STATUTORY INSTRUMENTS

2013 No. 2033

The Veterinary Medicines Regulations 2013

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;**]**

F3…

[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;**]**

F4…

"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;

F3…

F4…

[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;**]**

F3…

[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;

"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 **[**F5a 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**][**F5an 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(**4**);

[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 **[**F6intended to be**]** administered to **[**F7an animal**]** in order to produce active or passive immunity or to diagnose **[**F8its 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;

(**4**) OJ No L 149, 7.6.2008, p. 3.

"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;

"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(**2**);**]**

[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(**3**);**]**

F11…

[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(**5**);**]**

“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(**5**);

“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(**6**)**[**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;**]**

F3…

[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).**]**

(**2**) OJ No L334, 12.12.2008, p.7.
(**3**) OJ No L 15, 20.1.2010, p. 1.
(**5**) OJ No L152, 16.6.2009, p. 11.
(**5**) OJ No L152, 16.6.2009, p. 11.
(**6**) 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).

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

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 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(**1**);

"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(**2**)**[**[F19], as last amended by Regulation (EU) No 712/2012**]**(**1**);

"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(**3**);

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

(**1**) OJ No L136, 30.4.2004, p. 1.
(**2**) OJ No L334, 12.12.2008, p.7.
(**1**) OJ No L136, 30.4.2004, p. 1.
(**3**) OJ No L 15, 20.1.2010, p. 1.

"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(**4**);

"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;

[[F20]"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(**2**);**]**

[[F21]"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(**3**);**]**

[F22]...

[[F23]"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(**5**);**]**

"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(**5**);

"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(**6**)**[**[F24], as last amended by Regulation (EU) No 2017/2279**]**;

[[F25]"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.

(**4**) OJ No L 149, 7.6.2008, p. 3.
(**2**) OJ No L334, 12.12.2008, p.7.
(**3**) OJ No L 15, 20.1.2010, p. 1.
(**5**) OJ No L152, 16.6.2009, p. 11.
(**5**) OJ No L152, 16.6.2009, p. 11.
(**6**) 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).

Extent Information

E2 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

F19 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)**

F20 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)**

F21 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)**

F22 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)**

F23 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)**

F24 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)**

F25 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(**7**), 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.

(**7**) 1986 c. 14.

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, PART 1.