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 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.