SCHEDULE 1

Marketing authorisations **[**[F1]in Great Britain**][**[F2]in Northern Ireland**]**

Textual Amendments

F1 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)**

F2 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 8

Pharmacovigilance

Qualified persons responsible for pharmacovigilance E+W+S

[F3]**55.** . . . . . .

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

F3 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 **[**[F41]or the United Kingdom**]**.

Extent Information

E7 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

F41 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)**

[[F4]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.

(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

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

F4 Sch. 1 paras. 56-56C substituted for Sch. 1para. 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

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

[F4Duties 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

F4 Sch. 1 paras. 56-56C substituted for Sch. 1para. 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;

(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

F4 Sch. 1 paras. 56-56C substituted for Sch. 1para. 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

F4 Sch. 1 paras. 56-56C substituted for Sch. 1para. 56 (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **68**

[F5Adverse 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) **[**F6adverse event in respect of an animal**]**;

(b) human **[**F7adverse event**]**; F8...

(c) unintended transmission of an infectious agent through a veterinary medicinal product,

[F9(d) occurrence of an adverse environmental event, or

(e) lack of efficacy,**]**

following the administration of the product F10....

[F11(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 **[**F1230**]** 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 **[**F13event**]**, 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.

[F14(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.**]**

F15(5) . . . . . .

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

Textual Amendments

F5 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)**

F6 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)**

F7 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)**

F8 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)**

F9 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)**

F10 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)**

F11 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)**

F12 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)**

F13 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)**

F14 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)**

F15 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 [F42Northern 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 **[**F43Northern 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

E9 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

F42 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)**

F43 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 [F16another] country E+W+S

F17 58. . . . . . .

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

F16 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)**

F17 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 [F44Northern 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 [F45]... 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

E10 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

F44 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)**

F45 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)**

[F18Annual benefit-risk] reports E+W+S

59.—(1) The marketing authorisation holder must submit to the Secretary of State **[**F19a summary of pharmacovigilance activity**]** in the form of **[**F20an annual benefit-risk report**]** for each marketing authorisation in accordance with this paragraph F21....

F22(2) . . . . . .

(3) Following the placing on the market in **[**F23Great Britain**]**, the marketing authorisation holder must submit a **[**F24benefit-risk report**]** to the Secretary of State immediately upon **[**F25request 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 **[**F26submission dates for the annual benefit-risk reports**]**.

[F27(5) The report must include a statement regarding the benefit-risk balance of the veterinary medicinal product.**]**

[F28(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.**]**

F29(7) . . . . . .

F30(8) . . . . . .

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

F18 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)**

F19 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)**

F20 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)**

F21 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)**

F22 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)**

F23 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)**

F24 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)**

F25 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)**

F26 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)**

F27 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)**

F28 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)**

F29 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)**

F30 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 **[**[F46]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 **[**[F47]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.

(8) Data relating to different formulations (either different dosage forms or different strengths) must be provided in separate reports.

Extent Information

E11 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

F46 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)**

F47 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 **[**[F31]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.

[[F32](3) For the purposes of this paragraph "information" includes any information contained in advertising material.**]**

Textual Amendments

F31 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)**

F32 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)**

[F33Pharmacovigilance 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

F33 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**

[F33Powers 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

F33 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 **[**F34, 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; F35...

(v) add a new precautionary measure, **[**F36or

(vi) implement a risk management plan,**]**

the Secretary of State must forthwith inform F37... 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 productF38....

F39(3) . . . . . .

F40(4) . . . . . .

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

F34 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)**

F35 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)**

F36 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)

F37 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)**

F38 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)**

F39 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)**

F40 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 [F48]... member States (irrespective of whether the product is authorised in **[**[F49]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 [F50]... 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

E12 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

F48 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)**

F49 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)**

F50 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)**

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 8.