EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

Brussels,
SANTE.DDG1.D4/AP/ci(2023)3418755

Sent by e-mail only

Subject: **Implementing measures under Article 114(3) of Regulation (EU) 2019/6 as regards substances used in veterinary medicinal products authorised in the Union for use in food-producing terrestrial animal species or substances contained in a medical 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 Article 114(1)**

Dear Ms Cooke,

According to Article 114(3) of Regulation (EU) 2019/6 ('VMP Regulation'), the Commission is to establish, by means of implementing acts, 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 Article 114(1) ('the list').

I would like to request the Agency to provide scientific advice on the substances that may be considered for inclusion in the list. The Agency's assessment of those substances must be based on the criteria laid down in Article 114(3):

> *'(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.'*

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Criterion (a) is about the risks associated with harmful effects that uses of a substance in accordance with Article 114(1) may cause to the environment. In the case of antimicrobials, the development of resistance as a result of exposure of the environment and the related risks for animal and public health are outside the scope of criterion (a). This aspect is considered under Article 107(6).

Criterion (b) is about the impact on animal and public health where food-producing aquatic species cannot be treated with antimicrobials which might not be allowed for use on the basis of Article 107(6).

Criterion (c) aims to underline the importance of the availability of treatment for food-producing aquatic species, which in the case of antimicrobial substances might also be impacted by any prohibition or conditions of use recommended in the Agency's scientific advice in relation to Article 107(6).

When performing the assessment, the Agency should take into account the following elements:

1. The overall objective of the VMP Regulation is to increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.

2. Substances included in the Annex to Commission Implementing Regulation (EU) No 2022/1255 ([1]) designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans are prohibited for use in animals and outside the scope of this mandate.

3. Pursuant to Article 114(6), pharmacologically active substances included in the medicinal product used in accordance with paragraph 1 of that article need to be allowed in accordance with Regulation (EC) No 470/2009 ([2]) and any acts adopted on its basis. Therefore, only the substances included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([3]) and used in veterinary medicinal products authorised in the Union or 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 should be assessed against the criteria laid down in Article 114(3) and considered for the Agency's scientific advice. The substances included in Table 2 of that Annex are outside the scope of this mandate.

4. Antimicrobial substances that could be recommended for a prohibition or conditions of use in food-producing aquatic animals in the Agency's scientific advice requested

([1]) Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 191, 20.7.2022, p. 58)

([2]) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11)

([3]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1), as amended

by the Commission in relation to Article 107(6) should be assessed under the criteria laid down in Article 114(3).

5. Any scientific and technical evidence available that is relevant for the assessment of risks to the environment if the food-producing aquatic species are treated with the substances concerned.

6. Various productions systems in the EU, such as sea cages, ponds, raceways, on-land recirculating aquaculture systems, and their specificities, as well as various routes of administration or pharmaceutical forms should also be taken into account when assessing substances under this mandate. In this respect, conditions of use and risk mitigation measures for the protection of the environment could be proposed in relation to the substances recommended for inclusion in the list.

Article 114(3) requires the Commission to adopt the implementing act at the latest by 27 January 2027. Given this timeline, we would appreciate receiving your scientific advice by 30 November 2024. We would also ask that the Agency updates our services on the main progress of its work quarterly.

We would like to thank you for your collaboration.

Yours sincerely,

[e-signed]

Sandra GALLINA

c.c.: Mr I. Claassen (EMA)
Ms E. Zamora Escribano, Mr A. Las Heras, Mr L. Goranov,
Ms A. Pagida (SANTE)