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 5

Suspension, etc. of a marketing authorisation

Suspension [F3, revocation, etc] of a marketing authorisation: grounds E+W+S

38.—**[**[F4](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.

[[F5](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

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 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)**

F4 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)**

F5 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

E4 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.

F6(3) . . . . . .

F7(4) . . . . . .

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

F6 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)**

F7 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 **[**F11Northern Ireland**]** pending a decision of the Agency, but must inform the Commission and the F12... 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

E5 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

F11 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)**

F12 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.—**[**F8(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—

(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.

F9(3) . . . . . .

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

F8 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**

F9 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 **[**F13a**]** 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

E6 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

F13 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)**

[F10Temporary 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

F10 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**

[F10Restrictions 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

F10 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**

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 5.