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**Hybrid veterinary medicinal products**

10A. An applicant for a marketing authorisation must provide the results of relevant pre-clinical studies or clinical trials where—

(a) bioavailability studies are not capable of demonstrating bioequivalence between the veterinary medicinal product for which the authorisation is sought and a reference veterinary medicinal product for the purposes of paragraph 10; or

(b) the veterinary medicinal product for which the authorisation is sought is not pharmacologically equivalent to a reference veterinary medicinal product for the purposes of paragraph 10 as a result of a difference in relation to—

(i) the active substance or substances contained in the product;

(ii) the strength of the product;

(iii) the indications for use of the product;

(iv) the pharmaceutical form of the product;

(v) the route of administration of the product;

(vi) the withdrawal period for the product.**]**

Textual Amendments

F1 Sch. 1 para. 10A inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **34**

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, Paragraph 10A.