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 1

General provisions

Article 5

Marketing authorisations

1 A veterinary medicinal product shall be placed on the market only when a competent authority or the Commission, as applicable, has granted a marketing authorisation for that product in accordance with Article 44, 47, 49, 52, 53 or 54.

2 A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time.

3 Decisions to grant, refuse, suspend, revoke or amend by way of a variation a marketing authorisation shall be made public.

4 A marketing authorisation for a veterinary medicinal product shall only be granted to an applicant established in the Union. The requirement to be established in the Union shall also apply to marketing authorisation holders.

5 A marketing authorisation for a veterinary medicinal product intended for one or more food-producing animal species may only be granted if the pharmacologically active substance is allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof for the animal species concerned.

6 In the case of veterinary medicinal products intended for animals which are exclusively kept as pets: aquarium or pond animals, ornamental fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits, Member States may allow exemptions from this Article, provided that such veterinary medicinal products are not subject to a veterinary prescription and that all necessary measures are in place in the Member State to prevent unauthorised use of those veterinary medicinal products for other animals.

Article 6

Submission of applications for marketing authorisations

1 Applications for marketing authorisations shall be submitted to the competent authority where they concern the granting of marketing authorisations in accordance with any of the following procedures:

a the national procedure laid down in Articles 46 and 47;
b the decentralised procedure laid down in Articles 48 and 49;
c the mutual recognition procedure laid down in Articles 51 and 52;
d the subsequent recognition procedure laid down in Article 53.

2 Applications for marketing authorisations shall be submitted to the Agency where they concern the granting of marketing authorisations in accordance with the centralised marketing authorisation procedure laid down in Articles 42 to 45.

3 Applications referred to in paragraphs 1 and 2 shall be submitted electronically and the formats made available by the Agency shall be used.

4 The applicant shall be responsible for the accuracy of the information and documentation submitted with respect to its application.

5 Within 15 days of receipt of the application, the competent authority or the Agency, as applicable, shall notify the applicant as to whether all the information and documentation required in accordance with Article 8 have been submitted and whether the application is valid.

6 Where the competent authority or the Agency, as applicable, considers that the application is incomplete, it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn.

7 If the applicant fails to provide a complete translation of the required documentation within a period of six months after having received the information referred to in Article 49(7), 52(8) or 53(2), the application shall be considered to have been withdrawn.

Article 7

Languages

1 The language or languages of the summary of the product characteristics and the information on the labelling and on the package leaflet shall, unless the Member State determines otherwise, be an official language or languages of the Member State where the veterinary medicinal product is made available on the market.

2 Veterinary medicinal products may be labelled in several languages.

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.

Section 3

Clinical trials

Article 9

Clinical trials

1 An application for the approval of a clinical trial shall be submitted in accordance with the applicable national law to a competent authority of the Member State in which the clinical trial is to take place.

2 Approvals of clinical trials shall be granted on condition that food-producing animals used in the clinical trials or their produce do not enter the food chain unless an appropriate withdrawal period has been set by the competent authority.

3 The competent authority shall issue a decision to approve or refuse a clinical trial within 60 days of the receipt of a valid application.

4 The clinical trials shall be carried out taking due account of the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ('VICH').

5 Data stemming from clinical trials shall be submitted with the application for a marketing authorisation for the purposes of providing the documentation referred to in point (b) of Article 8(1).

6 Data stemming from clinical trials conducted outside the Union may be taken into consideration for the assessment of an application for a marketing authorisation only if those trials were designed, implemented and reported in accordance with the international guidelines on good clinical practice of the VICH.

Section 4

Labelling and package leaflet

Article 10

Labelling of the immediate packaging of veterinary medicinal products

1 The immediate packaging of a veterinary medicinal product shall contain the following information and shall, subject to Article 11(4), contain no information other than:

a the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;

b a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names;

c the batch number, preceded by the word 'Lot';

d the name or company name or logo name of the marketing authorisation holder;

e the target species;

f the expiry date, in the format: 'mm/yyyy', preceded by the abbreviation 'Exp.';

g special storage precautions, if any;

h route of administration; and

i if applicable, the withdrawal period, even if such period is zero.

2 The information referred to in paragraph 1 of this Article shall appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms common throughout the Union as listed in accordance with Article 17(2).

3 Notwithstanding paragraph 1, a Member State may decide that, on the immediate packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1.

Article 11

Labelling of the outer packaging of veterinary medicinal products

1 The outer packaging of a veterinary medicinal product shall contain the following information and shall contain no information other than:

a the information referred to in Article 10(1);

b the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;

c a warning that the veterinary medicinal product must be kept out of the sight and reach of children;

d a warning that the veterinary medicinal product is ‘for animal treatment only’;

e without prejudice to Article 14(4), a recommendation to read the package leaflet;

f in the case of homeopathic veterinary medicinal products, the statement ‘homeopathic veterinary medicinal product’;

g in the case of veterinary medicinal products not subject to a veterinary prescription, the indication or indications;

h the marketing authorisation number.

2 A Member State may decide that, on the outer packaging of a veterinary medicinal product made available in its territory, an identification code shall be added to the information required under paragraph 1. Such a code may be used to replace the marketing authorisation number referred to in point (h) of paragraph 1.

3 The information referred to in paragraph 1 of this Article shall appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms common throughout the Union, as listed in accordance with Article 17(2).

4 Where there is no outer packaging, all the information referred to in paragraphs 1 and 2 shall appear on the immediate packaging.

Article 12

Labelling of small immediate packaging units of veterinary medicinal products

1 By way of derogation from Article 10, immediate packaging units which are too small to contain in a readable form the information referred to in that Article shall contain the following information and shall contain no information other than:

a the name of veterinary medicinal product;

b the quantitative particulars of the active substances;

c the batch number, preceded by the word 'Lot';

d the expiry date, in the format: 'mm/yyyy', preceded by the abbreviation 'Exp.'.

2 The immediate packaging units referred to in paragraph 1 of this Article shall have an outer packaging containing information required in Article 11(1), (2) and (3).

Article 13

Additional information on the immediate packaging or outer packaging of veterinary medicinal products

By way of derogation from Articles 10(1), 11(1) and 12(1), Member States may, within their territory, and on request of the applicant, allow an applicant to include on the immediate packaging or outer packaging of a veterinary medicinal product additional useful information which is compatible with the summary of the product characteristics and which is not an advertisement for a veterinary medicinal product.

Article 14

Package leaflet of veterinary medicinal products

1 The marketing authorisation holder shall make readily available a package leaflet for each veterinary medicinal product. That package leaflet shall contain at least the following information:

a the name or company name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where applicable, of the representative of the marketing authorisation holder;

b the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;

c qualitative and quantitative composition of the active substance or substances;

d the target species, the dosage for each species, the method and route of administration and, if necessary, advice on correct administration;

e the indications for use;

f the contra-indications and adverse events;

g if applicable, the withdrawal period, even if such period is zero;

h special storage precautions, if any;

i information essential for safety or health protection, including any special precautions relating to use and any other warnings;

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

k the marketing authorisation number;

l contact details of the marketing authorisation holder or its representative, as appropriate, for the reporting of suspected adverse events;

m classification of the veterinary medicinal product as referred to in Article 34.

2 The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. That additional information shall appear in the package leaflet clearly separated from the information referred to in paragraph 1.

3 The package leaflet shall be written and designed to be readable, clear and understandable, in terms that are comprehensible to the general public. Member States may decide that it shall be made available on paper or electronically, or both.

4 By derogation from paragraph 1, the information required in accordance with this Article may, alternatively, be provided on the packaging of the veterinary medicinal product.

Article 15

General requirement regarding product information

The information listed in Articles 10 to 14 shall comply with the summary of the product characteristics as set out in Article 35.

Article 16

Package leaflet of registered homeopathic veterinary medicinal products

By way of derogation from Article 14(1), the package leaflet of homeopathic veterinary medicinal products registered in accordance with Article 86 shall contain at least the following information:

(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the *European Pharmacopoeia* or, in the absence thereof, of the pharmacopoeias used officially in Member States;

(b) name or company name and permanent address or registered place of business of the registration holder and, where appropriate, of the manufacturer;

(c) method of administration and, if necessary, route of administration;

(d) pharmaceutical form;

(e) special storage precautions, if any;

(f) the target species and, where appropriate, dosage for each such species;

(g) a special warning, if necessary, for the homeopathic veterinary medicinal product;

(h) registration number;

(i) withdrawal period, if applicable;

(j) the statement ‘homeopathic veterinary medicinal product’.

Article 17

Implementing powers with respect to this Section

1 The Commission shall, when appropriate, by means of implementing acts, establish uniform rules on the identification code referred to in Articles 10(3) and 11(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

2 The Commission shall, by means of implementing acts, adopt a list of the abbreviations and pictograms common throughout the Union to be used for the purposes of Articles 10(2) and 11(3). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3 The Commission shall, by means of implementing acts, provide uniform rules on the size of small immediate packaging units referred to in Article 12. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Section 5

Specific requirements for generic, hybrid and combination veterinary medicinal products and for applications based on informed consent and bibliographic data

Article 18

Generic veterinary medicinal products

1 By way of derogation from point (b) of Article 8(1), it shall not be required that an application for a marketing authorisation for a generic veterinary medicinal product contain the documentation on safety and efficacy if all the following conditions are fulfilled:

a bioavailability studies have demonstrated bioequivalence of a generic veterinary medicinal product with the reference veterinary medicinal product or a justification is provided as to why such studies were not performed;

b the application satisfies the requirements set out in Annex II;

c the applicant demonstrates that the application concerns a generic veterinary medicinal product of a reference veterinary medicinal product for which the period of protection of the technical documentation laid down in Articles 39 and 40 has elapsed or is due to elapse in less than two years.

2 Where the active substance of a generic veterinary medicinal product consists of salts, esters, ethers, isomers and mixtures of isomers, complexes or derivatives differing from the active substance used in the reference veterinary medicinal product, it shall be considered to be the same active substance as that used in the reference veterinary medicinal product, unless it differs significantly in respect of properties with regard to safety or efficacy. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.

3 Where several immediate-release oral pharmaceutical forms of a generic veterinary medicinal product are presented, they shall be considered to be the same pharmaceutical form.

4 Where the reference veterinary medicinal product is not authorised in the Member State in which the application for the generic veterinary medicinal product is submitted, or the application is submitted in accordance with Article 42(4) and the reference veterinary medicinal product is authorised in a Member State, the applicant shall indicate in its application the Member State in which the reference veterinary medicinal product has been authorised.

5 The competent authority or the Agency, as applicable, may request information on the reference veterinary medicinal product from the competent authority of the Member State where it is authorised. Such information shall be transmitted to the requestor within 30 days of receipt of the request.

6 The summary of the product characteristics of the generic veterinary medicinal product shall be essentially similar to that of the reference veterinary medicinal product. However, that requirement shall not apply to those parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are still covered by patent law at the time when the generic veterinary medicinal product is authorised.

7 A competent authority or the Agency, as applicable, may require the applicant to provide safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment where the marketing authorisation for the reference veterinary medicinal product was granted before 1 October 2005.

Article 19

Hybrid veterinary medicinal products

1 By way of derogation from Article 18(1), the results of appropriate pre-clinical studies or clinical trials shall be required when the veterinary medicinal product does not meet all the characteristics of a generic veterinary medicinal product because of one or more of the following reasons:

a there are changes in the active substance or substances, indications for use, strength, pharmaceutical form or route of administration of the generic veterinary medicinal product compared to the reference veterinary medicinal product;

b bioavailability studies cannot be used to demonstrate bioequivalence with the reference veterinary medicinal product; or

c there are differences relating to raw materials or in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product.

2 The pre-clinical studies or clinical trials for a hybrid veterinary medicinal product may be conducted with batches of the reference veterinary medicinal product authorised in the Union or in a third country.

The applicant shall demonstrate that the reference veterinary medicinal product authorised in a third country has been authorised in accordance with requirements equivalent to those established in the Union for the reference veterinary medicinal product and are so highly similar that they can substitute each other in the clinical trials.

Article 20

Combination veterinary medicinal products

By way of derogation from point (b) of Article 8(1), in the case of veterinary medicinal products containing active substances used in the composition of authorised veterinary medicinal products it shall not be required to provide safety and efficacy data relating to each individual active substance.

Article 21

Application based on informed consent

By way of derogation from point (b) of Article 8(1), an applicant for a marketing authorisation for a veterinary medicinal product shall not be required to provide the technical documentation on quality, safety and efficacy if that applicant demonstrates permission, in the form of a letter of access, to use such documentation submitted in respect of the already authorised veterinary medicinal product.

Article 22

Application based on bibliographic data

1 By way of derogation from point (b) of Article 8(1), the applicant shall not be required to provide the documentation on safety and efficacy if that applicant demonstrates that the active substances of the veterinary medicinal product have been in well-established veterinary use within the Union for at least 10 years, that their efficacy is documented and that they provide an acceptable level of safety.

2 The application shall satisfy the requirements set out in Annex II.

Section 6

Marketing authorisations for limited market and in exceptional circumstances

Article 23

Applications for limited markets

1 By way of derogation from point (b) of Article 8(1), the applicant shall not be required to provide the comprehensive safety or efficacy documentation required in accordance with Annex II, if all of the following conditions are met:

a the benefit of the availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;

b the applicant provides the evidence that the veterinary medicinal product is intended for a limited market.

2 Where a veterinary medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of safety or efficacy has been conducted due to the lack of comprehensive safety or efficacy data.

Article 24

Validity of a marketing authorisation for a limited market and procedure for its re-examination

1 By way of derogation from Article 5(2), a marketing authorisation for a limited market shall be valid for a period of five years.

2 Before the expiry of the five-year period of validity referred to in paragraph 1 of this Article, marketing authorisations for a limited market granted in accordance with Article 23 shall be re-examined on the basis of an application from the holder of that marketing authorisation. That application shall include an updated benefit-risk assessment.

3 A holder of a marketing authorisation for a limited market shall submit an application for a re-examination to the competent authority that granted the authorisation or to the Agency, as applicable, at least six months before the expiry of the five-year period of validity referred to in paragraph 1 of this Article. The application for re-examination shall be limited to demonstrating that the conditions referred to in Article 23(1) continue to be fulfilled.

4 When an application for re-examination has been submitted, the marketing authorisation for a limited market shall remain valid until a decision has been adopted by the competent authority or the Commission, as applicable.

5 The competent authority or the Agency, as applicable, shall assess applications for a re-examination and for an extension of the validity of the marketing authorisation.

On the basis of that assessment, if the benefit-risk balance remains positive, the competent authority or the Commission, as applicable, shall extend the validity of the marketing authorisation by additional periods of five years.

6 The competent authority or the Commission, as applicable, may at any time grant a marketing authorisation valid for an unlimited period of time in respect of a veterinary medicinal product authorised for a limited market, provided that the holder of the marketing authorisation for a limited market submits the missing data on safety or efficacy referred to in Article 23(1).

Article 25

Applications in exceptional circumstances

By way of derogation from point (b) of Article 8(1), in exceptional circumstances related to animal or public health, an applicant may submit an application which does not meet all requirements of that point, for which the benefit of the immediate availability on the market of the veterinary medicinal product concerned to the animal or public health outweighs the risk inherent in the fact that certain quality, safety or efficacy documentation has not been provided. In such a case, the applicant shall be required to demonstrate that for objective and verifiable reasons certain quality, safety or efficacy documentation required in accordance with Annex II cannot be provided.

Article 26

Terms of the marketing authorisation in exceptional circumstances

1 In the exceptional circumstances referred to in Article 25, a marketing authorisation may be granted subject to one or more of the following requirements for the marketing authorisation holder:

a a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;

b a requirement to notify to the competent authorities or the Agency, as applicable, of any adverse event relating to the use of the veterinary medicinal product;

c a requirement to conduct post-authorisation studies.

2 Where a veterinary medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.

Article 27

Validity of a marketing authorisation in exceptional circumstances and procedure for its re-examination

1 By way of derogation from Article 5(2), a marketing authorisation in exceptional circumstances shall be valid for a period of one year.

2 Before the expiry of the one-year period of validity referred to in paragraph 1 of this Article, marketing authorisations granted in accordance with Articles 25 and 26 shall be re-examined on the basis of an application from the holder of that marketing authorisation. That application shall include an updated benefit-risk assessment.

3 A holder of a marketing authorisation in exceptional circumstances shall submit an application for re-examination to the competent authority that granted the authorisation or to the Agency, as applicable, at least three months before the expiry of the one-year period of validity referred to in paragraph 1. The application for re-examination shall demonstrate that the exceptional circumstances related to animal health or public health remain.

4 When an application for re-examination has been submitted, the marketing authorisation shall remain valid until a decision has been adopted by the competent authority or the Commission, as applicable.

5 The competent authority or the Agency, as applicable, shall assess the application.

On the basis of that assessment, if the benefit-risk balance remains positive, the competent authority or the Commission, as applicable, shall extend the validity of the marketing authorisation for one year.

6 The competent authority or the Commission, as applicable, may at any time grant a marketing authorisation valid for an unlimited period of time in respect of a veterinary medicinal product authorised in accordance with Articles 25 and 26, provided that the marketing authorisation holder submits the missing data on quality, safety or efficacy referred to in Article 25.

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[(2)], 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.

Section 8

Protection of technical documentation

Article 38

Protection of technical documentation

1 Without prejudice to the requirements and obligations laid down in Directive 2010/63/EU, technical documentation on quality, safety and efficacy originally submitted with a view to obtaining a marketing authorisation or a variation thereof shall not be referred to by other applicants for a marketing authorisation or a variation of the terms of a marketing authorisation for a veterinary medicinal product unless:

a the period of the protection of technical documentation as set out in Articles 39 and 40 of this Regulation has elapsed, or is due to elapse in less than two years;

b the applicants have obtained written agreement in the form of a letter of access with regard to that documentation.

2 The protection of the technical documentation as set out to in paragraph 1 (‘the protection of technical documentation’) shall also apply in Member States where the veterinary medicinal product is not authorised or is no longer authorised.

3 A marketing authorisation or a variation to the terms of a marketing authorisation differing from the marketing authorisation previously granted to the same marketing authorisation holder only with regard to target species, strengths, pharmaceutical forms, administration routes or presentations shall be regarded as the same marketing authorisation as the one previously granted to the same marketing authorisation holder for the purpose of applying the rules of the protection of technical documentation.

Article 39

Periods of the protection of technical documentation

1 The period of the protection of technical documentation shall be:

a 10 years for veterinary medicinal products for cattle, sheep for meat production, pigs, chickens, dogs and cats;

b 14 years for antimicrobial veterinary medicinal products for cattle, sheep for meat production, pigs, chickens, dogs and cats containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application;

c 18 years for veterinary medicinal products for bees;

d 14 years for veterinary medicinal products for animal species other than those referred to in points (a) and (c).

2 The protection of technical documentation shall apply from the day when the marketing authorisation for the veterinary medicinal product was granted in accordance with Article 5(1).

Article 40

Prolongation and additional periods of the protection of technical documentation

1 Where the first marketing authorisation is granted for more than one animal species referred to in point (a) or (b) of Article 39(1) or a variation is approved in accordance with Article 67 extending the marketing authorisation to another species referred to in point (a) or (b) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by one year for each additional target species, provided that, in the case of a variation, the application has been submitted at least three years before the expiration of the protection period laid down in point (a) or (b) of Article 39(1).

2 Where the first marketing authorisation is granted for more than one animal species referred to in point (d) of Article 39(1), or a variation is approved in accordance with Article 67 extending the marketing authorisation to another animal species not referred to in point (a) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by four years, provided that, in the case of a variation, the application has been submitted at least three years before the expiration of the protection period laid down in point (d) of Article 39(1).

3 The period of the protection of technical documentation provided for in Article 39 of the first marketing authorisation, prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation, shall not exceed 18 years.

4 Where an applicant for a marketing authorisation for a veterinary medicinal product or for a variation to the terms of a marketing authorisation submits an application in accordance with Regulation (EC) No 470/2009 for the establishment of a maximum residue limit, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of five years from the granting of the marketing authorisation for which they were carried out. The prohibition on using those results shall not apply, insofar as the other applicants have obtained a letter of access with regard to those tests, studies and trials.

5 If a variation to the terms of the marketing authorisation approved in accordance with Article 67 involves a change to the pharmaceutical form, administration route or dosage, which is assessed by the Agency or the competent authorities referred to in Article 66 to have demonstrated:

a a reduction in the antimicrobial or antiparasitic resistance; or

b an improvement of the benefit-risk balance of the veterinary medicinal product,

the results of the concerned pre-clinical studies or clinical trials shall benefit from four years protection.

The prohibition on using those results shall not apply, insofar as the other applicants have obtained a letter of access with regard to those studies and trials.

Article 41

Patent-related rights

Conducting the necessary tests, studies and trials with a view to applying for a marketing authorisation in accordance with Article 18 shall not be regarded as contrary to

patent-related rights or to supplementary-protection certificates for veterinary medicinal products and medicinal products for human use.

(**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).

(**2**) 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).

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/6 of the European Parliament and of the Council, CHAPTER II.