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 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.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/6 of the European Parliament and of the Council, Section 3.