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 VII

SUPPLY AND USE

Section 1

Wholesale distribution

Article 99

Wholesale distribution authorisations

1 The wholesale distribution of veterinary medicinal products shall be subject to the holding of a wholesale distribution authorisation.

2 The holders of a wholesale distribution authorisation shall be established in the Union.

3 Wholesale distribution authorisations shall be valid throughout the Union.

4 Member States may decide that supplies of small quantities of veterinary medicinal products from one retailer to another in the same Member State shall not be subject to the requirement of holding a wholesale distribution authorisation.

5 By derogation from paragraph 1, a holder of a manufacturing authorisation shall not be required to hold a wholesale distribution authorisation for the veterinary medicinal products covered by the manufacturing authorisation.

6 The Commission shall, by means of implementing acts, adopt measures on good distribution practice for veterinary medicinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 100

Application and procedures for wholesale distribution authorisations

1 An application for a wholesale distribution authorisation shall be submitted to the competent authority in the Member State in which the site or sites of the wholesale distributor are located.

2 An applicant shall demonstrate in the application that the following requirements are met:

a the applicant has at its disposal technically competent staff and in particular at least one person designated as responsible person, meeting the conditions provided for in national law;

b the applicant has suitable and sufficient premises complying with the requirements laid down by the relevant Member State as regards the storage and handling of veterinary medicinal products;

c the applicant has a plan guaranteeing effective implementation of any withdrawal or recall from the market ordered by the competent authorities or the Commission or undertaken in cooperation with the manufacturer or marketing authorisation holder of the veterinary medicinal product concerned;

d the applicant has an appropriate record-keeping system ensuring compliance with the requirements referred to in Article 101;

e the applicant has a statement to the effect that it fulfils the requirements referred to in Article 101.

3 Member States shall lay down procedures to grant, refuse, suspend, revoke or change a wholesale distribution authorisation.

4 The procedures referred to in paragraph 3 shall not exceed 90 days, starting, if applicable, from the date on which the competent authority receives an application in accordance with national law.

5 The competent authority shall:

a inform the applicant of the outcome of the evaluation;

b grant, refuse or change the wholesale distribution authorisation; and

c upload the relevant information of the authorisation in the manufacturing and wholesale distribution database referred to in Article 91.

Article 101

Obligations of wholesale distributors

1 Wholesale distributors shall obtain veterinary medicinal products only from holders of a manufacturing authorisation or from other holders of a wholesale distribution authorisation.

2 A wholesale distributor shall supply veterinary medicinal products only to persons permitted to carry out retail activities in a Member State in accordance with Article 103(1), other wholesale distributors of veterinary medicinal products and to other persons or entities in accordance with national law.

3 The holder of a wholesale distribution authorisation shall have permanently at its disposal the services of at least one responsible person for wholesale distribution.

4 Wholesale distributors shall, within the limits of their responsibility, ensure appropriate and continued supply of veterinary medicinal product to persons authorised to supply it in accordance with Article 103(1), so that the needs for animal health in the relevant Member State are covered.

5 A wholesale distributor shall comply with the good distribution practice for veterinary medicinal products as referred to in Article 99(6).

6 Wholesale distributors shall immediately inform the competent authority and, where applicable, the marketing authorisation holder, of veterinary medicinal products they receive or are offered which they identify as falsified or suspected to be falsified.

7 A wholesale distributor shall keep detailed records of at least the following information in respect of each transaction:

a date of the transaction;

b name of the veterinary medicinal product including, as appropriate, pharmaceutical form and strength;

c batch number;

d expiry date of the veterinary medicinal product;

e quantity received or supplied, stating pack size and number of packs;

f name or company name and permanent address or registered place of business of the supplier in the event of purchase or of the recipient in the event of sale.

8 At least once a year, the holder of a wholesale distribution authorisation shall carry out a detailed audit of the stock and compare the incoming and outgoing veterinary medicinal products recorded with veterinary medicinal products currently held in stock. Any discrepancies found shall be recorded. The records shall be available for inspection by the competent authorities for a period of five years.

Article 102

Parallel trade in veterinary medicinal products

1 For the purpose of parallel trade in veterinary medicinal products, the wholesale distributor shall ensure that the veterinary medicinal product it intends to obtain from a Member State (‘source Member State’) and distribute in another Member State (‘destination Member State’) share a common origin with the veterinary medicinal product already authorised in the destination Member State. The veterinary medicinal products are considered as sharing a common origin if they fulfil all the following conditions:

a they have the same qualitative and quantitative composition in terms of active substances and excipients;

b they have the same pharmaceutical form;

c they have the same clinical information and, if applicable, withdrawal period; and

d they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation.

2 The veterinary medicinal product obtained from a source Member State shall comply with the labelling and language requirements of the destination Member State.

3 Competent authorities shall lay down administrative procedures for the parallel trade in veterinary medicinal products and administrative procedure for the approval of the application for parallel trade in such products.

4 Competent authorities of the destination Member State shall, in the product database as referred to in Article 55, make available to public the list of veterinary medicinal products that are parallel traded in that Member State.

5 A wholesale distributor that is not the marketing authorisation holder shall notify the marketing authorisation holder and the competent authority of the source Member State of its intention to parallel trade the veterinary medicinal product to a destination Member State.

6 Each wholesale distributor intending to parallel trade a veterinary medicinal product to a destination Member State shall comply with at least the following obligations:

a submit a declaration to the competent authority in the destination Member State and take appropriate measures to ensure that the wholesale distributor in the source Member State will keep it informed of any pharmacovigilance issues;

b notify the marketing authorisation holder in the destination Member State about the veterinary medicinal product to be obtained from the source Member State and intended to be placed on the market in the destination Member State at least one month prior to submitting to the competent authority the application for parallel trade in that veterinary medicinal product;

c submit a written declaration to the competent authority of the destination Member State that the marketing authorisation holder in the destination Member State was notified in accordance with point (b) together with a copy of that notification;

d not trade a veterinary medicinal product which has been recalled from the market of the source Member State or destination Member State for quality, safety or efficacy reasons;

e collect suspected adverse events and report them to the marketing authorisation holder of the parallel-traded veterinary medicinal product.

7 The following information shall be attached to the list referred to in paragraph 4 in respect of all veterinary medicinal products:

a name of the veterinary medicinal products;

b active substances;

c pharmaceutical forms;

d classification of the veterinary medicinal products in the destination Member State;

e marketing authorisation number of the veterinary medicinal products in the source Member State;

f marketing authorisation number of the veterinary medicinal products in the destination Member State;

g name or company name and permanent address or registered place of business of the wholesale distributor in the source Member State and of the wholesale distributor in the destination Member State.

8 This Article shall not apply to centrally authorised veterinary medicinal products.

Section 2

Retail

Article 103

Retail of veterinary medicinal products and record keeping

1 The rules on retail of veterinary medicinal products shall be determined by national law, unless otherwise provided in this Regulation.

2 Without prejudice to Article 99(4), retailers of veterinary medicinal products shall obtain veterinary medicinal products only from holders of a wholesale distribution authorisation.

3 Retailers of veterinary medicinal products shall keep detailed records of the following information in respect of each transaction of veterinary medicinal products requiring a veterinary prescription under Article 34:

a date of the transaction;

b name of the veterinary medicinal product including, as appropriate, pharmaceutical form and strength;

c batch number;

d quantity received or supplied;

e name or company name and permanent address or registered place of business of the supplier in the event of purchase, or of the recipient in the event of sale;

f name and contact details of the prescribing veterinarian and, where appropriate, a copy of the veterinary prescription;

g marketing authorisation number.

4 Where Member States consider it necessary, they may require retailers to keep detailed records of any transaction of veterinary medicinal products not subject to veterinary prescription.

5 At least once a year, a retailer shall carry out a detailed audit of the stock and compare the incoming and outgoing veterinary medicinal products recorded with veterinary medicinal products currently held in stock. Any discrepancies found shall be recorded. The results of the detailed audit and the records referred to in paragraph 3 of this Article shall be available for inspection by the competent authorities in accordance with Article 123 for a period of five years.

6 Member States may impose conditions justified on grounds of protection of public and animal health or of the environment for the retail on their territory of veterinary medicinal products provided that such conditions comply with Union law, are proportionate and non-discriminatory.

Article 104

Retail of veterinary medicinal products at a distance

1 Persons permitted to supply veterinary medicinal products in accordance with Article 103(1) of this Regulation may offer veterinary medicinal products by means of information society services in the meaning of Directive (EU) 2015/1535 of the European Parliament and of the Council[(1)] to natural or legal persons established in the Union provided that those veterinary medicinal products are not subject to a veterinary prescription pursuant to Article 34 of this Regulation and that they comply with this Regulation and applicable law of the Member State in which the veterinary products are retailed.

2 By way of derogation from paragraph 1 of this Article, a Member State may allow persons permitted to supply veterinary medicinal products in accordance with Article 103(1) to offer veterinary medicinal products subject to a veterinary prescription pursuant to Article 34 by means of information society services, provided that the Member State has provided a secure system for such supplies. Such permission shall only be granted to persons established in their territory and supply shall only occur within the territory of that Member State.

3 The Member State referred to in paragraph 2 shall ensure that adapted measures are in place in order to guarantee that the requirements relating to a veterinary prescription are respected as regards supply by means of information society services and shall notify the Commission and other Member States if it makes use of the derogation referred to in paragraph 2 and shall, when necessary, cooperate with the Commission and other Member States to avoid any unintended consequences of such supply. The Member States shall establish rules on appropriate penalties to ensure that the national rules adopted are respected, including rules on the withdrawal of such permissions.

4 The persons and activities referred to in paragraphs 1 and 2 of this Article shall be subject to the controls referred to in Article 123 by the competent authority of the Member State in which the retailer is established.

5 In addition to the information requirements set out in Article 6 of Directive 2000/31/EC of the European Parliament and of the Council[(2)], retailers offering veterinary medicinal products by means of information society services shall provide at least the following information:

a the contact details of the competent authority of the Member State in which the retailer offering the veterinary medicinal products is established;

b a hyperlink to the website of the Member State of establishment set up in accordance with paragraph 8 of this Article;

c the common logo established in accordance with paragraph 6 of this Article is clearly displayed on every page of the website that relates to the offer for sale at a distance of veterinary medicinal products and contains a hyperlink to the entry of the retailer in the list of permitted retailers referred to in point (c) of paragraph 8 of this Article.

6 The Commission shall establish a common logo pursuant to paragraph 7 that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering veterinary medicinal products for sale at a distance is established. The logo shall be clearly displayed on websites offering veterinary medicinal products for sale at a distance.

7 The Commission shall, by means of implementing acts, adopt the design of the common logo referred to in paragraph 6 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

8 Each Member State shall set up a website regarding sale of veterinary medicinal products at a distance, providing at least the following information:

a information on its national law applicable to the offering of veterinary medicinal products for sale at a distance by means of information society services, in accordance with paragraphs 1 and 2, including information on the fact that there may be differences between Member States regarding the classification of the supply of the veterinary medicinal products;

b information on the common logo;

c a list of retailers established in the Member State permitted to offer veterinary medicinal products for sale at a distance by means of information society services in accordance with paragraphs 1 and 2 as well as the website addresses of those retailers.

9 The Agency shall set up a website providing information on the common logo. The Agency's website shall explicitly mention that the websites of Member States contain information on persons permitted to offer veterinary medicinal products for sale at a distance by means of information society services in the relevant Member State.

10 Members States may impose conditions, justified on grounds of public health protection, for the retail, on their territory, of veterinary medicinal products offered for sale at a distance by means of information society services.

11 The websites set up by Member States shall contain a hyperlink to the website of the Agency set up in accordance with paragraph 9.

Article 105

Veterinary prescriptions

1 A veterinary prescription for an antimicrobial medicinal product for metaphylaxis shall only be issued after a diagnosis of the infectious disease by a veterinarian.

2 The veterinarian shall be able to provide justification for a veterinary prescription of antimicrobial medicinal products, in particular for metaphylaxis and for prophylaxis.

3 A veterinary prescription shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian.

4 By way of derogation from point (33) of Article 4 and paragraph 3 of this Article, a Member State may allow a veterinary prescription to be issued by a professional, other than a veterinarian, who is qualified to do so in accordance with applicable national law at the time of entry into force of this Regulation. Such prescriptions shall be valid only in that Member State and shall exclude prescriptions of antimicrobial medicinal products and any other veterinary medicinal products where a diagnosis by a veterinarian is necessary.

Veterinary prescriptions issued by a professional, other than a veterinarian shall be, *mutatis mutandis*, subject to paragraphs 5, 6, 8, 9 and 11 of this Article.

5 A veterinary prescription shall contain at least the following elements:

- a identification of the animal or groups of animals to be treated;
- b full name and contact details of the animal owner or keeper;
- c issue date;
- d full name and contact details of the veterinarian including, if available, the professional number;
- e signature or an equivalent electronic form of identification of the veterinarian;
- f name of the prescribed medicinal product, including its active substances;
- g pharmaceutical form and strength;
- h quantity prescribed, or the number of packs, including pack size;
- i dosage regimen;
- j for food-producing animal species, withdrawal period even if such period is zero;
- k any warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials;
- l if a medicinal product is prescribed in accordance with Articles 112, 113 and 114, a statement to that effect;
- m if a medicinal product is prescribed in accordance with Article 107(3) and (4), a statement to that effect.

6 The quantity of the medicinal products prescribed shall be limited to the amount required for the treatment or therapy concerned. As regards antimicrobial medicinal products for metaphylaxis or prophylaxis, they shall be prescribed only for a limited duration to cover the period of risk.

7 Veterinary prescriptions issued in accordance with paragraph 3 shall be recognised throughout the Union.

8 The Commission may, by means of implementing acts, set a model format for the requirements set in paragraph 5 of this Article. That model format shall also be made available in electronic version. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

9 The medicinal product prescribed shall be supplied in accordance with applicable national law.

10 A veterinary prescription for antimicrobial medicinal products shall be valid for five days from the date of its issue.

11 In addition to the requirements set out in this Article, Member States may lay down rules on record-keeping for veterinarians when issuing veterinary prescriptions.

12 Notwithstanding Article 34, a veterinary medicinal product classified as subject to veterinary prescription under that Article may be administered without a veterinary prescription by a veterinarian personally, unless otherwise provided for under applicable national law. The veterinarian shall keep records of such personal administration without prescription in accordance with applicable national law.

Section 3

Use

Article 106

Use of medicinal products

1 Veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation.

2 The use of veterinary medicinal products in accordance with this Section shall be without prejudice to Articles 46 and 47 of Regulation (EU) 2016/429.

3 Member States may lay down any procedures they deem necessary for the implementation of Articles 110 to 114 and 116.

4 Member States may, if duly justified, decide that a veterinary medicinal product shall be administered only by a veterinarian.

5 Inactivated immunological veterinary medicinal products referred to in Article 2(3) shall only be used in the animals referred to therein in exceptional circumstances, in accordance with a veterinary prescription, and if no immunological veterinary medicinal product is authorised for the target animal species and the indication.

6 The Commission shall adopt delegated acts in accordance with Article 147, in order to supplement this Article, as necessary, which establish the rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food-producing animals. The Commission shall take into account the scientific advice of the Agency, when adopting those delegated acts.

Article 107

Use of antimicrobial medicinal products

1 Antimicrobial medicinal products shall not be applied routinely nor used to compensate for poor hygiene, inadequate animal husbandry or lack of care or to compensate for poor farm management.

2 Antimicrobial medicinal products shall not be used in animals for the purpose of promoting growth nor to increase yield.

3 Antimicrobial medicinal products shall not be used for prophylaxis other than in exceptional cases, for the administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe.

In such cases, the use of antibiotic medicinal products for prophylaxis shall be limited to the administration to an individual animal only, under the conditions laid down in the first subparagraph.

4 Antimicrobial medicinal products shall be used for metaphylaxis only when the risk of spread of an infection or of an infectious disease in the group of animals is high and where no other appropriate alternatives are available. Member States may provide guidance regarding such other appropriate alternatives and shall actively support the development and application of guidelines which promote the understanding of risk factors associated with metaphylaxis and include criteria for its initiation.

5 Medicinal products which contain the designated antimicrobials referred to in Article 37(5) shall not be used in accordance with Articles 112, 113 and 114.

6 The Commission may, by means of implementing acts, and taking into consideration scientific advice of the Agency, establish a list of antimicrobials which:

a shall not be used in accordance with Articles 112, 113 and 114; or

b shall only be used in accordance with Articles 112, 113 and 114 subject to certain conditions.

When adopting those implementing acts, the Commission shall take account of the following criteria:

a risks to animal or public health if the antimicrobial is used in accordance with Articles 112, 113 and 114;

b risk for animal or public health in case of development of antimicrobial resistance;

c availability of other treatments for animals;

d availability of other antimicrobial treatments for humans;

e impact on aquaculture and farming if the animal affected by the condition receives no treatment.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

7 A Member State may further restrict or prohibit the use of certain antimicrobials in animals on its territory if the administration of such antimicrobials to animals is contrary to the implementation of a national policy on prudent use of antimicrobials.

8 Measures adopted by the Member States on the basis of paragraph 7 shall be proportionate and justified.

9 The Member State shall inform the Commission of any measure it has adopted on the basis of paragraph 7.

Article 108

Record-keeping by owners and keepers of food-producing animals

1 Owners or, where the animals are not kept by the owners, keepers of food-producing animals shall keep records of the medicinal products they use and, if applicable, a copy of the veterinary prescription.

2 Records referred to in paragraph 1 shall include:

a date of the first administration of the medicinal product to the animals;

b name of the medicinal product;

c quantity of the medicinal product administered;

d name or company name and permanent address or registered place of business of the supplier;

e evidence of acquisition of the medicinal products they use;

f identification of the animal or group of animals treated;

g name and contact details of the prescribing veterinarian, if applicable;

h withdrawal period even if such period is zero;

i duration of treatment.

3 If the information to be recorded in accordance with paragraph 2 of this Article is already available on the copy of a veterinary prescription, in a record kept on the farm or for equine animals recorded in the single lifetime identification document referred to in Article 8(4), it does not need to be recorded separately.

4 Member States may lay down additional requirements for record-keeping by owners and keepers of food-producing animals.

5 The information contained in those records shall be available for inspections by the competent authorities in accordance with Article 123 for a period of at least five years.

Article 109

Record-keeping obligations for equine animals

1 The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Regulation as regards the content and format of the information necessary to apply Articles 112(4) and 115(5) and to be contained in the single lifetime identification document referred to in Article 8(4).

2 The Commission shall, by means of implementing acts, lay down model forms for entering the information necessary to apply Articles 112(4) and 115(5) and to be contained in the single lifetime identification document referred to in Article 8(4). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 110

Use of immunological veterinary medicinal products

1 The competent authorities may, in accordance with the applicable national law, prohibit the manufacture, import, distribution, possession, sale, supply or use of immunological veterinary medicinal products on their territory or in a part of it if at least one of the following conditions is fulfilled:

a the administration of the product to animals may interfere with the implementation of a national programme for the diagnosis, control or eradication of animal disease;

b the administration of the product to animals may cause difficulties in certifying the absence of disease in live animals or contamination of foodstuffs or other products obtained from treated animals;

c the strains of disease agents to which the product is intended to confer immunity is largely absent in terms of geographic spread from the territory concerned.

2 By way of derogation from Article 106(1) of this Regulation, and in the absence of a veterinary medicinal product as referred to in Article 116 of this Regulation, in the event of an outbreak of a listed disease as referred to in Article 5 of Regulation (EU) 2016/429 or an emerging disease as referred to in Article 6 of that Regulation, a competent authority may allow the use of an immunological veterinary medicinal product not authorised within the Union.

3 By way of derogation from Article 106(1) of this Regulation, when an immunological veterinary medicinal product has been authorised but is no longer available within the Union for a disease which is not referred to in Article 5 or 6 of Regulation (EU) 2016/429 but which is already present in the Union, a competent authority may, in the interest of animal health and welfare and public health, allow the use of an immunological veterinary medicinal product not authorised within the Union on a case by case basis.

4 The competent authorities shall inform the Commission without delay when paragraphs 1, 2 and 3 are applied, together with information on the conditions imposed within the implementation of those paragraphs.

5 If an animal is to be exported to a third country and thereby subject to specific binding health rules in that third country, a competent authority may permit the use, solely for that animal concerned, of an immunological veterinary medicinal product that is not covered by a marketing authorisation in the relevant Member State but its use is allowed in the third country to where the animal is to be exported.

Article 111

Use of veterinary medicinal products by veterinarians providing services in other Member States

1 A veterinarian providing services in a Member State other than the one in which the veterinarian is established (‘host Member State’) shall be allowed to possess and administer veterinary medicinal products which are not authorised in the host Member State to animals or groups of animals which are under the veterinarian’s care in the necessary quantity not exceeding the amount required for the treatment prescribed by the veterinarian, provided that the following conditions are met:

a a marketing authorisation for the veterinary medicinal product to be administered to the animals has been granted by the competent authorities of the Member State in which the veterinarian is established or by the Commission;

b the veterinary medicinal products concerned are transported by the veterinarian in their original packaging;

c the veterinarian follows the good veterinary practice applied in the host Member State;

d the veterinarian sets the withdrawal period specified on the labelling or package leaflet of the veterinary medicinal product used;

e the veterinarian does not retail any veterinary medicinal product to an owner or keeper of animals treated in the host Member State unless this is permissible under the rules of the host Member State.

2 Paragraph 1 shall not apply to immunological veterinary medicinal products except in the case of toxins and sera.

Article 112

Use of medicinal products outside the terms of the marketing authorisation in non-food-producing animal species

1 By way of derogation from Article 106(1), where there is no authorised veterinary medicinal product in a Member State for an indication concerning a non-food-producing animal species, the veterinarian responsible may, under his or her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with the following medicinal product:

a a veterinary medicinal product authorised under this Regulation in the relevant Member State or in another Member State for use in the same species or another animal species for the same indication or for another indication;

b if there is no veterinary medicinal product as referred to in point (a) of this paragraph, a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004;

c if there is no medicinal product as referred to in point (a) or (b) of this paragraph, a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.

2 Except as regards immunological veterinary medicinal products, where there is no medicinal product available as referred to in paragraph 1, the veterinarian responsible may under his or her direct responsibility and in particular to avoid causing unacceptable suffering exceptionally treat a non-food-producing animal with a veterinary medicinal product authorised in a third country for the same animal species and same indication.

3 The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility, in accordance with national provisions.

4 This Article shall also apply to the treatment by a veterinarian of an animal of the equine species provided that it is declared as not being intended for slaughter for human consumption in the single lifetime identification document referred to in Article 8(4).

5 This Article shall apply also when an authorised veterinary medicinal product is not available in the relevant Member State.

Article 113

Use of medicinal products outside the terms of the marketing authorisation in food-producing terrestrial animal species

1 By way of derogation from Article 106(1), where there is no authorised veterinary medicinal product in a Member State for an indication concerning a food-producing terrestrial animal species, the veterinarian responsible may, under his or her direct personal responsibility, and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with the following medicinal product:

a a veterinary medicinal product authorised under this Regulation in the relevant Member State or in another Member State for use in the same or in another food-producing terrestrial animal species for the same indication, or for another indication;

b if there is no veterinary medicinal product as referred to in point (a) of this paragraph, a veterinary medicinal product authorised under this Regulation in the relevant Member State for use in a non-food-producing animal species for the same indication;

c if there is no veterinary medicinal product as referred to in point (a) or (b) of this paragraph, a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004; or

d if there is no medicinal product as referred to in point (a), (b) or (c) of this paragraph, a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.

2 Except as regards immunological veterinary medicinal products, where there is no medicinal product available as referred to in paragraph 1, the veterinarian responsible may under his or her direct personal responsibility, and in particular to avoid causing unacceptable suffering, exceptionally treat food-producing terrestrial animals with a veterinary medicinal product authorised in a third country for the same animal species and same indication.

3 The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility, in accordance with national provisions.

4 Pharmacologically active substances included in the medicinal product used in accordance with paragraphs 1 and 2 of this Article shall be allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.

5 This Article shall apply also when an authorised veterinary medicinal product is not available in the relevant Member State.

Article 114

Use of medicinal products for food-producing aquatic species

1 By way of derogation from Article 106(1), where there is no authorised veterinary medicinal product in a Member State for an indication concerning a food-producing aquatic species, the veterinarian responsible may, under his or her direct personal responsibility, and in particular to avoid causing unacceptable suffering, treat the animals concerned with the following medicinal product:

a a veterinary medicinal product authorised under this Regulation in the relevant Member State or in another Member State for use in the same or in another food-producing aquatic species and for the same indication or for another indication;

b if there is no veterinary medicinal product as referred to in point (a) of this paragraph, a veterinary medicinal product authorised under this Regulation in the relevant Member State or in another Member State for use with a food-producing terrestrial species containing a substance present in the list established in accordance with paragraph 3;

c if there is no veterinary medicinal product as referred to in point (a) or (b) of this paragraph, a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 and containing substances present in the list established in accordance with paragraph 3 of this Article; or

d if there is no medicinal product as referred to in point (a), (b) or (c) of this paragraph, a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.

2 By way of derogation from points (b) and (c) of paragraph 1, and until the list referred to in paragraph 3 is established, the veterinarian responsible may, under his or her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food-producing aquatic species of a particular holding with the following medicinal product:

a a veterinary medicinal product authorised under this Regulation in the relevant Member State or in another Member State for use with a food-producing terrestrial animal species;

b if there is no veterinary medicinal product as referred to in point (a) of this paragraph, a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004.

3 The Commission shall, by means of implementing acts, at the latest within five years from 28 January 2022, establish a list of substances used in veterinary medicinal products authorised in the Union for use in food-producing terrestrial animal species or substances contained in a medicinal product for human use authorised in the Union in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, which may be used in food-producing aquatic species in accordance with paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

The Commission, when adopting those implementing acts, shall take account of the following criteria:

a risks to the environment if the food-producing aquatic species are treated with those substances;

b impact on animal and public health if the food-producing aquatic species affected cannot receive an antimicrobial listed in accordance with Article 107(6);

c availability or lack of availability of other medicinal products, treatments or measures for prevention or treatment of diseases or certain indications in food-producing aquatic species.

4 Except as regards immunological veterinary medicinal products, where there is no medicinal product available as referred to in paragraphs 1 and 2, the veterinarian responsible may, under his or her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat food-producing aquatic species with a veterinary medicinal product authorised in a third country for the same species and same indication.

5 The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility, in accordance with national provisions.

6 Pharmacologically active substances included in the medicinal product used in accordance with paragraphs 1, 2 and 4 of this Article shall be allowed in accordance with Regulation (EC) No 470/2009 and any acts adopted on the basis thereof.

7 This Article shall apply also when an authorised veterinary medicinal product is not available in the relevant Member State.

Article 115

Withdrawal period for medicinal products used outside the terms of the marketing authorisation in food-producing animal species

1 For the purpose of Articles 113 and 114, unless a medicinal product used has a withdrawal period provided in its summary of the product characteristics for the animal species in question, a withdrawal period shall be set by the veterinarian in accordance with the following criteria:

a for meat and offal from food-producing mammals and poultry and farmed game birds the withdrawal period shall not be less than:

(i) the longest withdrawal period provided in its summary of the product characteristics for meat and offal multiplied by factor 1,5;

(ii) 28 days if the medicinal product is not authorised for food-producing animals;

(iii) one day, if the medicinal product has a zero withdrawal period and is used in a different taxonomic family than the target species authorised;

b for milk from animals producing milk for human consumption the withdrawal period shall not be less than:

(i) the longest withdrawal period for milk provided in the summary of the product characteristics for any animal species multiplied by factor 1,5;

(ii) seven days, if the medicinal product is not authorised for animals producing milk for human consumption;

(iii) one day, if the medicinal product has a zero withdrawal period;

c for eggs from animals producing eggs for human consumption the withdrawal period shall not be less than:

(i) the longest withdrawal period for eggs provided in the summary of the product characteristics for any animal species multiplied by factor 1,5;

(ii) 10 days, if the product is not authorised for animals producing eggs for human consumption;

d for aquatic species producing meat for human consumption the withdrawal period shall not be less than:

(i) the longest withdrawal period for any of the aquatic species indicated in the summary of the product characteristics multiplied by factor of 1,5 and expressed as degree-days;

(ii) if the medicinal product is authorised for food-producing terrestrial animal species, the longest withdrawal period for any of the food-producing animal species indicated in the summary of product characteristics multiplied by a factor of 50 and expressed as degree-days, but not exceeding 500 degree-days;

(iii) 500 degree-days, if the medicinal product is not authorised for food-producing animal species;

(iv) 25 degree-days if the highest withdrawal period for any animal species is zero.

2 If the calculation of the withdrawal period according to points (a)(i), (b)(i), (c)(i), (d)(i) and (ii) of paragraph 1 results in a fraction of days, the withdrawal period shall be rounded up to the nearest number of days.

3 The Commission shall adopt delegated acts in accordance with Article 147 in order to amend this Article by amending the rules laid down in paragraphs 1 and 4 thereof in the light of new scientific evidence.

4 For bees, the veterinarian shall determine the appropriate withdrawal period by assessing the specific situation of the particular beehive or beehives on a case-by-case basis and in particular the risk of residue in honey or in any other foodstuffs harvested from beehives intended for human consumption.

5 By way of derogation from Article 113(1) and (4), the Commission shall, by means of implementing acts, establish a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 116

Health situation

By way of derogation from Article 106(1), a competent authority may allow the use in its territory of veterinary medicinal products not authorised in that Member State, where the situation of animal or public health so requires, and the marketing of those veterinary medicinal products is authorised in another Member State.

Article 117

Collection and disposal of waste of veterinary medicinal products

Member States shall ensure that appropriate systems are in place for the collection and disposal of waste of veterinary medicinal products.

Article 118

Animals or products of animal origin imported into the Union

1 Article 107(2) shall apply, *mutatis mutandis*, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union.

2 The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Article by providing the necessary detailed rules on the application of paragraph 1 of this Article.

Section 4

Advertising

Article 119

Advertising of veterinary medicinal products

1 Only veterinary medicinal products that are authorised or registered in a Member State may be advertised in that Member State, unless otherwise decided by the competent authority in accordance with applicable national law.

2 The advertising of a veterinary medicinal product shall make it clear that it aims at promoting the supply, sale, prescription, distribution or use of the veterinary medicinal product.

3 The advertising shall not be formulated in such a way as to suggest that the veterinary medicinal product could be a feed or a biocide.

4 The advertising shall comply with the summary of the product characteristics of the advertised veterinary medicinal product.

5 The advertising shall not include information in any form which could be misleading or lead to incorrect use of the veterinary medicinal product.

6 The advertising shall encourage the responsible use of the veterinary medicinal product, by presenting it objectively and without exaggerating its properties.

7 The suspension of a marketing authorisation shall preclude any advertising, during the period of that suspension, of the veterinary medicinal product in the Member State in which it is suspended.

8 Veterinary medicinal products shall not be distributed for promotional purposes except for small quantities of samples.

9 Antimicrobial veterinary medicinal products shall not be distributed for promotional purposes as samples or in any other presentation.

10 The samples referred to in paragraph 8 shall be appropriately labelled indicating that they are samples and shall be given directly to veterinarians or other persons allowed to supply such veterinary medicinal products during sponsored events or by sales representatives during their visits.

Article 120

Advertising of veterinary medicinal products subject to veterinary prescription

1 The advertising of veterinary medicinal products that are subject to veterinary prescription in accordance with Article 34 shall be allowed only when made exclusively to the following persons:

a veterinarians;

b persons permitted to supply veterinary medicinal products in accordance with national law.

2 By way of derogation from paragraph 1 of this Article, advertising of veterinary medicinal products that are subject to veterinary prescription in accordance with Article 34 to

professional keepers of animals may be permitted by the Member State provided the following conditions are met:

a the advertising is limited to immunological veterinary medicinal products;

b the advertising includes an express invitation to the professional keepers of animal to consult the veterinarian about the immunological veterinary medicinal product.

3 Notwithstanding paragraphs 1 and 2, the advertising of inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit having a confirmed epidemiological link shall be prohibited.

Article 121

Promotion of medicinal products used in animals

1 Where medicinal products are being promoted to persons qualified to prescribe or supply them in accordance with this Regulation, no gifts, pecuniary advantages or benefit in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of prescription or supply of medicinal products.

2 Persons qualified to prescribe or supply medicinal products as referred to in paragraph 1 shall not solicit or accept any inducement prohibited under that paragraph.

3 Paragraph 1 shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality shall always be strictly limited to the main objectives of the event.

4 Paragraphs 1, 2 and 3 shall not affect existing measures or trade practice in Member States relating to prices, margins and discounts.

Article 122

Implementation of advertising provisions

Member States may lay down any procedures they deem necessary for the implementation of Articles 119, 120 and 121.

(**1**) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

(**2**) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).

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 VII.