DRAFT STATUTORY INSTRUMENTS

2024 No.

The Veterinary Medicines (Amendment etc.) Regulations 2024

PART 3

Amendments to Schedule 1 to the 2013 Regulations

Amendment to paragraph 10

33. In paragraph 10 (application for a pharmacologically equivalent medicinal product)—

(a) in sub-paragraph (1)—

(i) at the beginning insert "Subject to sub-paragraphs (2A), (9) and (10) and paragraph 10A,";

(ii) for "pharmacologically equivalent to a" substitute "a generic of a";

(iii) at the end add "("the reference veterinary medicinal product"), provided that the applicant provides data demonstrating the matters referred to in sub-paragraph (2)";

(b) in sub-paragraph (2)—

(i) for "pharmacologically equivalent to" substitute "a generic of";

(ii) in paragraph (b) after "pharmaceutical form" insert "as the reference product";

(iii) for paragraph (c) substitute—

"(c) bioequivalence with the reference product has been demonstrated";

(c) after sub-paragraph (2) insert—

"(2A) Sub-paragraph (1) does not apply to applications for biological (including immunological) veterinary medicinal products.";

(d) in sub-paragraph (5) after "Agency" insert "or the Secretary of State";

(e) omit sub-paragraph (6);

(f) after sub-paragraph (6) insert—

"(7) For the purposes of these Regulations, subject to sub-paragraph (8), the summary of product characteristics of a generic veterinary medicinal product must be essentially similar to the summary of product characteristics for the reference product.

(8) The requirement in sub-paragraph (7) does not apply in relation to those parts of the summary of product characteristics of the reference product that refer to indications or pharmaceutical forms which are covered by patents at the time when the generic veterinary medicinal product is authorised.

(9) Notwithstanding sub-paragraph (1), in respect of generic veterinary medicinal products intended to be administered by intramuscular, subcutaneous or transdermal routes, the applicant must provide—

(a) administration site target animal tolerance data;

(b) in respect of products intended for administration to food-producing species only, residues depletion data from the site of administration.

(10) Notwithstanding sub-paragraph (1), in respect of generic veterinary medicinal products containing antimicrobial or antiparasitic substances, the applicant must provide all available data (including published data) on the current level of resistance, together with a review of that data as it relates to target pathogens to the active substances concerned.

(11) An applicant must provide an environmental risk assessment for a generic veterinary medicinal product where—

(a) the marketing authorisation for the reference veterinary medicinal product was granted before 1st October 2005, and

(b) no marketing authorisation has been granted since 1st October 2005 in respect of a veterinary medicinal product which has the same active substance and pharmaceutical form as the reference veterinary medicinal product, and which is indicated for use in the same target species when administered at the same or a higher total dose,

unless the Secretary of State holds an environmental risk assessment for the reference veterinary medicinal product and has confirmed this to the applicant.";

(g) in the heading for "pharmacologically equivalent" substitute "generic veterinary".