SCHEDULE 1

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

F1 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 4

Variations of marketing authorisations on the application of the holder

Variation of a marketing authorisation

33.—(1) The Secretary of State is the competent authority for the purposes of Commission Regulation (EC) No 1234/2008(**1**).

(2) The holder of a marketing authorisation may apply to the Secretary of State for a variation of that marketing authorisation.

(3) An application for a variation under paragraph (2) may only relate to a "single variation" unless the application is submitted in accordance with—

(a) Article 7 of Commission Regulation (EC) No 1234/2008 ("grouped variations"), or

(b) Article 20 of Commission Regulation (EC) No 1234/2008 ("workshare variations").

(4) The Secretary of State, when granting a variation of a veterinary medicinal product, may (unless there are exceptional circumstances necessary to protect human or animal health or the environment) specify transitional measures to enable products produced in accordance with the previous authorisation to continue to be marketed for the transitional period.

Refusal of a variation of a marketing authorisation

34.—(1) This paragraph applies in relation to the refusal by the Secretary of State of an application for a variation unless the procedure following the refusal of a variation is one of those set out in Article 13 of Regulation 1234/2008.

(2) The grounds on which the Secretary of State may refuse an application for a variation of a marketing authorisation are those set out in paragraph 24 of this Schedule (refusal of a marketing authorisation).

(3) The Secretary of State must give written reasons for refusing to grant a variation; and if—

(a) those reasons are on the grounds of safety, quality or efficacy; and

(b) the variation is Type II or an extension application (whether or not in each case as part of an application for a worksharing or grouped application),

the applicant may appeal to the Veterinary Products Committee.

(**1**) OJ No L334, 12.12.2008, p. 7.

Administrative variations

35.—(1) The holder of a marketing authorisation may apply for a minor change in a marketing authorisation to be made without the Secretary of State considering any scientific data (an "administrative variation").

(2) If the Secretary of State grants an administrative variation, and subsequently establishes that this should have been a variation requiring consideration of scientific data, the Secretary of State may notify the marketing authorisation holder, require the holder to submit an application for a variation enabling data to be assessed and revoke the administrative variation.

Changes after a marketing authorisation has been issued

36. After a marketing authorisation has been issued, the holder must take account of scientific and technical progress in manufacturing and control methods, and apply to the Secretary of State for any variation in the marketing authorisation that may be required to enable that veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

Compulsory variation

37.—(1) If the Secretary of State decides, for any of the reasons for suspending a marketing authorisation specified in paragraph 38, or because the classification of a veterinary medicinal product should be changed, that a variation to a marketing authorisation is necessary, the Secretary of State must by a notification in writing to the holder of the marketing authorisation require that person to apply for a variation of the marketing authorisation, giving reasons for requiring the application to be made.

(2) The notification may specify a time limit within which the marketing authorisation holder must apply for the variation.

(3) If the variation is on the grounds of safety, quality or efficacy, the applicant may, within 28 days of the notification, appeal to the Veterinary Products Committee.

(4) If the marketing authorisation holder fails to apply for the variation within that time limit the Secretary of State may suspend or revoke the marketing authorisation.

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