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 2

Derogations from some of the requirements in Part 1

Time limits for marketing authorisations granted under the procedure for a [F3generic veterinary medicinal] product E+W+S

11.—(1) This paragraph establishes the time limits relating to granting a marketing authorisation under the procedure for a **[**[F4]generic veterinary medicinal**]** product.

(2) An application for a marketing authorisation cannot be made until two years before the product may be placed on the market in accordance with this paragraph.

[[F5](3) The product may not be placed on the market until the end of the longest of the following periods which is relevant—

(a) subject to sub-paragraph (3A), 10 years in the case of a veterinary medicinal product authorised for major species;

(b) 18 years in the case of a veterinary medicinal product authorised for bees; and

(c) 14 years for a veterinary medicinal product authorised for all other species.

(3A) Where the product—

(a) is intended for administration to a major species; and

(b) contains an active substance which is an antimicrobial which has not been an active substance in a veterinary medicinal product previously subject to a marketing authorisation in Great Britain,

the period mentioned in sub-paragraph (3)(a) is 14 years.

(3B) Where a patent in relation to a reference product has lapsed, the summary of product characteristics of the relevant generic product must be updated in order to include the protected information.

(3C) Where, as a result of a variation to an existing marketing authorisation a product is accorded a new marketing authorisation number any relevant protection period applies in relation to that product.

(3D) In this regulation "major species" means cattle, sheep (for meat production), pigs, chickens, dogs and cats.**]**

(4) Time limits in this paragraph are calculated from the first grant of the marketing authorisation for the reference product.

Textual Amendments

F3 Words in Sch. 1 para. 11 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **35(c)**

F4 Words in Sch. 1 para. 11(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **35(a)**

F5 Sch. 1 para. 11(3)-(3D) substituted for Sch. 1para. 11(3) (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **35(b)**

Time limits for marketing authorisations granted under the procedure for a pharmacologically equivalent product N.I.

11.—(1) This paragraph establishes the time limits relating to granting a marketing authorisation under the procedure for a pharmacologically equivalent product.

(2) An application for a marketing authorisation cannot be made until two years before the product may be placed on the market in accordance with this paragraph.

(3) The product may not be placed on the market until ten years (or, in the case of medicinal products for fish or bees where the application for a marketing authorisation was submitted after 30th October 2005, thirteen years) have elapsed from the initial authorisation of the reference product.

(4) Time limits in this paragraph are calculated from the first grant of the marketing authorisation for the reference product.

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 11.