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 4

Variations of marketing authorisations on the application of the holder

Variation of a marketing authorisation E+W+S

33.—F3(1) . . . . . .

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

[F4(3) An application for a variation under paragraph (2) may only relate to—

(a) a single variation, which may relate to one or more marketing authorisations, or

(b) one or more variations to a single marketing authorisation.**]**

(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.

Textual Amendments

F3 Sch. 1 para. 33(1) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **53(a)**

F4 Sch. 1 para. 33(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **53(b)**

Variation of a marketing authorisation N.I.

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

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

(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.

Extent Information

E1 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

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 33.