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 9

Homeopathic remedies

Meaning of "homeopathic remedy" E+W+S

62. For the purposes of these Regulations, a homeopathic remedy is a veterinary medicinal product (which may contain a number of principles) prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia(**1**) or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission [F3]....

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. 62 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(30)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Meaning of "homeopathic remedy" N.I.

62. For the purposes of these Regulations, a homeopathic remedy is a veterinary medicinal product (which may contain a number of principles) prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia(**1**) or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission or by the competent authority of any member State.

(**1**) ISBN 9287145873.
(**1**) ISBN 9287145873.

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

Placing a homeopathic remedy on the market in accordance with a registration E+W+S

63.—(1) By way of derogation from the provisions of these Regulations requiring a marketing authorisation for a veterinary medicinal product, a homeopathic remedy may be placed on the market in accordance with a registration by the Secretary of State instead of in accordance with a marketing authorisation if it complies with this paragraph.

(2) It must not be an immunological product.

(3) The route of administration must be as described in the European Pharmacopoeia[F4]....

(4) There must be a sufficient degree of dilution to guarantee the safety of the product, and in any event it must not contain more than one part in 10,000 of the mother tincture.

(5) All other provisions relating to marketing authorisations apply in the same way to registrations of a homeopathic remedy.

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 Words in Sch. 1 para. 63(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(31)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Placing a homeopathic remedy on the market in accordance with a registration N.I.

63.—(1) By way of derogation from the provisions of these Regulations requiring a marketing authorisation for a veterinary medicinal product, a homeopathic remedy may be placed on the market in accordance with a registration by the Secretary of State instead of in accordance with a marketing authorisation if it complies with this paragraph.

(2) It must not be an immunological product.

(3) The route of administration must be as described in the European Pharmacopoeia or, if it is not described there, by a pharmacopoeia currently used officially in any member State.

(4) There must be a sufficient degree of dilution to guarantee the safety of the product, and in any event it must not contain more than one part in 10,000 of the mother tincture.

(5) All other provisions relating to marketing authorisations apply in the same way to registrations of a homeopathic remedy.

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

Application for registration E+W+S

64.—(1) An applicant for registration must submit the following to the Secretary of State—

(a) the scientific name or other name of the homeopathic stock given in a pharmacopoeia, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution;

(b) a dossier describing how the homeopathic stock is obtained and controlled, and justifying its homeopathic nature, on the basis of an adequate bibliography;

(c) in the case of a product containing biological substances, a description of the measures taken to ensure the absence of pathogens;

(d) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;

(e) a copy of the manufacturing authorisation for the product;

(f) copies of any registrations or authorisations obtained for the same homeopathic remedy[F5]...;

(g) a mock-up of the outer packaging and immediate packaging;

(h) stability data;

(i) the proposed withdrawal period necessary to ensure that the provisions of Regulation (EC) No 470/2009 of the European Parliament and of the Council are complied with together with all necessary justification.

(2) These documents must demonstrate the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned.

(3) In the case of a food-producing animal, if the applicant states in the application that the homeopathic remedy contains an active substance, or has been manufactured using an active substance, that substance must be one **[**[F6]for which a maximum residue limit has been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council.**]**

[F7](4) . . . . . .

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 Words in Sch. 1 para. 64(1)(f) 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(32)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Words in Sch. 1 para. 64(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(32)(b)** (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. 64(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(32)(c)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Application for registration N.I.

64.—(1) An applicant for registration must submit the following to the Secretary of State—

(a) the scientific name or other name of the homeopathic stock given in a pharmacopoeia, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution;

(b) a dossier describing how the homeopathic stock is obtained and controlled, and justifying its homeopathic nature, on the basis of an adequate bibliography;

(c) in the case of a product containing biological substances, a description of the measures taken to ensure the absence of pathogens;

(d) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;

(e) a copy of the manufacturing authorisation for the product;

(f) copies of any registrations or authorisations obtained for the same homeopathic remedy in other member States;

(g) a mock-up of the outer packaging and immediate packaging;

(h) stability data;

(i) the proposed withdrawal period necessary to ensure that the provisions of Regulation (EC) No 470/2009 of the European Parliament and of the Council are complied with together with all necessary justification.

(2) These documents must demonstrate the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned.

(3) In the case of a food-producing animal, if the applicant states in the application that the homeopathic remedy contains an active substance, or has been manufactured using an active substance, that substance must be one that appears in Table 1 in the Annex to Commission Regulation (EU) No 37/2010 and complies with any requirements in that Table relating to that substance.

(4) If a product is registered in **[**[F8]a**]** member State, the Secretary of State may waive some or all of the requirements of this paragraph on being satisfied that it is reasonable to do so.

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

F8 Word in Sch. 1 para. 64(4) 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)(k)**

Procedure for registration

65.—(1) The procedure for registration is the same as the procedure for granting a marketing authorisation in accordance with Part 3, except—

(a) the applicant is not required to provide proof of efficacy;

(b) the product is not required to have a summary of product characteristics;

(c) the Secretary of State is not required to publish an assessment report.

(2) The procedure for variation, suspension and revocation is the same as for a marketing authorisation.

Products on the market before 1994

66. A homeopathic remedy that was on the market before 1st January 1994 may be placed on the market without being registered.

Classification

67. The registration must specify the classification of the homeopathic remedy, which must be one of the classifications specified for a veterinary medicinal product in Schedule 3.

Offences

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

(a) a requirement made under paragraph 27(1);

(b) a request made under paragraph 27(2);

(c) paragraph 28(1) or (2);

(d) a requirement made under paragraph 28(3);

(e) paragraph 29(3);

(f) paragraph 30;

(g) paragraph 31(1) or (2);

(h) a request made under paragraph 31(3);

(i) a prohibition or requirement made under paragraph 39(4);

(j) a prohibition or requirement made under paragraph 41(1);

(k) paragraph 55;

(l) paragraph 56;

(m) paragraph 57;

(n) paragraph 58;

(o) paragraph 59; or

(p) paragraph 60.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 9.