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 7

Examination of applications and basis for granting marketing authorisations

Article 28

Examination of applications

1 The competent authority or the Agency, as applicable, to which the application has been submitted in accordance with Article 6 shall:

a verify that the data submitted complies with the requirements laid down in Article 8;

b assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided;

c draw up a conclusion on the benefit-risk balance for the veterinary medicinal product.

2 During the process of examination of applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms as referred to in Article 8(5) of this Regulation, the Agency shall hold the necessary consultations with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC.

Article 29

Requests to laboratories in the course of the examination of applications

1 The competent authority or the Agency, as applicable, examining the application may require an applicant to provide to the European Union reference laboratory, an official medicines control laboratory or a laboratory that a Member State has designated for that purpose samples which are necessary to:

a test the veterinary medicinal product, its starting materials and, if necessary, intermediate products or other constituent materials in order to ensure that the control methods employed by the manufacturer and described in the application documents are satisfactory;

b verify that, in the case of veterinary medicinal products intended for food-producing animals, the analytical detection method proposed by the applicant for the purposes of residue depletion tests is satisfactory and suitable for use to reveal the presence of residue levels, particularly those exceeding the maximum residue level of the pharmacologically active substance established by the Commission in accordance with Regulation (EC) No 470/2009, and for the purpose of official controls of animals and products of animal origin in accordance with Regulation (EU) 2017/625.

2 The time limits laid down in Articles 44, 47, 49, 52 and 53 shall be suspended until the samples requested in accordance with paragraph 1 of this Article have been provided.

Article 30

Information on manufacturers in third countries

The competent authority or the Agency, as applicable, to which the application has been submitted in accordance with Article 6 shall ascertain, through the procedure laid down in Articles 88, 89 and 90, that the manufacturers of veterinary medicinal products from third countries are able to manufacture the veterinary medicinal product concerned or carry out control tests in accordance with the methods described in the documentation submitted in support of the application in accordance with Article 8(1). A competent authority or the Agency, as applicable, may request the relevant competent authority to present information ascertaining that the manufacturers of veterinary medicinal products are able to carry out the activities referred to in this Article.

Article 31

Additional information from the applicant

The competent authority or the Agency, as applicable, to which the application has been submitted in accordance with Article 6, shall inform the applicant if the documentation submitted in support of the application is insufficient. The competent authority or the Agency, as applicable, shall request the applicant to provide additional information within a given time limit. In such a case the time limits laid down in Articles 44, 47, 49, 52 and 53 shall be suspended until the additional information has been provided.

Article 32

Withdrawal of applications

1 An applicant may withdraw the application for marketing authorisation submitted to a competent authority or the Agency, as applicable, at any time before the decision referred to in Article 44, 47, 49, 52 or 53 has been taken.

2 If an applicant withdraws the application for a marketing authorisation submitted to a competent authority or the Agency, as applicable, before the examination of the application as referred to in Article 28 has been completed, the applicant shall communicate the reasons for doing so to the competent authority or the Agency, as applicable, to which the application was submitted in accordance with Article 6.

3 The competent authority or the Agency, as applicable, shall make publicly available the information that the application has been withdrawn, together with the report or the opinion, as applicable, if already drawn up, after deletion of any commercially confidential information.

Article 33

Outcome of the assessment

1 The competent authority or the Agency, as applicable, examining the application in accordance with Article 28, shall prepare, respectively, an assessment report or an opinion. In case of a favourable assessment, that assessment report or opinion shall include the following:

a a summary of the product characteristics containing the information laid down in Article 35;

b details of any conditions or restrictions to be imposed as regards the supply or safe and effective use of the veterinary medicinal product concerned, including the classification of a veterinary medicinal product in accordance with Article 34;

c the text of the labelling and package leaflet referred to in Articles 10 to 14.

2 In the case of an unfavourable assessment, the assessment report or the opinion referred to in paragraph 1 shall contain the justification for its conclusions.

Article 34

Classification of veterinary medicinal products

1 The competent authority or the Commission, as applicable, granting a marketing authorisation as referred to in Article 5(1) shall classify the following veterinary medicinal products as subject to veterinary prescription:

a veterinary medicinal products which contain narcotic drugs or psychotropic substances, or substances frequently used in the illicit manufacture of those drugs or substances, including those covered by the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the United Nations Convention on Psychotropic Substances of 1971, the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 or by Union legislation on drug precursors;

b veterinary medicinal products for food-producing animals;

c antimicrobial veterinary medicinal products;

d veterinary medicinal products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic measures;

e veterinary medicinal products used for euthanasia of animals;

f veterinary medicinal products containing an active substance that has been authorised for less than five years in the Union;

g immunological veterinary medicinal products;

h without prejudice to Council Directive 96/22/EC[(1)], veterinary medicinal products containing active substances having a hormonal or thyrostatic action or beta-agonists.

2 The competent authority or the Commission, as applicable, may, notwithstanding paragraph 1 of this Article, classify a veterinary medicinal product as subject to veterinary prescription if it is classified as a narcotic drug in accordance with national law or where special precautions are contained in the summary of product characteristics referred to in Article 35.

3 By way of derogation from paragraph 1, the competent authority or the Commission, as applicable, may, except as regards veterinary medicinal products referred to in points (a), (c),

(e) and (h) of paragraph 1, classify a veterinary medicinal product as not subject to veterinary prescription if all of the following conditions are fulfilled:

a the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products;

b the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated or to other animals, to the person administering it or to the environment;

c the summary of the product characteristics of the veterinary medicinal product does not contain any warnings of potential serious adverse events deriving from its correct use;

d neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting;

e the summary of the product characteristics does not refer to contra-indications related to the use of the product concerned in combination with other veterinary medicinal products commonly used without prescription;

f there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal product is used incorrectly;

g there is no risk to public or animal health as regards the development of resistance to substances even where the veterinary medicinal product containing those substances is used incorrectly.

Article 35

Summary of the product characteristics

1 The summary of the product characteristics referred to in point (a) of Article 33(1) shall contain, in the order indicated below, the following information:

a name of the veterinary medicinal product followed by its strength and pharmaceutical form and, where applicable, a list of the names of the veterinary medicinal product, as authorised in different Member States;

b qualitative and quantitative composition of the active substance or substances and qualitative composition of excipients and other constituents stating their common name or their chemical description and their quantitative composition, if that information is essential for proper administration of the veterinary medicinal product;

c clinical information:

(i) target species;

(ii) indications for use for each target species;

(iii) contra-indications;

(iv) special warnings;

(v) special precautions for use, including in particular special precautions for safe use in the target species, special precautions to be taken by the person administering the veterinary medicinal product to the animals and special precautions for the protection of the environment;

(vi) frequency and seriousness of adverse events;

(vii) use during pregnancy, lactation or lay;

(viii) interaction with other medicinal products and other forms of interaction;

(ix) administration route and dosage;

(x) symptoms of overdose and, where applicable, emergency procedures and antidotes in the event of overdose;

(xi) special restrictions for use;

(xii) special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance;

(xiii) if applicable, withdrawal periods, even if such periods are zero;

d pharmacological information:

(i) Anatomical Therapeutic Chemical Veterinary Code (‘ATCvet Code’);

(ii) pharmacodynamics;

(iii) pharmacokinetics.

In case of an immunological veterinary medicinal product, instead of points (i), (ii) and (iii), immunological information;

e pharmaceutical particulars:

(i) major incompatibilities;

(ii) shelf life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time;

(iii) special precautions for storage;

(iv) nature and composition of immediate packaging;

(v) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products;

f name of the marketing authorisation holder;

g marketing authorisation number or numbers;

h date of the first marketing authorisation;

i date of the last revision of the summary of the product characteristics;

j if applicable, for veterinary medicinal products referred to in Article 23 or 25, the statement:

(i) ‘marketing authorisation granted for a limited market and therefore assessment based on customised requirements for documentation’; or

(ii) ‘marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation’;

k information on the collection systems referred to in Article 117 applicable to the veterinary medicinal product concerned;

l classification of the veterinary medicinal product as referred to in Article 34 for each Member State in which it is authorised.

2 In the case of generic veterinary medicinal products, the parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are protected by patent law in a Member State at the time of placing of the generic veterinary medicinal product on the market may be omitted.

Article 36

Decisions granting marketing authorisations

1 Decisions granting marketing authorisations referred to in Article 5(1) shall be taken on the basis of the documents prepared in accordance with Article 33(1) and shall set out any conditions attached to the placing on the market of the veterinary medicinal product and the summary of the product characteristics ('terms of the marketing authorisation').

2 Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission, as applicable, may require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive given the potential development of antimicrobial resistance.

Article 37

Decisions refusing marketing authorisations

1 Decisions refusing marketing authorisations referred to in Article 5(1) shall be taken on the basis of the documents prepared in accordance with Article 33(1) and shall be duly justified and include the reasons for refusal.

2 A marketing authorisation shall be refused if any of the following conditions are met:

a the application does not comply with this Chapter;

b the benefit-risk balance of the veterinary medicinal product is negative;

c the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product;

d the veterinary medicinal product is an antimicrobial veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals;

e the proposed withdrawal period is not long enough to ensure food safety or is insufficiently substantiated;

f the risk for public health in case of development of antimicrobial resistance or antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health;

g the applicant has not provided sufficient proof of efficacy as regards the target species;

h the qualitative or quantitative composition of the veterinary medicinal product is not as stated in the application;

i risks to public or animal health or to the environment are not sufficiently addressed; or

j the active substance within the veterinary medicinal product meets the criteria for being considered persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, and the veterinary medicinal product is intended to be used in food-producing animals, unless it is demonstrated that the active substance is essential to prevent or control a serious risk to animal health.

3 A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans as provided for in paragraph 5.

4 The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Regulation by establishing the criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of those antimicrobials.

5 The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

6 The Commission shall, when adopting the acts referred to in paragraphs 4 and 5, take into account the scientific advice of the Agency, the EFSA and other relevant Union agencies.

(**1**) Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p. 3).