must make a daily record of—
- (a) the types and quantities of all premixtures and feedingstuffs containing veterinary medicinal products bought and sold that day; and
 - (b) the quantity held.
- (3) A manufacturer and distributor must also record, as soon as reasonably practicable, for each consignment supplied—
- (a) the date of delivery;
 - (b) the name and address of each consignee (or, in the case of a manufacturer supplying to a distributor, the name and address of the distributor);
 - (c) the type of feedingstuffs or premixture supplied;
 - (d) the quantity;
 - (e) the type of veterinary medicinal product incorporated into the feedingstuffs; and
 - (f) the expiry date.
- (4) Records must be kept for five years.

Labelling [^{F423}an intermediate feedingstuff] containing a [^{F424}medicinal premix] **E+W+S**

12.—(1) [^{F425}An intermediate feedingstuff] containing a [^{F426}medicinal premix] must be clearly and legibly labelled with the following—

- (a) the words “[^{F427}INTERMEDIATE FEEDINGSTUFF]” (or, if it is to be labelled as “complementary feedingstuffs” under legislation implementing Council [Directive 79/373/EEC](#) on the marketing of compound feedingstuffs⁽⁴⁰⁾, “MEDICATED COMPLEMENTARY FEEDINGSTUFFS”) in upper case letters;
 - (b) the proprietary name of the [^{F428}medicinal premix] and the authorisation number;
 - (c) the name and amount of the active substance (mg/kg) in the [^{F429}intermediate feedingstuff];
 - (d) the range of acceptable inclusion rates of the [^{F430}intermediate feedingstuff] into the final feedingstuffs, the range of acceptable levels of the active ingredients in the final feedingstuffs and the words “refer to the [^{F431}medicated feedingstuffs prescription] for the exact inclusion rate” or equivalent wording;
 - (e) warnings and contra-indications;
- [^{F432}(ea) a statement that the product must be used in accordance with its summary of product characteristics;
- (eb) the contact details (including a free helpline number) for the supplier of the product;
 - (ec) the words “inappropriate disposal of this product poses a serious threat to the environment”;
 - (ed) in the case of a product containing an antibiotic, the words “inappropriate disposal of this product may contribute to antimicrobial resistance”;
 - (f) the withdrawal period, and a statement that, if the [^{F433}medicated feedingstuffs prescription] requires a longer withdrawal period, that is the one that applies;

⁽⁴⁰⁾ OJ No L86, 6.4.1979, p. 30.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- (g) the expiry date;
- (h) any special storage instructions [^{F434}required by the marketing authorisation];
- (i) where a [^{F435}medicated feedingstuffs prescription] is required, a statement to this effect.

(2) If there is more than one [^{F436}medicinal premix] used, the longest withdrawal period must be shown on the label.

(3) If the [^{F437}intermediate feedingstuff] also contains a specified feed additive to which this Schedule applies it must also contain the information required under Article 16 of Regulation (EC) No 1831/2003(41).

(4) No person may supply such [^{F438}an intermediate feedingstuff] unless it is labelled in accordance with this paragraph.

Extent Information

E114 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F423** Words in Sch. 5 para. 12 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(e)(i)** (with reg. 205)
- F424** Words in Sch. 5 para. 12 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(e)(ii)** (with reg. 205)
- F425** Words in Sch. 5 para. 12(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(i)(aa)** (with reg. 205)
- F426** Words in Sch. 5 para. 12(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(i)(bb)** (with reg. 205)
- F427** Words in Sch. 5 para. 12(1)(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(ii)** (with reg. 205)
- F428** Words in Sch. 5 para. 12(1)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(iii)** (with reg. 205)
- F429** Words in Sch. 5 para. 12(1)(c) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(iv)** (with reg. 205)
- F430** Words in Sch. 5 para. 12(1)(d) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(v)(aa)** (with reg. 205)
- F431** Words in Sch. 5 para. 12(1)(d) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(v)(bb)** (with reg. 205)
- F432** Sch. 5 para. 12(1)(ea)-(ed) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(vi)** (with reg. 205)
- F433** Words in Sch. 5 para. 12(1)(f) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(vii)** (with reg. 205)
- F434** Words in Sch. 5 para. 12(1)(h) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(viii)** (with reg. 205)
- F435** Words in Sch. 5 para. 12(1)(i) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(a)(ix)** (with reg. 205)
- F436** Words in Sch. 5 para. 12(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(b)** (with reg. 205)
- F437** Words in Sch. 5 para. 12(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(c)** (with reg. 205)

(41) OJ No L268, 18.10.2003, p. 29. Regulation (EC) no 1831/2003 was last amended by Article 29 of Regulation (EC) No 767/2009 (OJ No L229, 1.9.2009, p. 1.)

F438 Words in Sch. 5 para. 12(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **134(d)** (with reg. 205)

Labelling a premixture containing a veterinary medicinal product **N.I.**

12.—(1) A premixture containing a veterinary medicinal product must be clearly and legibly labelled with the following—

- (a) the words “MEDICATED PREMIXTURE” (or, if it is to be labelled as “complementary feedingstuffs” under legislation implementing Council [Directive 79/373/EEC](#) on the marketing of compound feedingstuffs⁽⁴⁰⁾, “MEDICATED COMPLEMENTARY FEEDINGSTUFFS”) in upper case letters;
- (b) the proprietary name of the veterinary medicinal product and the authorisation number;
- (c) the name and amount of the active substance (mg/kg) in the premixture;
- (d) the range of acceptable inclusion rates of the premixture into the final feedingstuffs, the range of acceptable levels of the active ingredients in the final feedingstuffs and the words “refer to the prescription for the exact inclusion rate” or equivalent wording;
- (e) warnings and contra-indications;
- (f) the withdrawal period, and a statement that, if the prescription requires a longer withdrawal period, that is the one that applies;
- (g) the expiry date;
- (h) any special storage instructions;
- (i) where a prescription is required, a statement to this effect.

(2) If there is more than one veterinary medicinal product used, the longest withdrawal period must be shown on the label.

(3) If the premixture also contains a specified feed additive to which this Schedule applies it must also contain the information required under Article 16 of Regulation [\(EC\) No 1831/2003](#)⁽⁴¹⁾.

(4) No person may supply such a premixture unless it is labelled in accordance with this paragraph.

Extent Information

E286 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Labelling of feedingstuffs containing a specified feed additive

13. No person may contravene the labelling requirements of Article 15 and Article 17 of Regulation [\(EC\) No 767/2009](#) of the European Parliament and of the Council.

Labelling of feedingstuffs containing a ^{F439}medicinal premix] **E+W+S**

14.—(1) Feedingstuffs containing a [^{F440}medicinal premix] must be clearly and legibly labelled with the following—

⁽⁴⁰⁾ OJ No L86, 6.4.1979, p. 30.

⁽⁴¹⁾ OJ No L268, 18.10.2003, p. 29. Regulation (EC) no 1831/2003 was last amended by Article 29 of Regulation [\(EC\) No 767/2009](#) (OJ No L229, 1.9.2009, p. 1.)

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (a) the words “MEDICATED COMPLETE FEED” in upper case letters, or where feedingstuffs are to be labelled as a complementary feedingstuff and intended to be fed to animals without further mixing with feed materials, the words “MEDICATED COMPLEMENTARY FEEDINGSTUFF”;
 - (b) the proprietary name, authorisation number and inclusion rate (kg/tonne or mg/kg) of the [F440 medicinal premix] incorporated into the feedingstuffs;
 - (c) the name and amount of the active substance (mg/kg) in the feedingstuffs;
 - (d) the species of animal for which the feedingstuffs are intended;
 - (e) warnings and contra-indications;
 - [F441](ea) the contact details (including a free helpline number) for the supplier of the product;
 - (eb) the words “inappropriate disposal of this product poses a serious threat to the environment”;
 - (ec) in the case of a product containing an antibiotic, the words “inappropriate disposal of this product may contribute to antimicrobial resistance”;
 - (f) the withdrawal period, and a statement that, if the [F442 medicated feedingstuffs prescription] requires a longer withdrawal period, that is the one that applies;
 - [F443](fa) the batch number;
 - (g) the expiry date;
 - (h) any special storage instructions required by the marketing authorisation;
 - (i) a statement to the effect that the feedingstuffs must only be fed in accordance with its [F444 medicated feedingstuffs prescription];
 - (j) the name and [F445 authorisation] number of the manufacturer or the distributor.
- (2) If there is more than one [F446 medicinal premix] used, the longest withdrawal period must be shown on the label.
- (3) If the feedingstuff also contains a specified feed additive to which this Schedule applies it must also contain the information required by Articles 15 and 17 of Regulation (EC) No 767/2009 of the European Parliament and of the Council.
- (4) No person may supply feedingstuffs [F447 containing a medicinal premix] unless they are labelled in accordance with this paragraph.

Extent Information

E115 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F439** Words in Sch. 5 para. 14 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **135(d)** (with reg. 205)
- F440** Words in Sch. 5 para. 14(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **135(a)(i)** (with reg. 205)
- F441** Sch. 5 para. 14(1)(ea)-(ec) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **135(a)(ii)** (with reg. 205)
- F442** Words in Sch. 5 para. 14(1)(f) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **135(a)(iii)** (with reg. 205)
- F443** Sch. 5 para. 14(1)(fa) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **135(a)(iv)** (with reg. 205)

- F444** Words in Sch. 5 para. 14(1)(i) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **135(a)(v)** (with reg. 205)
- F445** Word in Sch. 5 para. 14(1)(j) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **135(a)(vi)** (with reg. 205)
- F446** Words in Sch. 5 para. 14(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **135(b)** (with reg. 205)
- F447** Words in Sch. 5 para. 14(4) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **135(c)** (with reg. 205)

Labelling of feedingstuffs containing a veterinary medicinal product **N.I.**

14.—(1) Feedingstuffs containing a veterinary medicinal product must be clearly and legibly labelled with the following—

- (a) the words “MEDICATED COMPLETE FEED” in upper case letters, or where feedingstuffs are to be labelled as a complementary feedingstuff and intended to be fed to animals without further mixing with feed materials, the words “MEDICATED COMPLEMENTARY FEEDINGSTUFF”;
- (b) the proprietary name, authorisation number and inclusion rate (kg/tonne or mg/kg) of the veterinary medicinal product incorporated into the feedingstuffs;
- (c) the name and amount of the active substance (mg/kg) in the feedingstuffs;
- (d) the species of animal for which the feedingstuffs are intended;
- (e) warnings and contra-indications;
- (f) the withdrawal period, and a statement that, if the prescription requires a longer withdrawal period, that is the one that applies;
- (g) the expiry date;
- (h) any special storage instructions required by the marketing authorisation;
- (i) a statement to the effect that the feedingstuffs must only be fed in accordance with its prescription;
- (j) the name and approval number of the manufacturer or the distributor.

(2) If there is more than one veterinary medicinal product used, the longest withdrawal period must be shown on the label.

(3) If the feedingstuff also contains a specified feed additive to which this Schedule applies it must also contain the information required by Articles 15 and 17 of Regulation [\(EC\) No 767/2009](#) of the European Parliament and of the Council.

(4) No person may supply feedingstuffs unless they are labelled in accordance with this paragraph.

Extent Information

E287 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply of specified feed additives **E+W+S**

15.—(1) No person other than the person who manufactured a specified feed additive or an ^{F448}authorised distributor may supply a specified feed additive.

(2) The person who manufactured the specified feed additive may only supply it to—

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (a) an [^{F448}authorised] distributor;
 - (b) an [^{F448}authorised][^{F449}intermediate feedingstuff] manufacturer or an [^{F448}authorised] complementary feedingstuffs manufacturer; or
 - (c) a feedingstuff manufacturer [^{F448}authorised] to mix a specified feed additive directly into feedingstuff.
- (3) An [^{F448}authorised] distributor may only supply it to—
- (a) another [^{F448}authorised] distributor;
 - (b) an [^{F448}authorised][^{F450}intermediate feedingstuff] manufacturer or an [^{F448}authorised] complementary feedingstuffs manufacturer; or
 - (c) a feedingstuff manufacturer [^{F448}authorised] to mix a specified feed additive directly into feedingstuff.

Extent Information

E116 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F448 Word in Sch. 5 para. 15 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **136(a)**

F449 Words in Sch. 5 para. 15(2)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **136(b)**

F450 Words in Sch. 5 para. 15(3)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **136(c)**

Supply of specified feed additives **N.I.**

15.—(1) No person other than the person who manufactured a specified feed additive or an approved distributor may supply a specified feed additive.

- (2) The person who manufactured the specified feed additive may only supply it to—
- (a) an approved distributor;
 - (b) an approved premixture manufacturer or an approved complementary feedingstuffs manufacturer; or
 - (c) a feedingstuff manufacturer approved to mix a specified feed additive directly into feedingstuff.
- (3) An approved distributor may only supply it to—
- (a) another approved distributor;
 - (b) an approved premixture manufacturer or an approved complementary feedingstuffs manufacturer; or
 - (c) a feedingstuff manufacturer approved to mix a specified feed additive directly into feedingstuff.

Extent Information

E288 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply of ^{F451}intermediate feedingstuff or specified feed additive **E+W+S**

16.—(1) No person other than the person who manufactured ^{F452}an intermediate feedingstuff or specified feed additive] or an ^{F453}authorised] distributor may supply ^{F452}an intermediate feedingstuff or specified feed additive].

(2) The person who manufactured the ^{F454}intermediate feedingstuff or specified feed additive] may only supply it to—

- (a) an ^{F453}authorised] distributor; or
- (b) a feedingstuff manufacturer ^{F453}authorised] to incorporate that ^{F454}intermediate feedingstuff or specified feed additive].

(3) An ^{F453}authorised] distributor may only supply it to—

- (a) another ^{F453}authorised] distributor; or
- (b) a feedingstuff manufacturer ^{F453}authorised] to incorporate that ^{F455}intermediate feedingstuff or specified feed additive].

Extent Information

E117 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F451 Words in Sch. 5 para. 16 heading substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **137(e)**

F452 Words in Sch. 5 para. 16(1) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **137(b)**

F453 Word in Sch. 5 para. 16 substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **137(a)**

F454 Words in Sch. 5 para. 16(2) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **137(c)**

F455 Words in Sch. 5 para. 16(3) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **137(d)**

Supply of premixture **N.I.**

16.—(1) No person other than the person who manufactured a premixture or an approved distributor may supply a premixture.

(2) The person who manufactured the premixture may only supply it to—

- (a) an approved distributor; or
- (b) a feedingstuff manufacturer approved to incorporate that premixture.

(3) An approved distributor may only supply it to—

- (a) another approved distributor; or
- (b) a feedingstuff manufacturer approved to incorporate that premixture.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Extent Information

E289 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply of a complementary feedingstuff **E+W+S**

17.—(1) No person other than—

- (a) the person who manufactured a complementary feedingstuff containing a specified feed additive; or
- (b) an ^{F456}authorised distributor

may supply a complementary feedingstuff containing a specified feed additive.

(2) The person who manufactured such complementary feedingstuff may only supply it to—

- (a) an ^{F456}authorised distributor; or
- (b) a feedingstuff manufacturer registered to incorporate that complementary feedingstuff or ^{F456}authorised to incorporate ^{F457}an intermediate feedingstuff].

(3) An ^{F456}authorised distributor may only supply it to—

- (a) another ^{F456}authorised distributor, or
- (b) a feedingstuff manufacturer registered to incorporate that complementary feedingstuff or ^{F456}authorised to incorporate ^{F458}an intermediate feedingstuff].

^{F459}(4)

Extent Information

E118 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F456 Word in Sch. 5 para. 17 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **138(a)**

F457 Words in Sch. 5 para. 17(2)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **138(b)**

F458 Words in Sch. 5 para. 17(3)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **138(c)**

F459 Sch. 5 para. 17(4) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **138(d)**

Supply of a complementary feedingstuff **N.I.**

17.—(1) No person other than—

- (a) the person who manufactured a complementary feedingstuff containing a specified feed additive; or
- (b) an approved distributor

may supply a complementary feedingstuff containing a specified feed additive.

(2) The person who manufactured such complementary feedingstuff may only supply it to—

- (a) an approved distributor; or
 - (b) a feedingstuff manufacturer registered to incorporate that complementary feedingstuff or approved to incorporate a premixture.
- (3) An approved distributor may only supply it to—
- (a) another approved distributor, or
 - (b) a feedingstuff manufacturer registered to incorporate that complementary feedingstuff or approved to incorporate a premixture.
- (4) In this paragraph “complementary feedingstuff” has the meaning given in Article 3 of Regulation EC No 767/2009.

Extent Information

E290 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply of feedingstuffs containing a ^{F460}medicinal premix **E+W+S**

18.—(1) No person other than the person who manufactured the feedingstuffs or an ^{F461}authorised] distributor may supply feedingstuffs containing a ^{F462}medicinal premix].

(2) The person who manufactured the feedingstuff may only supply it to—

- (a) an ^{F461}authorised] distributor; or
- (b) ^{F463}an animal keeper] for feeding to those animals.

(3) A distributor may only supply it to—

- (a) another ^{F461}authorised] distributor; or
- (b) ^{F464}an animal keeper] for feeding to those animals.

(4) Supply to ^{F465}an animal keeper] must be in accordance with a written ^{F466}medicated feedingstuff prescription] as specified in the following paragraph.

(5) If a ^{F467}medicated feedingstuff prescription] is for a period of longer than one month, the supplier may not provide more than one month’s supply at any one time.

(6) No manufacturer or distributor may supply a feedingstuff to anyone not specified in this paragraph, or otherwise than in accordance with this paragraph.

(7) The person supplying the feedingstuff must keep the ^{F468}medicated feedingstuff prescription] for five years.

^{F469}(8) Nothing in this paragraph prevents a commercial feed manufacturer from incorporating a medicinal premix with a feedingstuff in advance of receiving a written prescription for that feedingstuff.]

Extent Information

E119 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F460 Words in [Sch. 5 para. 18](#) heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **139(i)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- F461** Word in Sch. 5 para. 18 substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **139(a)**
- F462** Words in Sch. 5 para. 18(1) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **139(b)**
- F463** Words in Sch. 5 para. 18(2)(b) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **139(c)**
- F464** Words in Sch. 5 para. 18(3)(b) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **139(d)**
- F465** Words in Sch. 5 para. 18(4) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **139(e)(i)**
- F466** Words in Sch. 5 para. 18(4) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **139(e)(ii)**
- F467** Words in Sch. 5 para. 18(5) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **139(f)**
- F468** Words in Sch. 5 para. 18(7) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **139(g)**
- F469** Sch. 5 para. 18(8) inserted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **139(h)**

Supply of feedingstuffs containing a veterinary medicinal product **N.I.**

18.—(1) No person other than the person who manufactured the feedingstuffs or an approved distributor may supply feedingstuffs containing a veterinary medicinal product.

(2) The person who manufactured the feedingstuff may only supply it to—

- (a) an approved distributor; or
- (b) a person who keeps animals for feeding to those animals.

(3) A distributor may only supply it to—

- (a) another approved distributor; or
- (b) a person who keeps animals for feeding to those animals.

(4) Supply to a person who keeps animals must be in accordance with a written prescription as specified in the following paragraph.

(5) If a prescription is for a period of longer than one month, the supplier may not provide more than one month's supply at any one time.

(6) No manufacturer or distributor may supply a feedingstuff to anyone not specified in this paragraph, or otherwise than in accordance with this paragraph.

(7) The person supplying the feedingstuff must keep the prescription for five years.

Extent Information

E291 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F470}Medicated feedingstuff prescriptions] for feedingstuffs containing a [^{F471}medicinal premix] **E+W+S**

19.—(1) A [^{F472}medicated feedingstuff prescription] for feedingstuffs containing a [^{F473}medicinal premix] must contain the following—

- (a) the name and address of the person prescribing the product;

- (b) the qualifications enabling the person to prescribe the product;
- (c) the name and address of the keeper of the animals to be treated;
- (d) the species of animal, identification and number of the animals;
- (e) the premises at which the animals are kept if this is different from the address of the keeper;
- [^{F474}(ea) the diagnosed disease to be treated or prevented (in the case of immunological veterinary medicinal products or antiparasitics without antimicrobial effects);]
- (f) the date of the prescription;
- (g) the signature or other authentication of the person prescribing the product;
- [^{F475}(h) the name, active substance, amount of the product prescribed and inclusion rate of the medicinal premix and resulting inclusion rate of the active substance;]
- (i) the dosage and administration instructions;
- (j) any necessary warnings;
- [^{F476}(ja) a statement that the prescription may not be re-used;]
- (k) the withdrawal period;
- (l) the manufacturer or the distributor of the feedingstuffs (who must be [^{F477}authorised] for the purpose) [^{F478}, whichever is the supplier to the end user];
- (m) if the validity exceeds one month, a statement that not more than 31 days' supply may be provided at any time;
- (n) the name, type and quantity of feedingstuffs to be used;
- [^{F479}(na) the overall amount of feedingstuff to be supplied under the prescription;]
- ^{F480}(o)
- (p) any special instructions;
- (q) the percentage of the prescribed feedingstuffs to be added to the daily ration; and
- (r) if it is prescribed under the cascade, a statement to that effect.

(2) It is valid for three months or such shorter period as may be specified in the [^{F481}medicated feedingstuff prescription].

[^{F482}(2A) In the case of a prescription to which sub-paragraph (1) applies which relates to an antibiotic, the time between a prescription being issued and the course of treatment starting must be no more than five working days.

(2B) Subject to paragraph 7A in Schedule 3, a prescription for a medicated feedingstuff containing a medicinal premix which includes an antibiotic may not be issued for prophylactic purposes.]

[^{F483}(3) In relation to food-producing animals a medicated feedingstuffs prescription may not confer authority for more than one course of treatment.]

Extent Information

E120 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F470 Words in [Sch. 5 para. 19](#) heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **140(e)(i)** (with reg. 206)

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- F471** Words in Sch. 5 para. 19 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(e)(ii)** (with reg. 206)
- F472** Words in Sch. 5 para. 19(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(i)** (with reg. 206)
- F473** Words in Sch. 5 para. 19(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(ii)** (with reg. 206)
- F474** Sch. 5 para. 19(1)(ea) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(iii)** (with reg. 206)
- F475** Sch. 5 para. 19(1)(h) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(iv)** (with reg. 206)
- F476** Sch. 5 para. 19(1)(ja) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(v)** (with reg. 206)
- F477** Word in Sch. 5 para. 19(1)(l) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(vi)(aa)** (with reg. 206)
- F478** Words in Sch. 5 para. 19(1)(l) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(vi)(bb)** (with reg. 206)
- F479** Sch. 5 para. 19(1)(na) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(vii)** (with reg. 206)
- F480** Sch. 5 para. 19(1)(o) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(a)(viii)** (with reg. 206)
- F481** Words in Sch. 5 para. 19(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(b)** (with reg. 206)
- F482** Sch. 5 para. 19(2A)(2B) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(c)** (with reg. 206)
- F483** Sch. 5 para. 19(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **140(d)** (with reg. 206)

Prescriptions for feedingstuffs containing a veterinary medicinal product **N.I.**

19.—(1) A prescription for feedingstuffs containing a veterinary medicinal product must contain the following—

- (a) the name and address of the person prescribing the product;
- (b) the qualifications enabling the person to prescribe the product;
- (c) the name and address of the keeper of the animals to be treated;
- (d) the species of animal, identification and number of the animals;
- (e) the premises at which the animals are kept if this is different from the address of the keeper;
- (f) the date of the prescription;
- (g) the signature or other authentication of the person prescribing the product;
- (h) the name and amount of the product prescribed;
- (i) the dosage and administration instructions;
- (j) any necessary warnings;
- (k) the withdrawal period;
- (l) the manufacturer or the distributor of the feedingstuffs (who must be approved for the purpose);
- (m) if the validity exceeds one month, a statement that not more than 31 days' supply may be provided at any time;
- (n) the name, type and quantity of feedingstuffs to be used;

- (o) the inclusion rate of the veterinary medicinal product and the resulting inclusion rate of the active substance;
 - (p) any special instructions;
 - (q) the percentage of the prescribed feedingstuffs to be added to the daily ration; and
 - (r) if it is prescribed under the cascade, a statement to that effect.
- (2) It is valid for three months or such shorter period as may be specified in the prescription.
- (3) It must be sufficient for only one course of treatment.

Extent Information

E292 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Writing the [F484 medicated feedingstuff prescription] **E+W+S**

20.—(1) The person who writes the [F485 medicated feedingstuff prescription] must—

- (a) give a copy to the person incorporating the [F486 medicinal premix] into the feedingstuffs or to the distributor of the feedingstuffs [F487, whichever is the supplier to the end user];
- (b) give one copy to the keeper of the animals to be treated;
- (c) keep a copy.

(2) The person must be satisfied that—

- (a) there is no undesirable interaction between the [F488 medicinal premix] and any feed additive used in the feedingstuffs; and
- (b) the active substance of the [F488 medicinal premix] is not the same as an active substance in any feed additive used in the feedingstuffs.

[F489] (3) The person must prescribe a [F490 medicinal premix] authorised for incorporation in feedingstuffs but may, if there is no [F490 medicinal premix] authorised for a condition in a particular species—

- (a) prescribe a [F490 medicinal premix] authorised for another species or for another condition in the same species, and
- (b) prescribe more than one [F490 medicinal premix],
provided all [F491 medicinal premixes] prescribed are authorised for incorporation in feedingstuffs.]

Extent Information

E121 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F484 Words in Sch. 5 para. 20 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **141(d)**

F485 Words in Sch. 5 para. 20(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **141(a)(i)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- F486** Words in Sch. 5 para. 20(1)(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **141(a)(ii)(aa)**
- F487** Words in Sch. 5 para. 20(1)(a) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **141(a)(ii)(bb)**
- F488** Words in Sch. 5 para. 20(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **141(b)**
- F489** Sch. 5 para. 20(3) substituted (14.4.2014) by [The Veterinary Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/599\)](#), regs. 1, **3(2)**
- F490** Words in Sch. 5 para. 20(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **141(c)(i)**
- F491** Words in Sch. 5 para. 20(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **141(c)(ii)**

Writing the prescription **N.I.**

20.—(1) The person who writes the prescription must—

- (a) give a copy to the person incorporating the veterinary medicinal product into the feedingstuffs or to the distributor of the feedingstuffs;
- (b) give one copy to the keeper of the animals to be treated;
- (c) keep a copy.

(2) The person must be satisfied that—

- (a) there is no undesirable interaction between the veterinary medicinal product and any feed additive used in the feedingstuffs; and
- (b) the active substance of the veterinary medicinal product is not the same as an active substance in any feed additive used in the feedingstuffs.

[^{F728}(3) The person must prescribe a veterinary medicinal product authorised for incorporation in feedingstuffs but may, if there is no veterinary medicinal product authorised for a condition in a particular species—

- (a) prescribe a veterinary medicinal product authorised for another species or for another condition in the same species, and
- (b) prescribe more than one veterinary medicinal product, provided all veterinary medicinal products prescribed are authorised for incorporation in feedingstuffs.]

Extent Information

E293 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F728 Sch. 5 para. 20(3) substituted (14.4.2014) by [The Veterinary Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/599\)](#), regs. 1, **3(2)**

Possession **E+W+S**

21.—(1) No person other than a person holding the appropriate [^{F492}authorisation] under this Schedule may be in possession of any—

- (a) specified feed additive or [^{F493}medicinal premix] to which this Schedule applies;

- (b) [^{F494}intermediate feedingstuffs] containing such an additive or a [^{F495}medicinal premix]; or
 - (c) feedingstuffs or complementary feedingstuffs containing [^{F496}a medicinal premix] unless supplied under these Regulations.
- (2) No person other than a manufacturer or distributor may be in possession of feedingstuffs incorporating a [^{F497}medicinal premix] unless it has been supplied under a [^{F498}medicated feedingstuffs prescription].

Extent Information

E122 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F492 Word in Sch. 5 para. 21(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **142(a)(i)**

F493 Words in Sch. 5 para. 21(1)(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **142(a)(ii)**

F494 Words in Sch. 5 para. 21(1)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **142(a)(iii)(aa)**

F495 Words in Sch. 5 para. 21(1)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **142(a)(iii)(bb)**

F496 Words in Sch. 5 para. 21(1)(c) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **142(a)(iv)**

F497 Words in Sch. 5 para. 21(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **142(b)(i)**

F498 Words in Sch. 5 para. 21(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **142(b)(ii)**

Possession **N.I.**

21.—(1) No person other than a person holding the appropriate approval under this Schedule may be in possession of any—

- (a) specified feed additive or veterinary medicinal product to which this Schedule applies;
- (b) premixtures containing such an additive or a veterinary medicinal product; or
- (c) feedingstuffs or complementary feedingstuffs containing such an additive or a veterinary medicinal product unless supplied under these Regulations.

(2) No person other than a manufacturer or distributor may be in possession of feedingstuffs incorporating a veterinary medicinal product unless it has been supplied under a prescription.

Extent Information

E294 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Sampling and analysis **E+W+S**

22.—(1) If any enforcement action is taken under this Schedule based on a sample, that sample must have been taken and analysed in accordance with [^{F499}Regulation (EC) No 152/2009 laying down methods of sampling and analysis for the official control of feedingstuffs.]

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

(2) Unless otherwise specified in the marketing authorisation, it is a defence if the active ingredient in the medicated feedingstuff sample is within the following tolerances—

[^{F500}Tolerance table for medicated feedingstuff

<i>Level of active ingredient specified on the label</i>	<i>Tolerance</i>
≤500mg/kg	±30%
>500mg/kg ≤5g/kg	±20%
>5g/kg	±10%]

(3) Unless otherwise specified in the Commission Regulation authorising the specified feed additive in question, it is a defence if the active ingredient of a specified feed additive in a feedingstuff sample is within the tolerances set out in Articles 11(5) and paragraph 2(e) of Annex IV to Regulation (EC) No 767/2009 of the European Parliament and of the Council.

Extent Information

E123 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F499 Words in Sch. 5 para. 22(1) substituted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(a), **2(4)(e)**

F500 Sch. 5 para. 22(2) Table substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **143** (with reg. 207)

Sampling and analysis **N.I.**

22.—(1) If any enforcement action is taken under this Schedule based on a sample, that sample must have been taken and analysed in accordance with [^{F729}Regulation (EC) No 152/2009 laying down methods of sampling and analysis for the official control of feedingstuffs.]

(2) Unless otherwise specified in the marketing authorisation, it is a defence if the active ingredient in the medicated feedingstuff sample is within the following tolerances—

Tolerance table for medicated feedingstuff

<i>Level of active ingredient specified on the label</i>	<i>Tolerance</i>
≤50 mg/kg	50%
>50 mg/kg ≤ 500 mg/kg	40%
>500 mg/kg ≤ 5g/kg	30%
>5g/kg ≤50g/kg	20%
>50g/kg	10%

(3) Unless otherwise specified in the Commission Regulation authorising the specified feed additive in question, it is a defence if the active ingredient of a specified feed additive in a feedingstuff

sample is within the tolerances set out in Articles 11(5) and paragraph 2(e) of Annex IV to Regulation (EC) No 767/2009 of the European Parliament and of the Council.

Extent Information

E295 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F729 Words in Sch. 5 para. 22(1) substituted (26.3.2019) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(a), **2(4)(e)**

[^{F501} Sampling for cross-contamination

22A.—(1) A feed business operator must ensure that cross-contamination of non-target feeds is as low as is reasonably achievable.

(2) A feed business operator must analyse samples of non-target feeds in order to determine whether cross-contamination into non-target feed has occurred.

(3) Where as a result of the process mentioned in sub-paragraph (2) it is determined that a cross-contamination rate has occurred which is 1% or more but less than 3% compared to the authorised maximum content, the feed business operator must make a record of this cross-contamination.

(4) Where as a result of the process mentioned in sub-paragraph (2) it is determined that a cross-contamination rate has occurred of 3% or more compared to the authorised maximum content, the feed business operator must conduct an investigation in order to discover the cause of the occurrence and make a record of the fact and any conclusions.

(5) The feed business operator must keep the records under sub-paragraphs (3) and (4) for at least five years.

(6) Upon request of the Secretary of State, the feed business operator must provide any information in the feed business operator's possession relating to the matters mentioned in this paragraph.]

Textual Amendments

F501 Sch. 5 para. 22A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **144** (with reg. 208)

Storage **E+W+S**

23. No person may store a [^{F502}medicinal premix] intended for incorporation into feedingstuffs, or [^{F503}an intermediate feedingstuff] or feedingstuffs containing a [^{F502}medicinal premix], except in—

- (a) a suitable storage area that is locked when not in use; or
- (b) a hermetic container designed to store those products.

Extent Information

E124 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

F502 Words in Sch. 5 para. 23 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **145(a)**

F503 Words in Sch. 5 para. 23 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **145(b)**

Storage **N.I.**

23. No person may store a veterinary medicinal product intended for incorporation into feedingstuffs, or a premixture or feedingstuffs containing a veterinary medicinal product, except in—

- (a) a suitable storage area that is locked when not in use; or
- (b) a hermetic container designed to store those products.

Extent Information

E296 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Packages and other containers **E+W+S**

24. No person may place on the market feedingstuffs containing a [^{F504}medicinal premix] except in packages or containers that are sealed in such a way that, when the package or container is opened, the seal is damaged.

Extent Information

E125 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F504 Words in Sch. 5 para. 24 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **146**

Packages and other containers **N.I.**

24. No person may place on the market feedingstuffs containing a veterinary medicinal product except in packages or containers that are sealed in such a way that, when the package or container is opened, the seal is damaged.

Extent Information

E297 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Transport **E+W+S**

25.—(1) No person may transport feedingstuffs by road tankers or in bulk unless the labelling requirements are set out in a document accompanying the feedingstuffs, and the transporter must

hand over details when delivering the feedingstuffs unless these have already been provided to the purchaser.

(2) Any person transporting feedingstuffs containing [^{F505} medicinal premixes] or specified feed additives in road tankers or similar containers must ensure that the vehicle or container is cleaned before any re-use if this is necessary to prevent undesirable interaction or contamination.

(3) In the case of feedingstuffs containing a [^{F506} medicinal premix or specified feed additive] the transporter must ensure that the vehicle is accompanied by documentation stating this.

(4) Any person operating an undertaking transporting feedingstuffs containing [^{F507} medicinal premixes] or specified feed additives must give written instructions to drivers on how to load and unload vehicles so as to avoid cross-contamination, and take reasonable steps to ensure that the driver complies with those instructions.

Extent Information

E126 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F505 Words in Sch. 5 para. 25(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **147(a)**

F506 Words in Sch. 5 para. 25(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **147(b)**

F507 Words in Sch. 5 para. 25(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **147(c)**

Transport **N.I.**

25.—(1) No person may transport feedingstuffs by road tankers or in bulk unless the labelling requirements are set out in a document accompanying the feedingstuffs, and the transporter must hand over details when delivering the feedingstuffs unless these have already been provided to the purchaser.

(2) Any person transporting feedingstuffs containing veterinary medicinal products or specified feed additives in road tankers or similar containers must ensure that the vehicle or container is cleaned before any re-use if this is necessary to prevent undesirable interaction or contamination.

(3) In the case of feedingstuffs containing a veterinary medicinal product the transporter must ensure that the vehicle is accompanied by documentation stating this.

(4) Any person operating an undertaking transporting feedingstuffs containing veterinary medicinal products or specified feed additives must give written instructions to drivers on how to load and unload vehicles so as to avoid cross-contamination, and take reasonable steps to ensure that the driver complies with those instructions.

Extent Information

E298 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Possession, placing on the market and use of feedingstuffs **E+W+S**

26.—(1) No person may possess, place on the market or feed to animals any feedingstuffs incorporating [^{F508}medicinal premixes] or specified feed additives unless they have been incorporated in accordance with this Schedule.

(2) No person may feed to any animal, or buy, possess or supply for the purpose of feeding to any animal, any feedingstuff containing a [^{F509}medicinal premix] or specified feed additive unless—

- (a) that [^{F509}medicinal premix] or specified feed additive is authorised for that species of animal and for the purpose for which it is used; or
- (b) in the case of a [^{F509}medicinal premix], it was prescribed for that animal.

[^{F510}(2A) An animal keeper must ensure that any product to which this Schedule applies is appropriately stored in accordance with its authorisation.

(2B) An animal keeper must ensure in respect of any such product that—

- (a) no cross-contamination occurs between products held by the keeper;
- (b) no product contaminates any feedingstuff or feed material;
- (c) no product escapes into the environment; and
- (d) a product is administered only to correctly identified animals mentioned on the medicated feedingstuffs prescription.

(2C) An animal keeper must comply with the withdrawal period in relation to any such product.]

(3) This paragraph does not apply in relation to feedingstuffs if the [^{F511}medicinal premix] has been incorporated in accordance with an animal test certificate or the feedingstuff has been imported in accordance with this Schedule.

Extent Information

E127 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F508 Words in Sch. 5 para. 26(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **148(a)**

F509 Words in Sch. 5 para. 26(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **148(b)**

F510 Sch. 5 para. 26(2A)-(2C) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **148(c)**

F511 Words in Sch. 5 para. 26(3) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **148(d)**

Possession, placing on the market and use of feedingstuffs **N.I.**

26.—(1) No person may possess, place on the market or feed to animals any feedingstuffs incorporating veterinary medicinal products or specified feed additives unless they have been incorporated in accordance with this Schedule.

(2) No person may feed to any animal, or buy, possess or supply for the purpose of feeding to any animal, any feedingstuff containing a veterinary medicinal product or specified feed additive unless—

(a) that veterinary medicinal product or specified feed additive is authorised for that species of animal and for the purpose for which it is used; or

(b) in the case of a veterinary medicinal product, it was prescribed for that animal.

(3) This paragraph does not apply in relation to feedingstuffs if the veterinary medicinal product has been incorporated in accordance with an animal test certificate or the feedingstuff has been imported in accordance with this Schedule.

Extent Information

E299 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F512}Unused and expired medicated feedingstuffs

26A. No person may feed medicated feedingstuffs which have passed their expiry date to an animal.]

Textual Amendments

F512 Sch. 5 para. 26A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **149**

Imports from third countries **E+W+S**

^{F513}27.

Extent Information

E128 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F513 Sch. 5 para. 27 omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(35)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Imports from third countries **N.I.**

27. No person may import a feedingstuff containing a veterinary medicinal product from a third country.

Extent Information

E300 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Trade between [F514 countries] E+W+S

28. No person may bring in from another [F515 country] a feedingstuff containing a veterinary medicinal product unless—

^{F516}(a)

(b) it only contains a veterinary medicinal product that has the same quantitative and qualitative composition as a [F517 medicinal premix] authorised in [F518 Great Britain].

Extent Information

E129 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F514 Word in Sch. 5 para. 28 heading substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(35)(c)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F515 Word in Sch. 5 para. 28 substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(35)(c)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F516 Sch. 5 para. 28(a) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(35)(c)(iii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F517 Words in Sch. 5 para. 28(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **150**

F518 Words in Sch. 5 para. 28(b) substituted (E.W.S.) (31.12.2020) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(b), **4(9)**

Trade [F730 with] member States N.I.

28. No person may bring in from [F731 a] member State a feedingstuff containing a veterinary medicinal product unless—

(a) the feedingstuff has been manufactured in accordance with the provisions of Council [Directive 90/167/EEC](#) (laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community(**42**)) and Regulation (EC) [No 183/2005](#) of the European Parliament and of the Council laying down requirements for food hygiene; and

(b) it only contains a veterinary medicinal product that has the same quantitative and qualitative composition as a veterinary medicinal product authorised in [F732 Northern Ireland].

Extent Information

E301 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

(42) OJ No L 92, 7.4.90, p. 42.

Textual Amendments

- F730** Word in Sch. 5 para. 28 heading substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(15)(c)(i)**
- F731** Word in Sch. 5 para. 28 substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(15)(c)(ii)**
- F732** Words in Sch. 5 para. 28(b) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(15)(c)(iii)**

Import for incorporation into [^{F519}intermediate feedingstuffs] or feedingstuffs for export **E
+W+S**

29.—^{F520}(1) A manufacturer of [^{F521}intermediate feedingstuffs] or feedingstuffs who imports a veterinary medicinal product authorised in another ^{F522}... country for the purposes of incorporating it into [^{F521}intermediate feedingstuffs] or feedingstuffs for export does not commit an offence under regulation 43(q) (importation of an unauthorised veterinary medicinal product) or regulation 43(r) (possession of an unauthorised veterinary medicinal product)]

(2) No person may place that [^{F523}intermediate feedingstuff] or feedingstuff on the market in the United Kingdom once the veterinary medicinal product has been incorporated into it.

Extent Information

- E130** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F519** Words in Sch. 5 para. 29 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **151(c)**
- F520** Sch. 5 para. 29(1) substituted (14.4.2014) by The Veterinary Medicines (Amendment) Regulations 2014 (S.I. 2014/599), regs. 1, **3(3)**
- F521** Words in Sch. 5 para. 29(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **151(a)**
- F522** Words in Sch. 5 para. 29(1) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(35)(d)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F523** Words in Sch. 5 para. 29(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **151(b)**

Import for incorporation into premixture or feedingstuffs for export **N.I.**

29.—^{F733}(1) A manufacturer of premixture or feedingstuffs who imports a veterinary medicinal product authorised in [^{F734}a] Member State or third country for the purposes of incorporating it into premixture or feedingstuffs for export does not commit an offence under regulation 43(q) (importation of an unauthorised veterinary medicinal product) or regulation 43(r) (possession of an unauthorised veterinary medicinal product)]

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

(2) No person may place that premixture or feedingstuff on the market in [^{F735}Northern Ireland] once the veterinary medicinal product has been incorporated into it.

Extent Information

E302 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F733 Sch. 5 para. 29(1) substituted (14.4.2014) by [The Veterinary Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/599\)](#), regs. 1, **3(3)**

F734 Word in Sch. 5 para. 29(1) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(15)(d)(i)**

F735 Words in Sch. 5 para. 29(2) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(15)(d)(ii)**

Animals on domestic premises **E+W+S**

30.—(1) The requirements of paragraph 7 (^{F524}authorisation] of manufacturers and distributors of feedingstuffs containing [^{F525}medicinal premix]) do not apply in relation to a person who incorporates a [^{F525}medicinal premix] into feedingstuffs in domestic premises for feeding, on those premises—

- (a) non-food-producing animals; or
- (b) food-producing animals provided that the animals or products from those animals are not sold or supplied commercially.

(2) Notwithstanding paragraphs 16 and 18 of this Schedule, a veterinary surgeon, a pharmacist or a suitably qualified person who is registered in accordance with paragraph 14 of Schedule 3 may be supplied with and may supply [^{F526}an intermediate feedingstuff] containing a [^{F527}medicinal premix], or feedingstuffs containing a [^{F527}medicinal premix], to such a producer.

(3) The requirement for a written prescription does not apply in relation to such supply, but the provisions of Schedule 3 relating to supply of a veterinary medicinal product apply in relation to the supply of [^{F528}intermediate feedingstuffs] and feedingstuffs in the same way as they apply to a veterinary medicinal product.

Extent Information

E131 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F524 Word in Sch. 5 para. 30(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **152(a)(i)**

F525 Words in Sch. 5 para. 30(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **152(a)(ii)**

F526 Words in Sch. 5 para. 30(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **152(b)(i)**

F527 Words in Sch. 5 para. 30(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **152(b)(ii)**

F528 Words in Sch. 5 para. 30(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **152(c)**

Animals on domestic premises **N.I.**

30.—(1) The requirements of paragraph 7 (approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal product) do not apply in relation to a person who incorporates a veterinary medicinal product into feedingstuffs in domestic premises for feeding, on those premises—

- (a) non-food-producing animals; or
- (b) food-producing animals provided that the animals or products from those animals are not sold or supplied commercially.

(2) Notwithstanding paragraphs 16 and 18 of this Schedule, a veterinary surgeon, a pharmacist or a suitably qualified person who is registered in accordance with paragraph 14 of Schedule 3 may be supplied with and may supply a premixture containing a veterinary medicinal product, or feedingstuffs containing a veterinary medicinal product, to such a producer.

(3) The requirement for a written prescription does not apply in relation to such supply, but the provisions of Schedule 3 relating to supply of a veterinary medicinal product apply in relation to the supply of premixture and feedingstuffs in the same way as they apply to a veterinary medicinal product.

Extent Information

E303 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Offences **E+W+S**

31. It is an offence to fail to comply with—

- (a) paragraph 2(2);
- (b) paragraph 3(3) or (4);
- (c) paragraph 5(2) or (3);
- (d) paragraph 6;
- (e) paragraph 7(2) or (5);
- (f) paragraph 8;
- (g) paragraph 9;
- (h) paragraph 10;
- (i) paragraph 11;
- (j) paragraph 12(4);
- (k) paragraph 13;
- (l) paragraph 14(4);
- (m) paragraph 15;
- (n) paragraph 16;
- (o) paragraph 17;
- (p) paragraph 18;

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

- [^{F529}(pa) paragraph 19;]
- (q) paragraph [^{F530}20];
- (r) paragraph 21;
- [^{F531}(ra) paragraph 22A;]
- (s) paragraph 23;
- (t) paragraph 24;
- (u) paragraph 25;
- (v) paragraph 26(1) [^{F532}, (2), (2A), (2B) or (2C)];
- [^{F533}(va) paragraph 26A;]
- ^{F534}(w)
- (x) paragraph 28; or
- (y) paragraph 29(2).

Extent Information

E132 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F529 Sch. 5 para. 31(pa) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **153(a)**

F530 Word in Sch. 5 para. 31(q) substituted (14.4.2014) by [The Veterinary Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/599\)](#), regs. 1, **3(4)**

F531 Sch. 5 para. 31(ra) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **153(b)**

F532 Words in Sch. 5 para. 31(v) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **153(c)**

F533 Sch. 5 para. 31(va) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **153(d)**

F534 Sch. 5 para. 31(w) omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Animals and Animal Products \(Examination of Residues and Maximum Residue Limits\) \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/676\)](#), regs. 1(2)(b), **3(35)(e)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Offences **N.I.**

- 31.** It is an offence to fail to comply with—
- (a) paragraph 2(2);
 - (b) paragraph 3(3) or (4);
 - (c) paragraph 5(2) or (3);
 - (d) paragraph 6;
 - (e) paragraph 7(2) or (5);
 - (f) paragraph 8;
 - (g) paragraph 9;
 - (h) paragraph 10;

- (i) paragraph 11;
- (j) paragraph 12(4);
- (k) paragraph 13;
- (l) paragraph 14(4);
- (m) paragraph 15;
- (n) paragraph 16;
- (o) paragraph 17;
- (p) paragraph 18;
- (q) paragraph [^{F736}20] ;
- (r) paragraph 21;
- (s) paragraph 23;
- (t) paragraph 24;
- (u) paragraph 25;
- (v) paragraph 26(1) or (2);
- (w) paragraph 27;
- (x) paragraph 28; or
- (y) paragraph 29(2).

Extent Information

E304 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F736 Word in Sch. 5 para. 31(q) substituted (14.4.2014) by [The Veterinary Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/599\)](#), regs. 1, **3(4)**

SCHEDULE 6

Regulation 15(4)

Exemptions for small pet animals

Animals to which this Schedule applies

1. This Schedule applies in relation to veterinary medicinal products intended solely for the following animals kept exclusively as a pet—

- (a) aquarium animals;
- (b) cage birds;
- (c) ferrets;
- (d) homing pigeons;
- (e) rabbits;
- (f) small rodents; and
- (g) terrarium animals.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Placing on the market, importing and administering the product

2. A veterinary medicinal product intended solely for an animal to which this Schedule applies may be placed on the market, imported or administered without a marketing authorisation if it complies with this Schedule [^{F535}and the manufacturer appears on the register maintained under paragraph 3A].

Textual Amendments

F535 Words in Sch. 6 para. 2 inserted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024* (S.I. 2024/567), regs. 1(1), **155**

Manufacture **E+W+S**

- 3.—^{F536}(1) The product must have been manufactured by—
- (a) the holder of a manufacturing authorisation if manufactured in [^{F537}Great Britain];
 - ^{F538}(b)
 - ^{F539}(c)
 - (d) in the case of any other country, a manufacturer whose premises have been inspected and approved by an officer of the Secretary of State.

^{F540}(2) Sub-paragraph (1)(d) does not apply where the United Kingdom has a formal agreement with the exporting country that includes mutual recognition of good manufacturing practice or where the Secretary of State is satisfied that the exporting country requires manufacturers of veterinary medicinal products to apply standards of good manufacturing practice which are at least equivalent to those in Great Britain.]

Extent Information

E133 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F536** Sch. 6 para. 3 renumbered as Sch. 6 para. 3(1) (E.W.S.) (31.12.2020) by *The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/676), regs. 1(2)(b), **3(36)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F537** Words in Sch. 6 para. 3(1)(a) substituted (E.W.S.) (31.12.2020) by *The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/676), regs. 1(2)(b), **3(36)(b)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)(3)(e)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F538** Sch. 6 para. 3(1)(b) omitted (E.W.S.) (31.12.2020) by *The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/676), regs. 1(2)(b), **3(36)(b)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)(3)(e)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F539** Sch. 6 para. 3(1)(c) omitted (E.W.S.) (31.12.2020) by *The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019* (S.I. 2019/676), regs. 1(2)(b), **3(36)(b)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)(3)(e)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F540 Sch. 6 para. 3(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **156**

Manufacture **N.I.**

3. The product must have been manufactured by—
- (a) the holder of a manufacturing authorisation if manufactured in the United Kingdom;
 - (b) the holder of a manufacturing authorisation issued under [Directive 2001/82/EC](#) if manufactured in [^{F737}a] member State;
 - (c) in the case of Australia, Canada, New Zealand, or Switzerland, the holder of an authorisation from the competent authority permitting the manufacture of medicinal products;
 - (d) in the case of any other country, a manufacturer whose premises have been inspected and approved by an officer of the Secretary of State.

Extent Information

E305 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F737 Word in [Sch. 6 para. 3\(b\)](#) substituted (N.I.) (31.12.2020) by [The Animals \(Health, Identification, Trade and Veterinary Medicines\) \(Amendment\) \(EU Exit\) Regulations \(Northern Ireland\) 2020 \(S.R. 2020/353\)](#), regs. 1(3), **10(16)**

[^{F541}Register of persons placing veterinary medicinal products on the market (small pet animals)]

3A.—(1) A person placing the product on the market must be registered in accordance with this paragraph.

(2) An application for registration in respect of that person must be submitted under sub-paragraph (4)—

- (a) at least two months before that person places the product on the market, or
- (b) where that person has already placed the product on the market, within six months of the date on which this provision comes into force.

(3) Information may be submitted to the Secretary of State pursuant to sub-paragraph (2) prior to the date on which this provision comes into force, and in such a case—

- (a) as regards an applicant for registration who has not already placed the product on the market, the period of two months is to be treated as having started on the date of submission;
- (b) as regards an applicant for registration who has already placed the product on the market, the information is to be treated as having been submitted within the period of six months.

(4) An application for registration must be made to the Secretary of State electronically and must include—

- (a) the name and address of the person placing the product on the market;
- (b) the individual making the application in respect of that person;
- (c) the telephone number and email address of the individual mentioned in sub-paragraph (b);

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (d) the name and address of the manufacturer of the product;
- (e) the brand name of the product;
- (f) the names and quantities of the active substances;
- (g) the method and (where applicable) route of administration;
- (h) the dosage instructions;
- (i) the category of animal mentioned in paragraph 1 for which the product is intended.

(5) For the purposes of sub-paragraph (1) the Secretary of State must establish and maintain a register of persons placing on the market products to which this Schedule applies.

(6) The particulars entered on the register must include the name and the address of the person mentioned in sub-paragraph (1).]

Textual Amendments

F541 Sch. 6 paras. 3A, 3B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **157**

[^{F541}Persons registered in accordance with paragraph 3A: annual return

3B. At least once each calendar year a person registered under paragraph 3A must notify the Secretary of State in writing of the following in respect of each product placed on the market—

- (a) the name and registered address of the person (if different from that listed on the register);
- (b) the individual designated for the purpose of making the annual return under this paragraph;
- (c) the telephone number and email address of the individual mentioned in sub-paragraph (b);
- (d) the name and address of the manufacturer of the product;
- (e) the brand name of the product;
- (f) the names and quantities of the active substances;
- (g) the method and (where applicable) route of administration;
- (h) the dosage instructions;
- (i) the category of animal mentioned in paragraph 1 for which the product is intended.]

Textual Amendments

F541 Sch. 6 paras. 3A, 3B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **157**

Approval of the active substance **E+W+S**

4.—(1) The Secretary of State may approve an active substance for use in a veterinary medicinal product manufactured under this Schedule.

(2) The Secretary of State may not grant an approval if the active substance requires veterinary control.

(3) The approval must specify the species of animals for which it is approved, and may specify how the active substance or a product containing it is to be administered.

(4) The Secretary of State may suspend or revoke the approval (or limit it to a smaller number of species) if—

- (a) it is demonstrated that the substance requires veterinary control;
- (b) [^{F542}adverse events] are reported making suspension or revocation necessary; or
- (c) it is demonstrated that the substance—
 - (i) is carcinogenic;
 - (ii) is genotoxic; or
 - (iii) shows developmental toxicity (including teratogenicity).

(5) The procedure for the refusal, suspension or revocation of an approval under this paragraph is the same as the procedure for a marketing authorisation.

Extent Information

E134 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F542 Words in Sch. 6 para. 4(4)(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **158**

Approval of the active substance **N.I.**

4.—(1) The Secretary of State may approve an active substance for use in a veterinary medicinal product manufactured under this Schedule.

(2) The Secretary of State may not grant an approval if the active substance requires veterinary control.

(3) The approval must specify the species of animals for which it is approved, and may specify how the active substance or a product containing it is to be administered.

(4) The Secretary of State may suspend or revoke the approval (or limit it to a smaller number of species) if—

- (a) it is demonstrated that the substance requires veterinary control;
- (b) serious adverse reactions are reported making suspension or revocation necessary; or
- (c) it is demonstrated that the substance—
 - (i) is carcinogenic;
 - (ii) is genotoxic; or
 - (iii) shows developmental toxicity (including teratogenicity).

(5) The procedure for the refusal, suspension or revocation of an approval under this paragraph is the same as the procedure for a marketing authorisation.

Extent Information

E306 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

The product

5.—(1) The active substance in the veterinary medicinal product must be approved under paragraph 4.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (2) The veterinary medicinal product must not be an antibiotic.
- (3) It must not contain any narcotic or psychotropic substance.
- (4) It must not be intended for treatments or pathological processes that require a precise prior diagnosis or the use of which may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures.

Labelling

6.—(1) The product must be clearly labelled as being exempt from the requirements of these Regulations in relation to a marketing authorisation.

- (2) The labelling must show the following—
 - (a) the name of the veterinary product, including, if it is part of the name, its strength and pharmaceutical form;
 - (b) the authorisation number of the manufacturer;
 - (c) the name and strength of each active substance;
 - (d) the route of administration;
 - (e) the batch number;
 - (f) the expiry date;
 - (g) the words “For animal treatment only”;
 - (h) the contents by weight, volume or number of dose units;
 - (i) the name and address of the manufacturer or distributor;
 - (j) the target species;
 - (k) the words “Keep out of reach of children”;
 - (l) storage instructions;
 - (m) the shelf-life after the immediate packaging has been opened for the first time;
 - (n) disposal advice;
 - (o) full indications, including—
 - (i) therapeutic indications;
 - (ii) contra-indications;
 - (iii) interaction with other medicines and other forms of interaction; and
 - (p) dosage instructions.
- (3) If there is insufficient room on the label, the information may instead be in a package leaflet, but the leaflet must contain all the information in the preceding sub-paragraph other than the batch number and the expiry date, but the label on the product must contain at least the following—
 - (a) the name of the veterinary medicinal product;
 - (b) its active substance and its strength;
 - (c) the route of administration;
 - (d) the batch number;
 - (e) the expiry date; and
 - (f) the words “For animal treatment only”.

Administration

7. The method of administration must be oral or topical or (in the case of a product for fish) by addition to the water.

Pack size

8. The pack size must only be sufficient for a single course of treatment or, in the case of a veterinary medicinal product for aquarium fish, sufficient for a single course of treatment of no more than 7 administrations to an aquarium of 25,000 litres.

[^{F543} Adverse events] **E+W+S**

- 9.—(1) The [^{F544} manufacturer or importer] of a veterinary medicinal product must—
- (a) notify the Secretary of State within 15 days of learning of any serious [^{F545} adverse events]; and
 - (b) make a record of each [^{F546} adverse event] and serious [^{F546} adverse event] on becoming aware of it and keep it for three years.

^{F547}(2)

Extent Information

E135 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F543 Words in Sch. 6 para. 9 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **159(e)**

F544 Words in Sch. 6 para. 9 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **159(a)**

F545 Words in Sch. 6 para. 9(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **159(b)**

F546 Words in Sch. 6 para. 9(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **159(c)**

F547 Sch. 6 para. 9(2) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **159(d)**

Adverse reactions **N.I.**

- 9.—(1) The manufacturer, importer or retailer of a veterinary medicinal product must—
- (a) notify the Secretary of State within 15 days of learning of any serious adverse reactions (as defined in paragraph 57 of Schedule 1); and
 - (b) make a record of each adverse reaction and serious adverse reaction on becoming aware of it and keep it for three years.
- (2) It is an offence to fail to comply with this paragraph.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Extent Information

E307 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F548} Offences

10. It is an offence to fail to comply with—

- (a) paragraph 3A(1);
- (b) paragraph 3B; or
- (c) paragraph 9(1).]

Textual Amendments

F548 Sch. 6 para. 10 inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **160**

SCHEDULE 7

Regulation 16

Fees

PART 1

Introduction

Interpretation **E+W+S**

1.—[^{F549}(1)] In this Schedule—

^{F550} ...

“pharmaceutical product” means any veterinary medicinal product other than an immunological product [^{F551}or a biological veterinary medicinal product that is not immunological];

“simultaneous application” is an application in which, at the time an authorisation for a product is applied for, one or more additional applications are submitted for products that are identical to the first product except that—

- (a) in the case of an immunological product, they have a lesser number of antigens than the first product, but only contain antigens contained in the first product; and
- (b) in the case of a pharmaceutical product, they have different strengths of the active substance,

^{F552} ...

[^{F553}(2)] For the purposes of this Schedule “manufacturing authorisation” means the following activities—

- (a) manufacture or import of an authorised veterinary medicinal product;

- (b) manufacture of a product to which paragraph 2 of Schedule 6 relates;
- (c) manufacture of a product for administration under the cascade;
- (d) manufacture of—
 - (i) an autogenous vaccine;
 - (ii) a stem cell product; or
 - (iii) a blood product for administration to non-food animals.]

Extent Information

E136 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F549 Sch. 7 para. 1 renumbered as Sch. 7 para. 1(1) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **162(a)**

F550 Words in Sch. 7 para. 1 omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(4)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F551 Words in Sch. 7 para. 1(1) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **162(b)**

F552 Words in Sch. 7 para. 1 omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(4)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F553 Sch. 7 para. 1(2) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **162(c)**

Interpretation **N.I.**

1. In this Schedule—

“national application” means an application for a marketing authorisation that does not involve another member State;

“pharmaceutical product” means any veterinary medicinal product other than an immunological product;

“simultaneous application” is an application in which, at the time an authorisation for a product is applied for, one or more additional applications are submitted for products that are identical to the first product except that—

- (a) in the case of an immunological product, they have a lesser number of antigens than the first product, but only contain antigens contained in the first product; and
- (b) in the case of a pharmaceutical product, they have different strengths of the active substance,

and, in the case of an application involving more than one member State, the additional applications do not include a member State that was not included in the first application.

Extent Information

E308 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

Payment of fees

2. All fees under this Schedule are payable to the Secretary of State.

Time of payment

3. All fees are payable on invoice unless otherwise specified.

Multiple inspections

4. If a site, premises or establishment is inspected for more than one type of authorisation [^{F554}, approval] or registration at the same time, [^{F555} and in relation to the same legal entity,] the fee is the sum of—

- (a) the highest fee payable; and
- (b) 50% of each of the other fees.

Textual Amendments
F554 Word in Sch. 7 para. 4 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **163(a)**
F555 Words in Sch. 7 para. 4 inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **163(b)**

Expenses for inspections outside the United Kingdom

5. Whenever premises outside the United Kingdom are inspected, the travel and subsistence costs of the inspectors and interpreters’ fees are payable in addition to the inspection fee specified.

Translation

6. All translation costs are charged additionally.

PART 2

Fees relating to marketing authorisations

[^{F556} **Application for a marketing authorisation for a pharmaceutical [^{F557}, immunological or biological that is not immunological] veterinary medicinal product**] **E+W+S**

7. The following table sets out the fees relating to a pharmaceutical [^{F558}, immunological or biological that is not immunological] veterinary medicinal product for—

- (a) [^{F559}an application] for a marketing authorisation that is—
 - (i) a full application under Part 1 of Schedule 1; [^{F560}or]
 - (ii) a bibliographic application [^{F561}for a pharmaceutical veterinary medicinal product];

	F562 ...
	F563(iii)
F564(b)
F565(c)

<i>F⁵⁶⁶ Application</i>	<i>Fee (£) per authorisation</i>
Base fee	27,995
Fee for 1st additional strength	4,590
Fee for each subsequent additional strength	1,465]

Extent Information

E137 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F556 Sch. 7 para. 7 heading substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F557 Words in Sch. 7 para. 7 heading inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **164(d)**

F558 Words in Sch. 7 para. 7 inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **164(a)**

F559 Words in Sch. 7 para. 7(a) substituted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F560 Word in Sch. 7 para. 7(a)(i) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **164(b)(i)**

F561 Words in Sch. 7 para. 7(a)(ii) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **164(b)(ii)(aa)**

F562 Word in Sch. 7 para. 7(a)(ii) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **164(b)(ii)(bb)**

F563 Sch. 7 para. 7(a)(iii) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **164(b)(iii)**

F564 Sch. 7 para. 7(b) omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F565 Sch. 7 para. 7(c) omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F566 Sch. 7 para. 7(c) Table substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **164(c)**

Specified pharmaceutical applications **N.I.**

7. The following table sets out the fees relating to a pharmaceutical veterinary medicinal product for—

- (a) a national application for a marketing authorisation that is—
 - (i) a full application under Part 1 of Schedule 1;
 - (ii) a bibliographic application; or
 - (iii) an application based on pharmacological equivalence;
- (b) an application for a marketing authorisation using the decentralised procedure where the United Kingdom is a concerned member State;

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

(c) an application for the mutual recognition of a product authorised in another member State.

<i>Application</i>	<i>Full national application under Part 1 of Schedule 1 (£)</i>	<i>Bibliographic national application (£)</i>	<i>Pharmacologically equivalent national application</i>		<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
			<i>Reference product authorised in UK (£)</i>	<i>Reference product not authorised in UK (£)</i>	
Base Fee:	13,530	12,115	7,195	9,220	6,515
Additional fee if any of the target species is a food-producing animal:	3,905	3,585	2,155	2,760	1,415
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom—					
food-producing animal:	7,465	6,595	5,885	7,495	2,630
non-food-producing animal:	6,525	5,855	5,590	7,155	2,295
Additional fee for each additional pack type:	740	740	605	775	330
Additional fee for each additional active ingredient (food-producing animal):	6,465	6,125	4,040	5,165	2,085
Additional fee for each additional active ingredient (non-food-producing animal):	4,310	4,105	3,235	4,135	1,475
Additional fee if there is more than one target species, for each additional species	3,970	3,565	2,425	3,100	1,280
					Applies for a maximum of 2 additional species

Status: Point in time view as at 17/05/2024.**Changes to legislation:** There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

<i>Application</i>	<i>Full national application under Part 1 of Schedule 1 (£)</i>	<i>Bibliographic national application (£)</i>	<i>Pharmacologically equivalent national application</i>		<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
			<i>Reference product authorised in UK (£)</i>	<i>Reference product not authorised in UK (£)</i>	
(food-producing animal):					
Additional fee if there is more than one target species, for each additional species (non-food-producing animal):	2,495	2,090	1,550	1,980	805 Applies for a maximum of 2 additional species
Additional fee for each additional recommended route of administration (food-producing animal):	2,695	2,490	1,620	2,070	940
Additional fee for each additional recommended route of administration (non-food-producing animal):	1,215	1,010	740	945	405
Simultaneous applications: fee for each additional product in the application:	2,895	2,895	2,895	3,705	1,685

Extent Information

E309 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F567} Application for a marketing authorisation for specific applications

7A. The fee for an application for a marketing authorisation which involves one or more of the following is £45,000—

- (a) any biotechnical process involving recombinant DNA or the controlled expression of genes;

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

- (b) a veterinary medicinal product containing a new active substance;
- (c) a biopharmaceutical product.]

Textual Amendments
F567 Sch. 7 para. 7A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **165**

Decentralised pharmaceutical application where the United Kingdom is the reference member State E+W+S

^{F568}8.

Extent Information
E138 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments
F568 Sch. 7 para. 8 omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(4)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Decentralised pharmaceutical application where the United Kingdom is the reference member State N.I.

8. The fee for a decentralised application for a pharmaceutical product where the United Kingdom is the reference member State is the same as for a national application as set out in the table in paragraph 7, with the addition of the fees in the following table.

Fees for decentralised pharmaceutical application where the United Kingdom is the reference member State

<i>Application</i>	<i>Additional fee for a pharmacologically equivalent product (£)</i>	<i>Additional fee otherwise (£)</i>
Food-producing animal: one member State:	5,230	3,705
Non-food-producing animal: one member State:	3,985	3,220
Each additional member State:	530	530
Simultaneous application: fee for each additional product in the application:		
one member State:	6,670	6,670
each additional member State:	120	120

Extent Information

E310 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for a marketing authorisation for an immunological or biosimilar product **E**
+W+S

F569 9.

Extent Information

E139 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F569 Sch. 7 para. 9 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **166**

Application for a marketing authorisation for an immunological or biosimilar product **N.I.**

9.—(1) The fee for a national application for a marketing authorisation relating to an immunological or biosimilar product, a decentralised application where the United Kingdom is the concerned member State or the mutual recognition of a product authorised in another member State is in accordance with the following table.

(2) In this paragraph a biosimilar application means an application made in accordance with Article 13(4) of [Directive 2001/82/EC](#) and a biosimilar product means a product which is the subject of such an application.

Fees for specified immunological and biosimilar applications

<i>Application</i>	<i>National application for a marketing authorisation(£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
1. Immunological or biosimilar product other than in paragraph 2 below: Base fee:	11,775	5,785
The following fees are in addition to the base fee—		
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom, and for each new combination of active ingredients:	7,405	2,490
Additional fee for each adjuvant or preservative not previously included in a veterinary medicinal product authorised in the United Kingdom and for each new combination of adjuvants or preservatives:	1,345	675

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

<i>Application</i>	<i>National application for a marketing authorisation (£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
More than one antigenic component – fee for each additional component:	1,350	405
More than one species – fee for each additional species:	5,380	1,615
		Applies for a maximum of 2 additional species
More than one route of administration – fee for each additional route of administration:	5,380	1,615
Simultaneous application - fee for each additional product in the application:	2,895	1,685
2. Immunological or product that is identical to a product already authorised in the United Kingdom but with a lesser number of antigens and that only contains antigens contained in that product:	10,430	5,380

Extent Information
E311 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Decentralised immunological application where the United Kingdom is the reference member State E+W+S

^{F570} 10.

Extent Information
E140 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments
F570 Sch. 7 para. 10 omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), [17\(4\)\(e\)](#); 2020 c. 1, Sch. 5 para. 1(1)

Decentralised immunological application where the United Kingdom is the reference member State N.I.

10. The fee for a decentralised application for a marketing authorisation for an immunological product where the United Kingdom is the reference member State is the same as for a national application set out in the previous table, with the addition of the fees in the following table—

Fees for decentralised immunological application where the United Kingdom is the reference member State

<i>Application</i>	<i>Additional fee (£)</i>
One member State:	3,470
Each additional member State:	530
Simultaneous applications: fee for each additional product in the application:	
one member State:	6,670
each additional member State:	120

Extent Information

E312 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F571} Application for a marketing authorisation based on informed consent **E+W+S**

11. The fee for applications for marketing authorisations using identical data submitted simultaneously or on the basis of information provided under paragraph 9 of Schedule 1 is as follows—

<i>Application</i>	<i>Fee (£) per authorisation</i>
Application	1,465]

Extent Information

E141 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F571 [Sch. 7 para. 11](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **167**

Applications for a marketing authorisation using data already assessed **N.I.**

11. The fees for applications for marketing authorisations using identical data submitted simultaneously or on the basis of information provided under Article 13(c) of [Directive 2001/82/EC](#) are in accordance with the following table.

Fees for a marketing authorisation using data already assessed

<i>Application</i>	<i>Fee (£) per authorisation</i>
Decentralised application where the United Kingdom is the reference member State—	
one member State:	4,165

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the
The Veterinary Medicines Regulations 2013. (See end of Document for details)

<i>Application</i>	<i>Fee (£) per authorisation</i>
each additional member State:	530
Any other application:	945

Extent Information

E313 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for an exceptional marketing authorisation (pharmaceutical)

12. The fee for an application for an exceptional marketing authorisation for a pharmaceutical product is in accordance with the following table.

Fees for an exceptional marketing authorisation for a pharmaceutical product

<i>Application</i>	<i>Provisional (£)</i>	<i>Limited (£)</i>
Base Fee:	12,015	6,765
The following fees are in addition to the base fee—		
Additional fee if any of the target species is a food-producing animal:	3,905	1,952
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom—		
food-producing animal:	5,850	3,732
non-food-producing animal:	4,910	3,262
Additional fee for each additional pack type:	710	370
Additional fee for each additional active ingredient (food-producing animal):	5,955	3,232
Additional fee for each additional active ingredient (non-food-producing animal):	3,800	2,155
Additional fee if there is more than one target species, for each additional species (food-producing animal):	2,965	1,985
Additional fee if there is more than one target species, for each additional species (non-food-producing animal):	1,485	1,247
Additional fee for each additional recommended route of administration (food-producing animal):	2,185	1,347
Additional fee for each additional recommended route of administration (non-food-producing animal):	710	608
Simultaneous applications— fee for each additional product in the application:	2,895	1,447

Fees for an application for an exceptional marketing authorisation [^{F572}(immunological or biological non-immunological)] **E+W+S**

13. The fee for an application for an exceptional marketing authorisation for an immunological product [^{F573}or a biological veterinary medicinal product that is not immunological] is in accordance with the following table.

Fees for an exceptional marketing authorisation for an immunological product [^{F573}or a biological veterinary medicinal product that is not immunological]

<i>Application</i>	<i>Provisional (£)</i>	<i>Limited (£)</i>
Base fee:	10,810	5,887
The following fees are in addition to the base fee—		
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom, and for each new combination of active ingredients:	5,650	3,702
Additional fee for each adjuvant or preservative not previously included in a veterinary medicinal product authorised in the United Kingdom and for each new combination of adjuvants or preservatives:	1,350	672
More than one antigenic component – fee for each additional component:	1,190	675
More than one species – fee for each additional species:	4,060	2,690
More than one route of administration – fee for each additional route of administration:	4,060	2,690
Simultaneous application - fee for each additional product in the application:	2,895	1,447

Extent Information

E142 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F572 Words in [Sch. 7 para. 13 heading](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **168(b)**

F573 Words in [Sch. 7 para. 13](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **168(a)**

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

Fees for an application for an exceptional marketing authorisation (immunological) N.I.

13. The fee for an application for an exceptional marketing authorisation for an immunological product is in accordance with the following table.

Fees for an exceptional marketing authorisation for an immunological product

<i>Application</i>	<i>Provisional (£)</i>	<i>Limited (£)</i>
Base fee:	10,810	5,887
The following fees are in addition to the base fee—		
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom, and for each new combination of active ingredients:	5,650	3,702
Additional fee for each adjuvant or preservative not previously included in a veterinary medicinal product authorised in the United Kingdom and for each new combination of adjuvants or preservatives:	1,350	672
More than one antigenic component – fee for each additional component:	1,190	675
More than one species – fee for each additional species:	4,060	2,690
More than one route of administration – fee for each additional route of administration:	4,060	2,690
Simultaneous application - fee for each additional product in the application:	2,895	1,447

Extent Information

E314 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Fee for the conversion from an exceptional to a full marketing authorisation

14. The fee for the conversion of an exceptional marketing authorisation to a full marketing authorisation is £3,000.

Application for a marketing authorisation relating to a parallel import E+W+S

^{F574}15.

Extent Information

E143 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F574 Sch. 7 para. 15 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **169**

Application for a marketing authorisation relating to a parallel import **N.I.**

15. The fee for a marketing authorisation for a parallel import is in accordance with the following table.

Parallel imports

<i>Application</i>	<i>Fee (£)</i>
Application where the imported product has been authorised in accordance with the mutual recognition procedure or decentralised procedure, and the United Kingdom is included in these procedures—	
import from one or more member States:	1,755
Application to add an additional member State after the marketing authorisation has been granted – fee for each member State:	455
Application where the imported product has not been authorised in accordance with the mutual recognition procedure or the decentralised procedure but where the imported product originates from the same manufacturing site as the product authorised in the United Kingdom to which the imported product is considered to be essentially similar:	2,130
Any other application – fee for each member State from which the product is imported:	4,710

Extent Information

E315 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

^{F575} Fee for a generic marketing authorisation

15A.—(1) The fee for a marketing authorisation in respect of a generic veterinary medicinal product is to be calculated in accordance with the following table.

<i>Application</i>	<i>Fee (£) per authorisation</i>	
	<i>Hybrid</i>	<i>Standard</i>
Base Fee	13,950	12,390

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

Application	Fee (£) per authorisation	
	Hybrid	Standard
Fee for 1st additional strength	4,590	
Fee for each subsequent additional strength	1,465.	

(2) In this paragraph “hybrid” means an application to which paragraph 10A of Schedule 1 applies.]

Textual Amendments
F575 Sch. 7 para. 15A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **170**

Application to change the distribution category of a product authorised through the centralised procedure E+W+S

^{F576}**16.**

Extent Information
E144 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments
F576 Sch. 7 para. 16 omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(4)(h)**; 2020 c. 1, Sch. 5 para. 1(1)

Application to change the distribution category of a product authorised through the centralised procedure N.I.

16. The fee to change the distribution category of a product authorised through the centralised procedure is £3,135.

Extent Information
E316 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for a variation to a marketing authorisation ^{F577}.... E+W+S

17.—(1) This paragraph applies in relation to an application for a variation to one or more marketing authorisations except where paragraph ^{F578}... 21 applies.

(2) The fees for the variations to which this paragraph applies are set out in the following table.

(3) Where applications are made at the same time seeking an identical change to the terms of more than one marketing authorisation, and those applications are based on identical data, fees are payable as for a grouped variation.

(4) References in this paragraph to a grouped variation being “led” by a particular type of variation indicate that the principal variation in that group is a variation of that type.

<i>F⁵⁷⁹</i> Type of variations	Fee (£)
Single variations; one change for each product	
Variation – standard	2,895
Unless the variation is—	
(a) a change of route of administration, or the addition of a new one, of—	
(i) an immunological product, or a pharmaceutical product for a non-food-producing animal	5,390
(ii) a pharmaceutical product for a food-producing animal	7,135
(b) a change of bioavailability	8,415
(c) a change of active substance, where the change is to—	
(i) use a different biologically active substance with a slightly different molecular structure	8,415
(ii) modify the vector used to produce the antigen or the source material, including a new master cell bank from a different source	8,415
(d) a change of pharmacokinetics	8,415
Simultaneous application falling within (a) to (d): fee for each additional product in the application	1,465
Variation – reduced	885
Variation - no assessment	455
Grouped variations	
Variation – standard led	
For the first nine changes	6,280
For each subsequent group of five or fewer changes	2,250
Variation – reduced led:	
For the first nine changes	1,770
For each subsequent group of five or fewer changes	2,250

Extent Information

E145 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F577 Words in [Sch. 7 para. 17](#) heading omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), [17\(4\)\(i\)](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

F578 Words in [Sch. 7 para. 17\(1\)](#) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), [171\(a\)](#)

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

F579 Sch. 7 para. 17 Table substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **171(b)**

Application for a variation to a marketing authorisation dealt with under national or mutual recognition variation procedures. N.I.

17.—(1) This paragraph applies in relation to an application for a variation to one or more marketing authorisations except where paragraph 18, 19 or 21 applies.

(2) The fees for the variations to which this paragraph applies are set out in the following table.

(3) Where applications are made at the same time seeking an identical change to the terms of more than one marketing authorisation, and those applications are based on identical data, fees are payable as for a grouped variation.

(4) References in this paragraph to a grouped variation being “led” by a particular type of variation indicate that the principal variation in that group is a variation of that type.

<i>Type of variation</i>	<i>National</i>	<i>UK is the reference member State</i>	<i>UK is a concerned member State</i>
Single variations; one change for each product			
Extension:			
Change of strength or potency or the addition of a new strength or potency:	6,670		1,998
Change of pharmaceutical form or the addition of a new pharmaceutical form:	8,415		2,301
Change of route of administration, or the addition of a new one, of—			
(i) an immunological product, or a pharmaceutical product for a ^{F738} non-food-producing animal:	5,390		1,737
(ii) a pharmaceutical product for a food-producing animal:	7,135		2,058
Change or addition of a food producing target species:	9,620		2,547
Change of active substance, including:	8,415		2,301
use of a different salt, ester, complex or derivative of the same therapeutic moiety:			
use of a different biologically active substance with a slightly different molecular structure:			
modification of the vector used to produce the antigen or the source material, including a new			

<i>Type of variation</i>	<i>National</i>	<i>UK is the reference member State</i>	<i>UK is a concerned member State</i>
master cell bank from a different source:			
use of a new ligand or coupling mechanism for a radiopharmaceutical:			
change of the extraction solvent or change of the ratio of herbal drug to herbal drug preparation:			
Change of bioavailability:	8,415		2,301
Change of pharmacokinetics:	8,415		2,301
Simultaneous application: fee for each additional product in the application:	2,895		1,011
Type II:	2,895	6,030	1,872
Type IB:	885	1,325	531
Type IA:	455	685	273

Grouped variations**Extension-led:**

The fee for an application for an extension-led grouped variation is the fee for that extension as specified above plus —

- (a) if there is one variation in addition to the extension, the fee for that variation as specified above; or
- (b) if there is more than one variation in addition to the extension, the fee that would be payable for a grouped variation of that type as specified below.

Type II led:

For the first nine changes:	6,280	12,060	3,768
For each subsequent group of up to ten changes:	4,500	4,500	2,700

Type IB led:

For the first nine changes:	1,770	2,650	1,062
For each subsequent group of up to ten changes:	4,500	4,500	2,700

Type IA led:

For the first nine changes:	885	1,325	531
For each subsequent group of up to ten changes:	4,500	4,500	2,700

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Extent Information

E317 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F738 Words in Sch. 7 para. 17 substituted (14.4.2014) by [The Veterinary Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/599\)](#), regs. 1, **4(2)**

Application for a variation to a marketing authorisation dealt with under worksharing procedures **E+W+S**

^{F580}**18.**

Textual Amendments

F580 Sch. 7 para. 18 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **172**

Application for a variation to a marketing authorisation dealt with under worksharing procedures **N.I.**

18.—(1) This paragraph applies in relation to an application for a variation to a marketing authorisation dealt with in accordance with worksharing procedures as set out in Article 20 of Commission Regulation (EC) No 1234/.

(2) The fee for a worksharing application, involving marketing authorisations obtained by a national procedure in the United Kingdom only, is the fee specified in the following table in the column headed “UK Only”.

(3) The fee for a worksharing application, involving marketing authorisations obtained through a national procedure in the United Kingdom and any other member State, is specified in the following table by reference to the United Kingdom’s role in the procedure, as “UK Reference Authority”, “UK Co-Reference Authority” or “Other”.

(4) The fee for a worksharing application, involving at least one marketing authorisation obtained through the mutual recognition or decentralised procedure, is specified in the following table by reference to the United Kingdom’s role in the procedure, as “UK Reference Authority”, “UK Co-Reference Authority” or “UK Concerned member State”.

(5) The fee for any kind of variation where the Agency co-ordinates worksharing is £455 for each marketing authorisation.

<i>Type of application</i>	<i>UK Only</i>	<i>Where the application involves nationally authorised products in more than one member State</i>			<i>Application involves mutually recognised products</i>		
	UK Only	UK Reference Authority	UK Co-Reference Authority	Other	UK Reference Authority	UK Co-Reference Authority	UK Concerned member State
Worksharing applications							
The following fees apply for each change to each product:							
Type II							
For the first nine changes:	6,240	12,060	7,485	12,060	13,265	6,745	3,372
For each subsequent group of up to ten changes:	4,500	4,500	4,500	4,500	4,500	4,500	2,700
Type IB							
For the first nine changes:	1,770	2,650	2,120	2,650	2,915	1,905	954
For each subsequent group of up to ten changes:	4,500	4,500	4,500	4,500	4,500	4,500	2,700

Extent Information

E318 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for an extension dealt with under the decentralised procedure where the United Kingdom is the reference member State **E+W+S**

^{F581} **19.**

Extent Information

E146 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F581 Sch. 7 para. 19 omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(4)(k)**; 2020 c. 1, Sch. 5 para. 1(1)

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

Application for an extension dealt with under the decentralised procedure where the United Kingdom is the reference member State N.I.

19. The fee for a decentralised application for an extension where the United Kingdom is the reference member State is the same as for a national application as set out in the table in paragraph 17, with the addition of the supplementary fees in the following table (save that, where the application is for the addition of more than one species, only one supplementary fee applies).

Decentralised application for an extension where the United Kingdom is the reference member State

<i>Application</i>	<i>Supplementary fee (£)</i>
Pharmaceutical product for a food-producing animal – one member State:	3,705
Pharmaceutical product for a non-food-producing animal – one member State:	3,220
Immunological product – one member State:	3,460
Each additional member State:	530
Simultaneous application: fee for each additional product in the application:	
one member State:	6,670
each additional member State:	120

Extent Information

E319 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Provision of information relating to the recognition of a United Kingdom marketing authorisation or an extension E+W+S

^{F582}20.

Extent Information

E147 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F582 Sch. 7 para. 20 omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(4)(k)**; 2020 c. 1, Sch. 5 para. 1(1)

Status: Point in time view as at 17/05/2024.**Changes to legislation:** There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)**Provision of information relating to the recognition of a United Kingdom marketing authorisation or an extension** **N.I.**

20.—(1) Where an application is made for the Secretary of State to provide information to other member States to enable them to recognise a marketing authorisation already granted by the United Kingdom the following fees are payable.

(2) Those fees also apply where a marketing authorisation has been granted in more than one member State, the holder applies for an extension for that marketing authorisation and the United Kingdom acts as reference member State.

(3) Where a valid application to provide information to another member State is received within six months of the original grant of the marketing authorisation, or where the Secretary of State has already provided the information to a member State, and a further valid application is made to provide the information to an additional member State within six months of the date the last information was provided, the fees are—

<i>Type of application</i>	<i>Fee for a pharmacologically equivalent product^(a)</i>	<i>Fee (other products) (£)</i>
Pharmaceutical product for a food-producing animal – one member State:	3,940	2,440
Pharmaceutical product for a non-food-producing animal one member State:	2,645	1,895
Immunological product – one member State:	2,130	2,130
Each additional member State:	535	535

(a) This fee is payable if the application for the marketing authorisation was on the basis that the product was pharmacologically equivalent to another veterinary medicinal product.

(4) Where the information to be provided relates to a product granted a marketing authorisation using identical data submitted simultaneously or on the basis of information provided under Article 13(c) of [Directive 2001/82/EC](#) the fees are—

<i>Application</i>	<i>Fee (£)</i>
Provision of information to—	
one member State:	4,165
each additional member State:	530

(5) In any other case the fees are—

<i>Type of application</i>	<i>Fee for a pharmacologically equivalent product (£)^(a)</i>	<i>Fee (other products) (£)</i>
Pharmaceutical product for a food-producing animal – one member State:	12,015	10,515

(a) This fee is payable if the application for the marketing authorisation was on the basis that the product was pharmacologically equivalent to another veterinary medicinal product.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

<i>Type of application</i>	<i>Fee for a pharmacologically equivalent product (£)^(a)</i>	<i>Fee (other products) (£)</i>
Pharmaceutical product for a non-food-producing animal – one member State:	8,115	7,365
Immunological product – one member State:	8,940	8,940
Each additional member State:	535	535

(a) This fee is payable if the application for the marketing authorisation was on the basis that the product was pharmacologically equivalent to another veterinary medicinal product.

(6) In the case of simultaneous applications, the above fees are payable for each additional product in the application for one member State, with a fee of £115 for each additional product for each additional member State.

Extent Information

E320 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Exception for a variation relating to animal testing **E+W+S**

21. If the only purpose of a variation is to remove animal testing or to reduce the numbers of animals used in testing, no fee is payable for the variation ^{F583}....

Extent Information

E148 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F583 Words in [Sch. 7 para. 21](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(4)(1)**; 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Exception for a variation relating to animal testing **N.I.**

21. If the only purpose of a variation is to remove animal testing or to reduce the numbers of animals used in testing, no fee is payable for the variation in the case of a national authorisation, and the United Kingdom element of the fee for the variation is not payable for an authorisation obtained through the mutual recognition procedure or the decentralised procedure.

Extent Information

E321 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F584}Application for a reassessment of an exceptional marketing authorisation] **E+W+S**

22.—^{F585}(1)

(2) The fee for the first reassessment of an exceptional marketing authorisation is £305, and the fee for each subsequent reassessment is £1,360.

Extent Information

E149 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F584 Sch. 7 para. 22 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **173(b)**

F585 Sch. 7 para. 22(1) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **173(a)**

Application for the renewal of a national marketing authorisation **N.I.**

22.—(1) The fee for an application for the renewal of a marketing authorisation is £1,360.

(2) The fee for the first reassessment of an exceptional marketing authorisation is £305, and the fee for each subsequent reassessment is £1,360.

Extent Information

E322 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Application for the renewal of a marketing authorisation obtained through mutual recognition or the decentralised procedure **E+W+S**

^{F586}23.

Extent Information

E150 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F586 Sch. 7 para. 23 omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(4)(n)**; 2020 c. 1, Sch. 5 para. 1(1)

Application for the renewal of a marketing authorisation obtained through mutual recognition or the decentralised procedure **N.I.**

23. The fee for an application for the renewal of a marketing authorisation obtained through mutual recognition or the decentralised procedure is —

- (a) £1,835 if the United Kingdom is the reference member State; and

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

(b) £1,225 if the United Kingdom is a concerned member State.

Extent Information

E323 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Registration of a homeopathic remedy **E+W+S**

24. The fee for an application for the registration of a homeopathic remedy is in accordance with the following table.

Fee for the registration of a homeopathic remedy

<i>Type of application</i>	<i>Fees (£)</i>
If all stocks and the formulation have already been assessed by the Secretary of State—	
not more than five stocks:	160
more than five stocks:	375
If either all the stocks have already been assessed by the Secretary of State but there is a new formulation, or if the formulation has already been assessed by the Secretary of State but one or more of the stocks have not been already assessed—	
not more than five stocks:	455
more than five stocks:	665
If the formulation and at least one of the stocks has not already been assessed by the Secretary of State—	
not more than five stocks:	760
more than five stocks:	985
If the product is already authorised for human use in the United Kingdom, or for human or veterinary use in the United Kingdom	
<small>F587</small>	
...—	
not more than five stocks:	160
more than five stocks:	375

Extent Information

E151 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F587 Words in Sch. 7 para. 24 Table omitted (E.W.S.) (31.12.2020) by virtue of The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), 17(4) (o); 2020 c. 1, Sch. 5 para. 1(1)

Registration of a homeopathic remedy **N.I.**

24. The fee for an application for the registration of a homeopathic remedy is in accordance with the following table.

Fee for the registration of a homeopathic remedy

<i>Type of application</i>	<i>Fees (£)</i>
If all stocks and the formulation have already been assessed by the Secretary of State—	
not more than five stocks:	160
more than five stocks:	375
If either all the stocks have already been assessed by the Secretary of State but there is a new formulation, or if the formulation has already been assessed by the Secretary of State but one or more of the stocks have not been already assessed—	
not more than five stocks:	455
more than five stocks:	665
If the formulation and at least one of the stocks has not already been assessed by the Secretary of State—	
not more than five stocks:	760
more than five stocks:	985
If the product is already authorised for human use in the United Kingdom, or for human or veterinary use in the United Kingdom or in another member State—	
not more than five stocks:	160
more than five stocks:	375

Extent Information

E324 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Renewal of a homeopathic remedy

^{F588}25. The fee for the renewal of a homeopathic remedy is £320.]

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

F588 Sch. 7 para. 25 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 174

Annual fees for marketing authorisations

26.—(1) Within 30 days of receiving a written demand from the Secretary of State, a holder of a marketing authorisation must provide the Secretary of State with a statement of turnover for the previous calendar year.

(2) The annual fee, rounded to the next £1, is—

$$£ \frac{0.67T}{100} + £230n$$

where—

- (a) T is the annual turnover in the previous calendar year;
- (b) and n is the number of active marketing authorisations held at any time during the previous calendar year.

(3) In the case of an authorisation holder with a turnover relating to all marketing authorisations held of less than £230,000, the annual fee, rounded to the next £1 is—

$$£ \frac{0.67T}{100} + £200n$$

where—

- (a) T is the annual turnover in the previous calendar year;
- (b) and n is the number of active marketing authorisations held at any time during the previous calendar year.

(4) In this paragraph—

“turnover” means the sales value at manufacturers’ prices of all authorised veterinary medicinal products sold or supplied in the United Kingdom;

“manufacturers’ prices” means the prices charged (excluding value added tax) for authorised products by manufacturers to wholesalers, except to the extent that—

- (a) the products are supplied by manufacturers direct to retailers, in which case it means the prices charged for the products by the manufacturers to the retailers reduced by such sum as, in the opinion of the Secretary of State, represents the difference between the prices paid by the retailers and those which could be expected to be charged by the manufacturers to wholesalers according to the practice prevailing during the period in question with regard to such products;
- (b) a marketing authorisation holder sells or supplies products that the marketing authorisation holder has neither manufactured nor obtained from the manufacturer, in which case it means the prices paid by the marketing authorisation holder for those products.

Auditor’s certificate

27.—(1) The Secretary of State may at any time require an audit certificate in support of a statement of turnover.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

(2) If the holder of the marketing authorisation does not provide an audit certificate before the date stipulated in the demand, an additional fee is payable for that year of £11,300 plus an additional £2,245 in respect of each marketing authorisation held.

(3) If the Secretary of State is not satisfied that the audit certificate provides sufficient assurance that the figures fairly present the financial records of the company, the Secretary of State may require the marketing authorisation holder to produce a further certificate and specify what further assurances are needed; and if these are not provided by the required date, the additional fee specified in sub-paragraph (2) is payable.

(4) Nothing in this paragraph limits the powers of an inspector to examine financial records.

PART 3

Fees payable by manufacturers

Application for a manufacturing authorisation **E+W+S**

28.—^{F589}(1) The fee for an application for a manufacturing authorisation for a veterinary medicinal product ^{F590}is £762]

^{F591}(2) Fees relating to an application for a manufacturing authorisation are payable with the application.]

Textual Amendments

F589 Sch. 7 para. 28 renumbered as Sch. 7 para. 28(1) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **175(a)**

F590 Words in Sch. 7 para. 28(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **175(b)**

F591 Sch. 7 para. 28(2) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **175(c)**

Application for a manufacturing authorisation **N.I.**

28. The fee for an application for a manufacturing authorisation for a veterinary medicinal product is—

- (a) £3,040; or
- (b) £530 if the authorisation only covers veterinary medicinal products manufactured under Schedule 6 (exemptions for small pet animals).

Application for a variation of a manufacturing authorisation **E+W+S**

29. The fee for an application for the variation of a manufacturing authorisation is—

- (a) ^{F592}£684] if the variation requires scientific or pharmaceutical assessment;
- ^{F593}(b) £105 if the variation only involves an administrative variation such as a change of ownership.”;]
- ^{F594}(c)
- ^{F595}(d)

Status: Point in time view as at 17/05/2024.
Changes to legislation: There are currently no known outstanding effects for the
 The Veterinary Medicines Regulations 2013. (See end of Document for details)

Extent Information

E152 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F592 Sum in Sch. 7 para. 29(a) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **176(a)**

F593 Sch. 7 para. 29(b) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **176(b)**

F594 Sch. 7 para. 29(c) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **176(c)**

F595 Sch. 7 para. 29(d) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **176(c)**

Application for a variation of a manufacturing authorisation **N.I.**

- 29.** The fee for an application for the variation of a manufacturing authorisation is—
- (a) £636 if the variation requires scientific or pharmaceutical assessment;
 - (b) £443 if the variation only involves a change of ownership;
 - (c) £210 if the authorisation only covers veterinary medicinal products manufactured under Schedule 6 (exemptions for small pet animals); and
 - (d) otherwise £350.

Extent Information

E325 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F596} Inspection of sites authorised to manufacture a product for administration under the cascade] **E+W+S**

30.—^{F597}(1)

^{F598}(2) The fees for the inspection of sites in connection with an authorisation (or an application for authorisation) for the manufacture of unauthorised veterinary medicinal products for administration under the cascade are set out in the following table—

Inspection fees

Type of site	Fee (£)	
	United Kingdom site	Site outside the United Kingdom
Super site	21,416	22,710
Major site	12,850	14,144
Standard site	6,425	7,719
Minor site	4,283	5,577]

F599(3)

F600(4)

Extent Information

E153 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F596 Sch. 7 para. 30 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **177(d)**

F597 Sch. 7 para. 30(1) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **177(a)**

F598 Sch. 7 para. 30(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **177(b)**

F599 Sch. 7 para. 30(3) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **177(c)**

F600 Sch. 7 para. 30(4) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **177(c)**

Application for an authorisation to manufacture an autogenous vaccine or a product for administration under the cascade N.I.

30.—(1) The fee for an application for a standard authorisation to manufacture an autogenous vaccine or a veterinary medicinal product for administration under the cascade is—

- (a) £3,435 for a site in the United Kingdom;
- (b) £3,270 for a site outside the United Kingdom.

(2) The fee for each inspection after a standard authorisation has been granted is (in each case) the same as the fee specified in paragraph (1).

(3) In the case of an application for an individual authorisation to manufacture a single batch of autogenous vaccine, or a single batch of veterinary medicinal product for administration under the cascade the fee is £1,635.

(4) The fee to vary an authorisation is £305 if no further inspection is required, and otherwise is the full application fee.

Extent Information

E326 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F601} Autogenous vaccines

30A.—(1) The fee for the scientific assessment of an authorisation (or an application for authorisation) to manufacture an autogenous vaccine is £6,962.

(2) The fees for the inspection of sites in connection with an authorisation (or an application for authorisation) to manufacture autogenous vaccines are set out in the following table—

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Inspection fees

Type of site	Fee (£)	
	United Kingdom site	Site outside the United Kingdom
Super site	21,416	22,710
Major site	12,850	14,144
Standard site	6,425	7,719
Minor site	4,283	5,577

Textual Amendments

F601 Sch. 7 paras. 30A, 30B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 178

[^{F601} Assessment of a variation of an authorisation to manufacture an autogenous vaccine

30B. The fee for the scientific assessment of an application for the variation of an authorisation to manufacture an autogenous vaccine is—

- (a) £2,895 if the variation requires complex scientific or pharmaceutical assessment;
- (b) £885 if the variation requires simple scientific or pharmaceutical assessment;
- (c) £455 in relation to an administrative variation.]

Textual Amendments

F601 Sch. 7 paras. 30A, 30B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 178

[^{F602} Annual fee (manufacturing authorisations) **E+W+S**

31. An annual fee of £575 is payable in respect of each manufacturing authorisation held.]

Extent Information

E154 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F602 Sch. 7 para. 31 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 179

Annual fees **N.I.**

31.—(1) An annual fee of £550 is payable in respect of each manufacturing authorisation held (other than as specified in this paragraph).

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

(2) The annual fee for a manufacturing authorisation for an autogenous vaccine or a veterinary medicinal product for administration under the cascade is 0.67% of the turnover in the previous calendar year rounded to the next £1, with a minimum fee of £10.

(3) There is no annual fee for a manufacturing authorisation for a veterinary medicinal product manufactured in accordance with Schedule 6 for small pet animals.

(4) In this paragraph “turnover” means the sales value at manufacturers’ prices net of value added tax of all authorised veterinary medicinal products sold or supplied in the United Kingdom.

Extent Information

E327 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Site inspections – type of site

32. For the purposes of deciding the fee for a site inspection—

“super site” is a site at which 250 or more relevant persons are employed;

“major site” is a site at which 60 or more, but fewer than 250, relevant persons are employed;

“standard site” is a site at which 10 or more, but fewer than 60 relevant persons are employed;

“minor site” is a site at which fewer than 10 relevant persons are employed;

“relevant person” means a person employed on the premises and systems inspected.

Inspection of a site where immunological veterinary medicinal products are manufactured **E+W+S**

33. The fees for the inspection of a site where immunological veterinary medicinal products are manufactured are in accordance with the following table.

^{F603}Sites where immunological veterinary medicinal products are manufactured

Type of site	Fee (£)	
	United Kingdom site	Site outside the United Kingdom
Super site	32,124	33,418
Major site	21,416	22,710
Standard site	10,708	12,002
Minor site	6,425	7,719]

Extent Information

E155 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F603 [Sch. 7 para. 33](#) Table substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **180**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Inspection of a site where immunological veterinary medicinal products are manufactured **N.I.**

33. The fees for the inspection of a site where immunological veterinary medicinal products are manufactured are in accordance with the following table.

Sites where immunological veterinary medicinal products are manufactured

Type of site	Fee (£)	
	United Kingdom site	Site outside United Kingdom
Super site	24,071	22,867
Major site	16,785	15,946
Standard site	6,661	6,327
Minor site	4,757	4,519

Extent Information

E328 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Inspection of a site where sterile veterinary medicinal products are manufactured **E+W+S**

34. The following fees are payable for the inspection of a site where no immunological veterinary medicinal products are manufactured, but where sterile products are manufactured.

[^{F604}Sites where sterile veterinary medicinal products are manufactured

Type of site	Fee (£)		
	United Kingdom site	Site outside the United Kingdom	
Super site	27,841	29,135	
Major site	19,274	20,569	
Standard site	10,708	12,002	
Minor site	6,425	7,719]	

Extent Information

E156 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F604 [Sch. 7 para. 34](#) Table substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **181**

Status: Point in time view as at 17/05/2024.**Changes to legislation:** There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)**Inspection of a site where sterile veterinary medicinal products are manufactured** **N.I.**

34. The following fees are payable for the inspection of a site where no immunological veterinary medicinal products are manufactured, but where sterile products are manufactured.

Sites where sterile veterinary medicinal products are manufactured

<i>Type of site</i>	<i>Fee (£)</i>	
	<i>United Kingdom site</i>	<i>Site outside the United Kingdom</i>
Super site	23,324	22,157
Major site	13,010	12,359
Standard site	8,244	7,832
Minor site	5,022	4,770

Extent Information

E329 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Inspection of a site where no immunological or sterile veterinary medicinal products are manufactured **E+W+S**

35. The following fees are payable for the inspection of a site where only non-immunological and non-sterile veterinary medicinal products are manufactured—

[^{F605}Sites where no immunological or sterile veterinary medicinal products are manufactured

<i>Type of site</i>	<i>Fee (£)</i>	
	<i>United Kingdom site</i>	<i>Site outside the United Kingdom</i>
Super site	21,416	22,710
Major site	12,850	14,144
Standard site	8,566	9,861
Minor site	4,283	5,577
If the site is only involved in the manufacture of veterinary medicinal products authorised under Schedule 6 (exemptions for small pet animals)—		
Standard site	3,212	4,507
Minor site	2,142	3,436]

Extent Information

E157 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Textual Amendments

F605 Sch. 7 para. 35 Table substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **182**

Inspection of a site where no immunological or sterile veterinary medicinal products are manufactured **N.I.**

35. The following fees are payable for the inspection of a site where only non-immunological and non-sterile veterinary medicinal products are manufactured—

Site where no immunological or sterile veterinary medicinal products are manufactured

Type of site	Fee (£)	
	United Kingdom site	Site outside the United Kingdom
Super site	14,180	13,471
Major site	8,325	7,909
Standard site	6,854	6,511
Minor site	3,789	3,600
If the site is only involved in the manufacture of veterinary medicinal products authorised under Schedule 6 (exemptions for small pet animals—		
Standard site	5,055	4,802
Minor site	2,728	2,592

Extent Information

E330 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Inspection of a site where veterinary medicinal products are assembled **E+W+S**

36. The following fees are payable for the inspection of a site where the only manufacturing process in relation to veterinary medicinal products is their assembly after the product has been put into its immediate container.

[^{F606}Sites where medicinal products are assembled

Type of site	Fee (£)			
	United Kingdom site	Site outside the United Kingdom	the	United Kingdom
Super site	17,133	18,427		
Major site	10,708	12,002		
Standard site	6,425	7,719		

Status: Point in time view as at 17/05/2024.**Changes to legislation:** There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

<i>Type of site</i>		<i>Fee (£)</i>
Minor site	4,283	5,577]

Extent Information

E158 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F606 Sch. 7 para. 36 Table substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **183**

Inspection of a site where veterinary medicinal products are assembled **N.I.**

36. The following fees are payable for the inspection of a site where the only manufacturing process in relation to veterinary medicinal products is their assembly after the product has been put into its immediate container.

Site where medicinal products are assembled

<i>Type of site</i>	<i>Fee (£)</i>	
	<i>United Kingdom site</i>	<i>Site outside the United Kingdom</i>
Super site	11,025	10,474
Major site	5,949	5,652
Standard site	4,917	4,671
Minor site	2,035	1,933

Extent Information

E331 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Test sites **E+W+S**

37. The fee for the inspection of a test site is [^{F607}£3,212], or [^{F608}£4,507] for a site outside the United Kingdom.

Extent Information

E159 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F607 Sum in Sch. 7 para. 37 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **184(a)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

F608 Sum in Sch. 7 para. 37 substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **184(b)**

Test sites **N.I.**

37. The fee for the inspection of a test site is £3,344, or £3,177 for a site outside the United Kingdom.

Extent Information

E332 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F609}Animal blood bank or non-food animal stem cell centre authorisations **E+W+S**

38.—(1) The fee for the inspection of a blood bank is—

- (a) £3,212 for a site in the United Kingdom; and
- (b) £4,507 for a site outside the United Kingdom.

(2) The fee for the inspection of a non-food animal stem cell centre is—

- (a) £2,142 for a site in the United Kingdom; and
- (b) £3,436 for a site outside the United Kingdom]

Extent Information

E160 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F609 [Sch. 7 para. 38](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **185**

Animal blood bank or equine stem cell centre authorisations **N.I.**

38.—(1) The fee for an authorisation to operate a blood bank is—

- (a) on a first inspection £3,113; and
- (b) on each subsequent inspection—
 - (i) £3,113 for a site in the United Kingdom; and
 - (ii) £2,966 for a site outside the United Kingdom.

(2) The fee for an authorisation to operate an equine stem cell centre is £3,427, and £3,092 for each subsequent inspection.

(3) The fee for a variation to an authorisation to operate a blood-bank or equine stem cell centre is £320.

Extent Information

E333 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

PART 4

Fees relating to a wholesale dealer's authorisation

[^{F610} Application for a wholesale dealer's authorisation **E+W+S]**

39.—(1) The fee for an application for a wholesale dealer's authorisation is £344.

(2) Fees relating to an application for a wholesale dealer's authorisation are payable with the application.]

Extent Information

E161 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F610 Sch. 7 para. 39 substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **186**

Application for a wholesale dealer's authorisation **N.I.**

39.—(1) The fee for an application for a wholesale dealer's authorisation is—

- (a) £1,745;
- (b) £785 if the application is accompanied by an estimate that the first year's turnover will be less than £35,000; or
- (c) £785 if the authorisation only relates to products classified as AVM-GSL, homeopathic remedies, or products authorised under Schedule 6 (exemptions for small pet animals).

(2) An applicant who has paid a fee of £785 on the grounds of turnover must send a declaration of turnover for the first year of trading on the anniversary of the grant of the authorisation, and if the figure is more than £35,000 must pay the balance of £960 within 30 days.

(3) If the applicant paid £1,745 but the turnover for the first year of trading was lower than £35,000, if the applicant sends a declaration certifying the turnover, the Secretary of State must refund the excess.

(4) Nothing in this paragraph limits the powers of an inspector to examine financial records.

(5) In this paragraph "turnover" means the sales value net of value added tax of all veterinary medicinal products (whether or not authorised for use in the United Kingdom) sold by way of wholesale dealing by the holder in the United Kingdom.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Extent Information

E334 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F611}Variation of a wholesale dealer's authorisation **E+W+S**

- 40.** The fee for an application to vary a wholesale dealer's authorisation is—
- (a) £265 if the variation requires scientific or pharmaceutical assessment;
 - (b) £105 for a change of ownership or other administrative variation.]

Extent Information

E162 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F611 [Sch. 7 para. 40](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **187**

Variation of a wholesale dealer's authorisation **N.I.**

- 40.** The fee for an application to vary a wholesale dealer's authorisation is—
- (a) £515 if the variation requires scientific or pharmaceutical assessment;
 - (b) £430 if the variation only involves a change of ownership; and
 - (c) otherwise £300.

Extent Information

E335 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F612}Annual fee for a wholesale dealer's authorisation **E+W+S**

- 41.** The annual fee for a wholesale dealer's authorisation is £427.]

Extent Information

E163 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F612 [Sch. 7 para. 41](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **188**

Annual fee for a wholesale dealer's authorisation **N.I.**

- 41.—(1)** The annual fee for a wholesale dealer's authorisation is—

- (a) £483; or
- (b) £315, if—
 - (i) the holder certifies when making the payment that the turnover during the previous year was less than £35,000; or
 - (ii) the authorisation only relates to products classified as AVM-GSL or homeopathic remedies;
- (c) £215 if the authorisation only relates to products authorised under Schedule 6 (exemptions for small pet animals).

(2) In this paragraph “turnover” means the sales value net of value added tax of all veterinary medicinal products (whether or not authorised for use in the United Kingdom) sold by way of wholesale dealing by the holder in the United Kingdom.

Extent Information

E336 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F613}Inspection of a wholesale dealer’s sites **E+W+S**]

42. The fee for inspection of a wholesale dealer’s site is—

- (a) £1,177; or
- (b) £877 if—
 - (i) the authorisation only relates to products classified as AVM-GSL or homeopathic remedies; or
 - (ii) the authorisation only relates to products marketed under Schedule 6 (exemptions for small pet animals).]

Extent Information

E164 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F613 [Sch. 7 para. 42](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **189**

Inspection of a wholesale dealer’s premises **N.I.**

42. The fee for the inspection of a wholesale dealer’s premises is—

- (a) £3,058; or
- (b) £1,442 if—
 - (i) the authorisation only relates to products classified as AVM-GSL or homeopathic remedies; or
 - (ii) the turnover relating to all veterinary medicinal products in the calendar year preceding the inspection was less than £35,000;
- (c) £830 if the authorisation only relates to products authorised under Schedule 6 (exemptions for small pet animals).

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Extent Information

E337 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

PART 5

Fees relating to feedingstuffs

Fees for [^{F614}applications for authorisation] and annual fees relating to feedingstuffs in Great Britain

43.—(1) Subject to sub-paragraph (3) the fee for the application for [^{F615}authorisation] of [^{F616}premises] manufacturing feedingstuffs and [^{F615}authorisation] of distributors of feedingstuffs in Great Britain is [^{F617}£105].

(2) An annual fee of [^{F618}£122] is payable in respect of any such [^{F619}authorisation].

(3) No fee is payable under sub-paragraph (1) in respect of [^{F620}premises] where specified feed additives are manufactured if a [^{F621}medicinal premix] is manufactured at [^{F622}those premises] in accordance with a manufacturing authorisation.

(4) Fees relating to feedingstuffs are payable with the application ^{F623}....

(5) Where more than one manufacturing activity is carried out at one [^{F624}premises] by the same legal entity] only one fee (the highest) is payable.

Textual Amendments

F614 Words in Sch. 7 para. 43 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(f)**

F615 Word in Sch. 7 para. 43(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(a)(i)**

F616 Word in Sch. 7 para. 43(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(a)(ii)**

F617 Sum in Sch. 7 para. 43(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(a)(iii)**

F618 Sum in Sch. 7 para. 43(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(b)(i)**

F619 Word in Sch. 7 para. 43(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(b)(ii)**

F620 Word in Sch. 7 para. 43(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(c)(i)**

F621 Words in Sch. 7 para. 43(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(c)(ii)**

F622 Words in Sch. 7 para. 43(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(c)(iii)**

F623 Words in Sch. 7 para. 43(4) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(d)**

F624 Words in Sch. 7 para. 43(5) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **190(e)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Inspection fees relating to feedingstuffs in Great Britain

44. Fees for the inspection of [^{F625}premises] manufacturing or distributing feedingstuffs in Great Britain are in accordance with the following table.

[^{F626}Inspection Fees

<i>Type of premises inspected</i>	<i>Fee payable (£)</i>
Manufacturer of a specified feed additive (SFA)	1,610
Manufacturer of an intermediate feedingstuff (including balancers) containing a medicinal premix or an SFA	976
Manufacturer of a feedingstuff for sale containing— a medicinal premix and/or an SFA, and/or an intermediate feedingstuff containing a medicinal premix or an SFA	841
Manufacturer of a feedingstuff for feeding to their own animals only, containing— a medicinal premix and/or an SFA incorporated at a rate of at least 2kg/t, and/or an intermediate feedingstuff containing a medicinal premix and/or an SFA incorporated at a rate of at least 2kg/t	476
Distributor or trader of Schedule 5 products (A distributor of specified feed additives, or intermediate feedingstuffs containing specified feed additives or medicinal premixes; or feedingstuffs containing a medicinal premix)	350]

Textual Amendments

F625 Word in Sch. 7 para. 44 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **191(a)**

F626 Sch. 7 para. 44 Table substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **191(b)**

Fees payable in relation to feedingstuffs in Northern Ireland **E+W+S**

^{F627}45.

Extent Information

E165 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Textual Amendments

F627 Sch. 7 para. 45 omitted (E.W.S.) (31.12.2020) by virtue of [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(b), **4(10)**

Fees payable in relation to feedingstuffs in Northern Ireland **N.I.**

45.—(1) The annual fees payable for the approval of establishments manufacturing and distributing feedingstuffs in Northern Ireland are in accordance with the following table.

(2) Fees are payable with the application or, for the subsequent annual fee, on invoice.

(3) Where more than one manufacturing activity is carried out at one establishment only the highest fee is payable.

Approval fees

	<i>Type of establishment</i>	<i>Fee payable (£)</i>
1	Establishment manufacturing a specified feed additive ^(a) :	545
2	Establishment manufacturing a premixture:	435
3	Establishment manufacturing feedingstuffs using specified feed additives and veterinary medicinal products directly at any concentration, or using premixtures or specified feed additive complementary feedingstuffs:	435
4	Establishment manufacturing feedingstuffs for placing on the market using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2 kg per tonne or more:	320
5	Establishment manufacturing feedingstuffs using premixtures or specified feed additive complementary feedingstuffs containing specified feed additives when the feedingstuffs are to be placed on the market:	170
6	Establishment manufacturing feedingstuffs for the manufacturers own use using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2 kg per tonne or more:	131
7	Establishment manufacturing feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs:	110
8	Establishment distributing specified feed additives, premixtures or feedingstuffs containing specified	70

(a) No fee is payable for establishments that already have a manufacturing authority relating to veterinary medicinal products for incorporating into feedingstuffs.

<i>Type of establishment</i>	<i>Fee payable (£)</i>
feed additives, or premixtures or feedingstuffs containing veterinary medicinal products:	
(a) No fee is payable for establishments that already have a manufacturing authority relating to veterinary medicinal products for incorporating into feedingstuffs.	

Extent Information

E338 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Fees relating to premises for supply by suitably qualified persons E+W+S

46.—(1) The fee [^{F628}for an application for the authorisation] of premises for the retail supply of veterinary medicinal products by suitably qualified persons is—

(a) [^{F629}£105]; ^{F630} ...

^{F630}(b)

[^{F631}(1A) The fees for the inspection of sites authorised for the retail supply of veterinary medicinal products by suitably qualified persons are set out in the following table—

Inspection Fees

<i>Type of sites inspected</i>	<i>Fee payable (£)</i>
Sites authorised to supply companion animal medicines	285
Sites authorised to supply equine medicines	285
Sites authorised to supply livestock medicines	338
Sites authorised to supply avian medicines	285.

(1B) Where a site is inspected in relation to a single authorisation, and falls within more than one of the categories in the table, only one fee (the highest) is payable.]

(2) The subsequent annual fee is—

(a) [^{F632}£57]; ^{F633} ...

^{F633}(b)

[^{F634}(3) The application fee for authorisation of sites for supply is payable with the application.]

Extent Information

E166 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F628 Words in Sch. 7 para. 46(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **192(a)(i)**

F629 Sum in Sch. 7 para. 46(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **192(a)(ii)**

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

- F630** Sch. 7 para. 46(1)(b) and word omitted (E.W.S.) (17.5.2024) by virtue of *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **192(a)(iii)**
- F631** Sch. 7 para. 46(1A)(1B) inserted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **192(b)**
- F632** Sum in Sch. 7 para. 46(2) substituted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **192(c)(i)**
- F633** Sch. 7 para. 46(2)(b) and word omitted (E.W.S.) (17.5.2024) by virtue of *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **192(c)(ii)**
- F634** Sch. 7 para. 46(3) inserted (E.W.S.) (17.5.2024) by *The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567)*, regs. 1(1), **192(d)**

Fees relating to premises for supply by suitably qualified persons **N.I.**

46.—(1) The fee to approve of premises for the retail supply of veterinary medicinal products by suitably qualified persons is—

- (a) £265; or
- (b) if the premises are only authorised to supply veterinary medicinal products for the treatment of—
 - (i) horses (or horses and companion animals) £145; or
 - (ii) companion animals £110.

(2) The subsequent annual fee is—

- (a) £185; or
- (b) if the premises are only authorised to supply veterinary medicinal products for the treatment of—
 - (i) horses (or horses and companion animals) £95; or
 - (ii) companion animals £70.

Extent Information

E339 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

PART 6

General

Testing samples

47. The fee for testing a sample required to be submitted by the Secretary of State is the full economic cost of the test.

Animal test certificates **E+W+S**

48.—(1) The fee for an animal test certificate is [^{F635}£1,170].

(2) The fee for an animal test certificate to administer medicinal products in a small scale trial to test them for clinical safety or efficacy is [^{F636}£40].

^{F637}(3)

[^{F638}(4) The fee for an application for the variation of the certificate is—

- (a) in the case of a small scale trial, £40; and
- (b) in the case of any other trial, £390.]

[^{F639}(5) The fee for an application to renew a certificate is—

- (a) in the case of a small scale trial, £40; and
- (b) in the case of any other trial, £190.]

(6) The Secretary of State may waive the fee if satisfied that the application is in relation to developing a veterinary medicinal product for a limited market (for example, for a minor species, a minor use, or for a disease with restricted regional distribution).

Extent Information

E167 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F635 Sum in Sch. 7 para. 48(1) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **193(a)**

F636 Sum in Sch. 7 para. 48(2) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **193(b)**

F637 Sch. 7 para. 48(3) omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(4)(p)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F638 Sch. 7 para. 48(4) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **193(c)**

F639 Sch. 7 para. 48(5) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **193(d)**

Animal test certificates **N.I.**

48.—(1) The fee for an animal test certificate is £345 in the case of—

- (a) an immunological veterinary medicinal product that has been authorised in another member State for the species on which the proposed test will be conducted;
- (b) a pharmaceutical veterinary medicinal product that has been authorised in another member State for use with a food-producing species on which the proposed test will be conducted where the same or similar dosage regime and method of administration is to be used in the medicinal test as is authorised; or
- (c) a pharmaceutical veterinary medicinal product authorised in another member State for human or animal use where the test is to be conducted on companion animals only.

(2) The fee for an animal test certificate to administer medicinal products in a small scale trial to test them for clinical safety or efficacy is £30.

(3) In any other case the fee is £815.

(4) The fee for an application for a variation of the certificate is £265 for each change.

(5) The fee for an application to renew a certificate is £130.

(6) The Secretary of State may waive the fee if satisfied that the application is in relation to developing a veterinary medicinal product for a limited market (for example, for a minor species, a minor use, or for a disease with restricted regional distribution).

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

Extent Information

E340 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Importation of a veterinary medicinal product for treatment under the cascade **E+W+S**

49.—(1) The fee for a certificate to import (if necessary) and be in possession of and administer a veterinary medicinal product under the cascade is—

^{F640}(a)

(b) £30 if the veterinary medicinal product is authorised in [^{F641}another] country.

(2) The fee is payable in respect of each animal treated, but in the case of administration to and treatment of a discrete group of animals, the Secretary of State may notify the applicant in writing that a fee for only one animal is payable.

(3) There is no fee if the application is made using the website of the Veterinary Medicines Directorate.

Extent Information

E168 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F640 Sch. 7 para. 49(1)(a) omitted (E.W.S.) (31.12.2020) by virtue of [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(4)(q)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F641 Word in Sch. 7 para. 49(1)(b) substituted (E.W.S.) (31.12.2020) by [The Food and Drink, Veterinary Medicines and Residues \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/865\)](#), regs. 1(2), **17(4)(q)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Importation of a veterinary medicinal product for treatment under the cascade **N.I.**

49.—(1) The fee for a certificate to import (if necessary) and be in possession of and administer a veterinary medicinal product under the cascade is—

(a) £15 if the veterinary medicinal product is authorised in another member State;

(b) £30 if the veterinary medicinal product is authorised in a third country.

(2) The fee is payable in respect of each animal treated, but in the case of administration to and treatment of a discrete group of animals, the Secretary of State may notify the applicant in writing that a fee for only one animal is payable.

(3) There is no fee if the application is made using the website of the Veterinary Medicines Directorate.

Extent Information

E341 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Wholesale dealer's import certificate

50.—(1) The fee payable by the holder of a wholesale dealer's authorisation for a certificate to import and store a veterinary medicinal product not authorised in the United Kingdom to enable it to be supplied for administration under Schedule 4 is [^{F642}£760] .

(2) The fee is only payable if, in the twelve month period immediately before the application, the applicant has supplied the veterinary medicinal product to which the certificate relates in accordance with at least 100 certificates.

Textual Amendments

F642 Word in [Sch. 7 para. 50](#) substituted (14.4.2014) by [The Veterinary Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/599\)](#), regs. 1, **4(3)**

Specific batch control

[^{F643}**51.** The fee for an authorisation to release a veterinary medicinal product under specific batch control is—

- (a) £560; and
- (b) £100 for each additional batch affected by the same issue where the specific batch control application is made at the same time.]

Textual Amendments

F643 [Sch. 7 para. 51](#) substituted (14.4.2014) by [The Veterinary Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/599\)](#), regs. 1, **4(4)**

Submission of control tests of an immunological product

52. The fee for the submission of the results of tests carried out on a batch of immunological products other than autogenous vaccines prior to release is £80.

Export certificates **E+W+S**

53. The fee for an application for an export certificate is [^{F644}£54]^{F645}....

Extent Information

E169 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F644 Sum in [Sch. 7 para. 53](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **194(a)**

F645 Words in [Sch. 7 para. 53](#) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **194(b)**

Export certificates **N.I.**

53. The fee for an application for an export certificate is £30, and £15 for each certified copy.

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the *The Veterinary Medicines Regulations 2013*. (See end of Document for details)

Extent Information

E342 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Provision of advice

54. The fee for an application for written advice from the Secretary of State as to whether or not a product requires a marketing authorisation is £885.

[^{F646}Provision of scientific advice

54A. The fee for an application for written advice from the Secretary of State in relation to scientific matters is £4,487.]

Textual Amendments

F646 Sch. 7 para. 54A inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **195**

Appeals to the Veterinary Products Committee

55. The fee for an appeal to the Veterinary Products Committee is £1,500.

Fee relating to an appointed person

56. The appellant is liable for the full economic cost of a referral to an appointed person subject to a maximum of £5,000.

Fees relating to a veterinary ^{F647}... practice premises **E+W+S**

57.—[^{F648}(1) The fees for the inspection of a veterinary practice premises are set out in the following table—

<i>Type of premises inspected</i>	<i>Fee payable (£)</i>
Sites registered to supply companion animal medicines	536
Sites registered to supply equine medicines	536
Sites registered to supply livestock medicines	536
Mixed practice premises	698
Any other type of practice	451]

(2) The initial registration and annual fee for the registration of veterinary practice premises with the Royal College of Veterinary Surgeons to supply veterinary medicinal products is [^{F649}£38].

(3) Notwithstanding paragraph 2 of this Schedule, this is payable to the Royal College of Veterinary Surgeons.

[^{F650}(4) For the purposes of sub-paragraph (1) “mixed practice” means premises supplying veterinary medicinal products to livestock in addition to any other category mentioned in that provision.]

Extent Information

E170 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F647 Word in [Sch. 7 para. 57 heading](#) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **196(d)**

F648 [Sch. 7 para. 57\(1\)](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **196(a)**

F649 Sum in [Sch. 7 para. 57\(2\)](#) substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **196(b)**

F650 [Sch. 7 para. 57\(4\)](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **196(c)**

Fees relating to a veterinary surgeon's practice premises **N.I.**

57.—(1) The fee for the inspection of a veterinary surgeon's practice premises is £350.

(2) The initial registration and annual fee for the registration of veterinary practice premises with the Royal College of Veterinary Surgeons to supply veterinary medicinal products is £34.

(3) Notwithstanding paragraph 2 of this Schedule, this is payable to the Royal College of Veterinary Surgeons.

Extent Information

E343 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F651}Fee in relation to verifying destruction of controlled drug

57A. The fee for verifying the destruction of a controlled drug listed in Schedule 2, 3 or 4 to the Misuse of Drugs Regulations 2001 is—

(a) £142; or

(b) £31 (where the verification takes place during the course of an inspection for other purposes).]

Textual Amendments

F651 [Sch. 7 paras. 57A, 57B](#) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **197**

[^{F651}Pharmacovigilance inspections

57B.—(1) In relation to a pharmacovigilance inspection the fee is—

(a) £3,600 in the case of a large marketing authorisation holder; and

(b) £1,650 in the case of a small marketing authorisation holder.

(2) In sub-paragraph (1)—

Status: Point in time view as at 17/05/2024.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013. (See end of Document for details)

“large marketing authorisation holder” means a marketing authorisation holder who holds 30 or more marketing authorisations;

“small marketing authorisation holder” means a marketing authorisation holder who holds fewer than 30 marketing authorisations.]

Textual Amendments

F651 Sch. 7 paras. 57A, 57B inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **197**

Refund of fees relating to the Veterinary Products Committee or appointed persons

58. The Secretary of State must refund the fee payable in relation to an appeal to the Veterinary Products Committee or to an appointed person if, as a result of the appeal, the Secretary of State changes the decision that was the subject of the appeal.

Fees relating to an improvement notice

59. If an improvement notice is served under these Regulations, the fee for any subsequent inspection necessary as a result of the notice is the full economic cost of the inspection, payable by the person on whom the notice was served.

Non-payment of fees

60. Where any fee [^{F652}(other than any fee relating to a manufacturing authorisation or wholesale dealer’s authorisation)] is not paid, the Secretary of State may, after giving one month’s written warning, suspend the processing of any application from the person [^{F653}or any authorisation held by the person] who has not paid the fee.

Textual Amendments

F652 Words in Sch. 7 para. 60 omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **198(a)**

F653 Words in Sch. 7 para. 60 inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **198(b)**

Waiver or reduction of fees

61.—(1) If the Secretary of State is satisfied that for reasons of human or animal health or the protection of the environment it is desirable that a product should be authorised for veterinary use or that an authorised product should remain on the market the Secretary of State may waive or reduce any fees payable under these Regulations.

[^{F654}(1A) If the Secretary of State is satisfied that exceptional circumstances exist the Secretary of State may waive or reduce an inspection fee payable under these Regulations.]

(2) An applicant or the holder of a marketing authorisation must provide full written justification for any waiver or reduction.

Textual Amendments

F654 Sch. 7 para. 61(1A) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), 199

Reduction of fees when an application is withdrawn

62.—(1) Where an application for a marketing authorisation, or any variation referred to in paragraph 17 or 18 as a Type II variation, an extension, an extension-led grouped variation or a Type II led grouped variation is withdrawn before determination, the fee is reduced in accordance with this paragraph.

(2) If no assessment (veterinary, scientific or pharmaceutical) has begun, the reduction is 90%.

(3) If assessment has begun but the Secretary of State has not yet requested further data, the reduction is 50%.

(4) If the Secretary of State has requested further information but it has not yet been provided, the reduction is 25%.

(5) If the further information requested has been supplied but has not yet been fully assessed or the application has not been referred to the Veterinary Products Committee, the reduction is 10%

(6) Once the further information has been fully assessed, or the application has been referred to the Veterinary Products Committee, there is no reduction.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and remake with amendments the Veterinary Medicines Regulations 2011 ([S.I. 2011/2159](#)).

Principal changes to the 2011 Regulations

The major change to the Regulations is the adjustment of the fees with a view to achieving full cost recovery while avoiding cross-subsidy of one activity by another.

In Great Britain food businesses will pay a much lower fee on application for approval but will pay a larger fee for any inspection. Premises will be selected for inspection on the basis of risk analysis.

The fees for appeals to the Veterinary Products Committee are simplified.

Criminal offences have also been amended. Instead of creating an individual offence in relation to every obligation there is now a single offence governing all relevant obligations in the body of the Regulations and a single offence in each of Schedules 1 to 5.

Other changes

Regulation 35 extends inspectors' power of seizure to cover anything they reasonably believe to be, or which purports to be, a veterinary medicine.

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Veterinary practice premises must be registered with the Royal College of Veterinary Surgeons and paragraph 8 of Schedule 3 gives the Secretary of State a power to require the removal of premises from this register where they fail to meet the necessary standard.

The Regulations

The Regulations make provision for the authorisation, manufacture, classification, distribution and administration of veterinary medicinal products.

They implement the following EU instruments that are Directives:

- (a) Council [Directive 90/167/EEC](#) laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, so far it is not superseded by Regulation [\(EC\) No 183/2005](#);
- (b) Commission [Directive 91/412/EEC](#) laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products; and
- (c) [Directive 2001/82/EC](#) of the European Parliament and of the Council on the Community code relating to veterinary medicinal products.

They provide for the enforcement of the following EU instruments that are Regulations besides that mentioned above:

- (d) Regulation [\(EC\) No 178/2002](#) of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ No L 31, 1.2.2002 p. 1), in so far as it applies to veterinary medicinal products used in feedingstuffs
- (e) Regulation [\(EC\) No 1831/2003](#) of the European Parliament and of the Council on additives for use in animal nutrition (OJ No L 268, 18.10.2003 p. 29), in so far as it applies to veterinary medicinal products used in feedingstuffs;
- (f) Regulation [\(EC\) No 882/2004](#) of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ NO L 191, 28.5.2004, p.1), in so far as it applies to veterinary medicinal products used in feedingstuffs;
- (g) Regulation [\(EC\) No 183/2005](#) of the European Parliament and of the Council laying down requirements for feed hygiene (OJ No L 35, 8.2.2005, p. 1), in so far as it applies to veterinary medicinal products used in feedingstuffs; and
- (h) Regulation [\(EC\) No 470/2009](#) of the European Parliament and of the Council, laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (OJ No L152, 16.6.2009, p. 11).

They provide that a veterinary medicinal product must have a marketing authorisation granted by the Secretary of State before being placed on the market, and they make provision for the grant of a marketing authorisation (regulation 4 and Schedule 1).

They specify that a veterinary medicinal product must be manufactured by a person holding a manufacturing authorisation, and make provision for granting an authorisation (regulation 5 and Schedule 2).

They regulate the supply and possession of veterinary medicinal products, and introduce new classifications of those products (regulation 7 and Schedule 3).

They provide that a veterinary medicinal product may only be administered as specified in its marketing authorisation or, in the case of administration by a veterinary surgeon, administration under the rules of the “cascade” (regulation 8 and Schedule 4).

They control bringing a veterinary medicinal product into the United Kingdom (regulation 9) and advertising (regulation 10 to 12).

They control wholesale dealing (regulation 13 and Schedule 3).

They control medicated feedingstuffs and feedingstuffs containing additives specified in the Regulations (regulation 14 and Schedule 5).

They provide for exemptions (regulation 15 and Schedule 6).

They provide for fees (regulation 16 and Schedule 7).

They require records to be kept (regulations 17 to 24).

They create an offence of importation, possession or supply of unauthorised veterinary medicinal products (regulation 43(q) to (s)).

They make provision for the existence of the Veterinary Products Committee (regulation 28). They make provision for an appeals procedure in the case of a refusal, etc., of a marketing authorisation (regulation 30).

They create administrative arrangements for the enforcement of the Regulations (regulations 32 to 36 and 38 to 42) and create offences of obstructing a person acting in the execution of these Regulations (regulation 43(u)) and of failing to comply with an improvement notice (regulation 43(v)).

Under regulation 44 breach of the Regulations is an offence punishable—

- (i) on summary conviction, by a fine not exceeding the statutory maximum or by imprisonment for a term not exceeding three months or both, or
- (j) on conviction on indictment, by a fine or to imprisonment for a term not exceeding two years or both.

Regulation 46 requires the Secretary of State to review the operation and effect of these Regulations, other than regulation 16 and Schedule 7 (which relate to fees), and lay a report before Parliament within five years after they come into force and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke the Regulations or to amend them.

Regulation 47 revokes the Veterinary Medicines Regulations 2011.

A full impact assessment has been prepared and placed in the libraries of both Houses of Parliament. It is available, together with a transposition note and a table showing fee changes, on www.vmd.defra.gov.uk at “Publications, Veterinary Medicines Regulations and Guidance”. It is also published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.

Status:

Point in time view as at 17/05/2024.

Changes to legislation:

There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013.