Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

CHAPTER II

MARKETING AUTHORISATIONS – GENERAL PROVISIONS AND RULES ON APPLICATIONS

Section 2

Dossier requirements

Article 8

Data to be submitted with the application

1 An application for a marketing authorisation shall contain the following:

a the information set out in Annex I;

b technical documentation necessary for demonstrating the quality, safety and efficacy of the veterinary medicinal product in accordance with the requirements set out in Annex II;

c a summary of the pharmacovigilance system master file.

2 Where the application concerns an antimicrobial veterinary medicinal product, the following shall be submitted in addition to the information, technical documentation and summary listed in paragraph 1:

a documentation on the direct or indirect risks to public or animal health or to the environment of use of the antimicrobial veterinary medicinal product in animals;

b information about risk mitigation measures to limit antimicrobial resistance development related to the use of the veterinary medicinal product.

3 Where the application concerns a veterinary medicinal product intended for food-producing animals and containing pharmacologically active substances that are not allowed in accordance with Regulation (EC) No 470/2009 and with any acts adopted on the basis thereof for the animal species concerned, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with that Regulation shall be submitted in addition to the information, technical documentation and summary listed in paragraph 1 of this Article.

4 Paragraph 3 of this Article shall not apply to veterinary medicinal products intended for animals of the equine species that have been declared as not being intended for slaughter for human consumption in the single lifetime identification document referred to in point (c) of Article 114(1) of Regulation (EU) 2016/429 and in any acts adopted on the basis thereof and the active substances contained in those veterinary medicinal products are not allowed in accordance with Regulation (EC) No 470/2009 or with any acts adopted on the basis thereof.

5 Where the application concerns a veterinary medicinal product containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive

2001/18/EC of the European Parliament and of the Council[(1)], the application shall, in addition to the information, technical documentation and summary listed in paragraph 1 of this Article, be accompanied by:

a a copy of the written consent of the competent authorities to the deliberate release into the environment of the genetically modified organisms for research and development purposes, as provided for in Part B of Directive 2001/18/EC;

b the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC;

c the environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and

d the results of any investigations performed for the purposes of research or development.

6 Where the application is submitted in accordance with the national procedure set out in Articles 46 and 47, the applicant shall, in addition to the information, technical documentation and summary listed in paragraph 1 of this Article, submit a declaration stating that he or she has not submitted an application for a marketing authorisation for the same veterinary medicinal product in another Member State or in the Union and, if applicable, that no such marketing authorisation has been granted in another Member State or in the Union.

(**1**) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).