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 2

Derogations from some of the requirements in Part 1

[F1**Time limits – supplementary**

12A.—(1) Subject to sub-paragraph (3), a study, residue test or pre-clinical study in relation to the establishment of residue limits submitted by an applicant in relation to an application for a marketing authorisation or a variation of a marketing authorisation may not be used for any other such application or variation until the period of five years from that submission has elapsed.

(2) Subject to sub-paragraph (3), a study, residue test or preclinical study submitted by an applicant for a marketing authorisation or a variation in a marketing authorisation which demonstrates a reduction in antimicrobial resistance in relation to a reference product may not be used for any other such application until a period of four years in addition to the relevant protection period has elapsed.

(3) Sub-paragraphs (1) and (2) do not apply where an applicant has obtained a written authorisation to access a study, residue test or pre-clinical study mentioned in the relevant sub-paragraph.**]**

Textual Amendments

F1 Sch. 1 para. 12A inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **37**

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, Paragraph 12A.