STATUTORY INSTRUMENTS

2013 No. 2033

The Veterinary Medicines Regulations 2013

PART 2

Authorised veterinary medicinal products

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

4.—**[**[F1](1) No person may place a veterinary medicinal product on the market unless the Secretary of State has—

(a) as regards a product to which Schedule 1B applies, issued a QNIG certificate in respect of that product;

(b) otherwise, granted a marketing authorisation in respect of that product.**]**

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

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

[[F2](4) Schedule 1A (converted EU marketing authorisations) has effect.**]**

[[F3](5) Schedule 1B (Northern Ireland qualifying good marketing authorisations) has effect. **]**

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

F2 Reg. 4(4) inserted (E.W.S.) (31.12.2020) by The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/865), regs. 1(2), **17(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Reg. 4(5) inserted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461), regs. 1(2)(b), **4(2)**

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

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

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

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

Extent Information

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

Manufacture of veterinary medicinal products

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

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

(3) "Manufacture" includes any part of the manufacture of a veterinary medicinal product until the finished product is ready for sale in its final form as specified in the marketing authorisation but does not include the manufacture of an ingredient or breaking open the package of a veterinary medicinal product(**2**).

Marketing of products not in accordance with a marketing authorisation

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

Classification, supply and possession of the product

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

(2) No person may supply a veterinary medicinal product that has passed its expiry date.

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

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

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

Administration of the product E+W+S

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

(a) the product has a marketing authorisation authorising its administration in the United Kingdom, and the administration is in accordance with that marketing authorisation; or

(**1**) If the manufacture is carried out in the United Kingdom the manufacturer must hold a manufacturing authorisation for that type of product granted by the Secretary of State.
(**2**) For provisions on breaking open packages see regulation 7(3).

(b) it is administered in accordance with Schedule 4 (administration of a veterinary medicinal product outside the terms of a marketing authorisation) or Schedule 6 (exemptions for small pet animals).

Extent Information

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

Administration of the product N.I.

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

(a) the product has a marketing authorisation authorising its administration in **[**F5Northern Ireland**]**, and the administration is in accordance with that marketing authorisation; or

(b) it is administered in accordance with Schedule 4 (administration of a veterinary medicinal product outside the terms of a marketing authorisation) or Schedule 6 (exemptions for small pet animals).

Extent Information

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

F5 Words in reg. 8(a) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(3)**

Importation of authorised veterinary medicinal products E+W+S

9.—**[**F4(1) No person may import, or move into Great Britain from Northern Ireland, a veterinary medicinal product authorised for use in Great Britain except in accordance with this regulation.**]**

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

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

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

(a) the authorisation covers the product; and

(b) the dealer has notified the holder of the marketing authorisation in writing before importation.

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

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

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

Extent Information

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

F4 Reg. 9(1) substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461), regs. 1(2)(b), **4(3)**

Importation of authorised veterinary medicinal products N.I.

9.—(1) No person may import a veterinary medicinal product authorised for use in **[**[F6]Northern Ireland**]** except in accordance with this regulation.

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

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

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

(a) the authorisation covers the product; and

(b) the dealer has notified the holder of the marketing authorisation in writing before importation.

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

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

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

Extent Information

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

F6 Words in reg. 9(1) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(4)**

Advertising the product

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

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

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

(a) the list is sent following a request from the veterinary surgeon to whom it is sent; and

(b) the list states clearly that the product does not have a marketing authorisation as a veterinary medicinal product, and may only be prescribed and administered under the cascade.

Advertising of prescription products and products containing psychotropic drugs or narcotics

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

(a) is available on veterinary prescription only; or

(b) contains psychotropic drugs or narcotics.

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

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

(a) veterinary surgeons;

(b) veterinary nurses;

(c) pharmacists; or

(d) professional keepers of animals.

(4) No person may advertise anti-microbials to professional keepers of animals.

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

(a) veterinary surgeons;

(b) pharmacists;

(c) suitably qualified persons registered in accordance with paragraph 14 of Schedule 3;

(d) other veterinary health care professionals; or

(e) professional keepers of animals.

Defence of publication in the course of business

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

(a) that that person's business is to publish or arrange for the publication of advertisements, and

(b) that the advertisement was received in the ordinary course of business and the person charged did not know and had no reason to suspect that its publication would amount to an offence under these Regulations.

Wholesale dealing

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

Feedingstuffs

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

Exemptions

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

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

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

(b) used for the treatment of—

(i) other animals on the same site;

(ii) animals intended to be sent to those premises; or

(iii) animals on a site that receives animals from those premises.

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

(a) blood or blood constituents from a blood bank authorised in accordance with Part 3 of Schedule 2;

(b) a product manufactured for administration under the cascade by a person and in premises authorised in accordance with Part 4 of Schedule 2; or

(c) equine stem cell products for use as an autologous treatment for horses from an equine collection centre authorised in accordance with Part 5 of Schedule 2.

(4) Schedule 6 (exemptions for small pet animals) has effect.

Fees

16. Schedule 7 (fees) has effect.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 2.