SCHEDULE 1

Marketing authorisations **[**F1in Great Britain**][**F2in 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

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[F3]...;

(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 **[**F4for which a maximum residue limit has been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council.**]**

F5(4) . . . . . .

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. 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)**

F4 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)**

F5 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 **[**[F6]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

E2 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 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)**

Status:
There are multiple versions of this provision on screen. These apply to different geographical extents.
Skip to:

– E+W+S - England, Wales and Scotland extent
– N.I. - Northern Ireland extent

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, Paragraph 64.