



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Veterinary Medicines
Head of Unit

Brussels
SANTE.D.4/AP/ci (2025)13324968

Subject: Guidance on scientific issues in relation to Articles 107(6) and 114(3) of Regulation (EU) 2019/6

Dear Dr Claassen,

I am writing to you seeking the guidance of the Committee for Veterinary Medicinal Products (CVMP) pursuant to Article 141(1)(f) of Regulation (EU) 2019/6.

In accordance with Article 114(3) of Regulation (EU) 2019/6, the Commission is to adopt an implementing act listing substances that may be used in food-producing aquatic species in accordance with Article 114(1). The Commission also intends to extend the scope of Commission Implementing Regulation (EU) 2024/1973 ⁽¹⁾ to food-producing aquatic species.

The Agency's scientific advice under Article 107(6) ⁽²⁾ included recommendations concerning food-producing aquatic species. The Agency's scientific advice under Article 114(3) ⁽³⁾ contains recommendations for listing several antimicrobials. Those two sets of recommendations are based on different sets of criteria established in Regulation (EU) 2019/6.

⁽¹⁾ Commission Implementing Regulation (EU) 2024/1973 of 18 July 2024 establishing a list of antimicrobials which shall not be used in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 of the European Parliament and of the Council or which shall only be used in accordance with those Articles subject to certain conditions (OJ L, 19.7.2024 ELI: http://data.europa.eu/eli/reg_impl/2024/1973/oj)

⁽²⁾ EMA/CVMP/151584/2021, 15 June 2023

⁽³⁾ EMA/CVMP/29892/2024, 15 May 2025

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In this context, we have identified nine antimicrobial substances for which CVMP's guidance would be needed. In view of the Agency's recommendations and to ensure coherence between the implementing acts referred to above, we are considering a set of possible conditions for each of those substances. Given the necessity for science-based decisions, we therefore seek CVMP's feedback on the questions contained in the enclosure to this letter.

Regulation (EU) 2019/6 requires that the list of substances allowed for use in food-producing aquatic species under Article 114(1) be established by means of implementing acts adopted by January 2027. To ensure compliance with that legal deadline, we would be grateful to receive the replies to the questions enclosed no later than **30 April 2026**.

Thank you in advance for your collaboration and invaluable contribution.

Yours sincerely,

(e-signed)
Eva Zamora Escribano

Enclosure: Questions for CVMP in relation to EMA's recommendations under Article 107(6) and under Article 114(3)

c.c.: N. Jarrett, J. Torren Edo (EMA)
A. Las Heras, L. Goranov, A. Pagida (SANTE)