SCHEDULE 4 Regulation 8

Administration of a veterinary medicinal product outside the terms of a marketing authorisation

CONTENTS

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 **[**F1country**]** 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 **[**F2country**]**, 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 **[**F3be substances for which a maximum residue limit has been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council**]**.

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

F1 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)**

F2 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)**

F3 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)**

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 **[**F13Northern 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 **[**F13Northern 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 **[**F13Northern 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

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

F13 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)**

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.

(2) The withdrawal period must ensure that, if there is a maximum residue limit **[**F4established for the active substance 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.

(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 **[**F5has been established**]**) 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(**1**) for fish meat.

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

F4 Words in Sch. 4 para. 2(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(34)(b)(i)** (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 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)**

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;

(**1**) The number of days of the withdrawal period is calculated by dividing 500 by the mean temperature of the water in degrees Celsius.

(c) 28 days for meat from poultry and mammals including fat and offal;

(d) 500 degree days(**1**) for fish meat.

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

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 (**2**)).

(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 E+W+S

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 [F6]... and may publicise any permit as the Secretary of State sees fit.

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

F6 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

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

(**1**) The number of days of the withdrawal period is calculated by dividing 500 by the mean temperature of the water in degrees Celsius.

(**2**) OJ No L42, 13.2.2013, p. 1.

Immunological products for an imported or exported animal E+W+S

5. If an animal is imported from, or exported to, **[**[F7]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 **[**[F8]that other**]** country.

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

F7 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)**

F8 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 **[**[F14]Northern Ireland**]** but is authorised under the legislation of the third country.

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

F14 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 [F9countries] E+W+S

6.—(1) Veterinary surgeons practising in another **[**[F10]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—

(a) the quantity does not exceed the requirements for the treatment of specific animals;

(b) the product is authorised in the **[**[F11]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(**3**).

(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

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

F9 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)**

F10 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)**

F11 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 F15... member States N.I.

6.—(1) Veterinary surgeons practising in **[**F16a**]** member State may bring into **[**F17Northern Ireland**]** and administer to animals small quantities of veterinary medicinal products that are not authorised for use in **[**F17Northern 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 **[**F18Northern Ireland**]** that has the same qualitative and quantitative composition in terms of active substances;

(**3**) Published at http://www.rcvs.org.uk/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/.

(e) the veterinary surgeon is acquainted with the Code of Professional Conduct for veterinary surgeons issued by the Royal College of Veterinary Surgeons(**3**).

(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—

[[F19](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 **[**[F20]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

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

F15 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)**

F16 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)**

F17 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)**

F18 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)**

F19 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)**

F20 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)**

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 **[**[F12]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.

(**3**) Published at http://www.rcvs.org.uk/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/.

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

F12 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

E12 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

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.

Offences

10. It is an offence to fail to comply with—

(a) paragraph 3(2);

(b) paragraph 6; or

(c) paragraph 9(3) or (4).

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, SCHEDULE 4.