STATUTORY INSTRUMENTS

2024 No. 567

The Veterinary Medicines (Amendment etc.) Regulations 2024

PART 3

Amendments to Schedule 1 to the 2013 Regulations

Amendment to paragraph 7

- **31.** In paragraph 7 (bibliographic application)—
 - (a) in sub-paragraph (1), for the words from "if the active" to the end substitute "if the applicant demonstrates that the active substances of the veterinary medicinal product have been in well-established veterinary use for at least 10 years, that their efficacy is documented and that they provide an acceptable level of safety";
 - (b) after sub-paragraph (1) insert—
 - "(1A) Sub-paragraph (1) does not apply to applications for—
 - (a) biological (including immunological) veterinary medicinal products;
 - (b) novel therapies.".