EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Animal nutrition, veterinary medicines
Head of Unit

Brussels,
SANTE E5/TA/ng(2022)6128551
By e-mail only

Dear Mr Fabris,

I would like to thank you for your letter of 22 June 2022 on the new EU legal framework concerning the oral distribution of veterinary medicines in the aquaculture sector.

DG SANTE is currently working on the preparation of the delegated acts to be adopted on the establishment of maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed under Article 7 of Regulation (EU) 2019/4[1] and on the oral administration of veterinary medicinal products under Article 106 (6) of Regulation (EU) 2019/6[2]. Those delegated acts are being developed taking into account both the EFSA opinion on maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed[3] and the EMA advice on implementing measures for oral administration[4].

We take good note of the concerns expressed in your letter in relation to the potential impact that the new measures could have in the aquaculture sector and of your request to keep stakeholders involved in future discussions. Please be reassured that stakeholders will have the opportunity to provide input and express their views through the feedback mechanism, before the adoption by the Commission of the above mentioned delegated acts. In addition, major stakeholder representatives on the area of animal nutrition will

[1] Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1)

[2] 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 (OJ L 4, 7.1.2019, p. 43)

[3] Maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6852

[4] Advice on implementing measures under Article 106 (6) of Regulation (EU) 2019/6 on veterinary medicinal products – scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via routes other than medicated feed REPORT - NVR oral administration - 19-08-2020 (europa.eu)

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also be able to provide their input in the framework of the Expert Group on Animal Nutrition for delegated acts under the medicated feed Regulation.

The Commission will give due consideration to the recommendation made in EMA's advice, including the one you mention in your letter to encourage the pharmaceutical industry to develop medicines for use in the preparation of medicated feed for fish, to ensure safe and efficient administration of medicines to fish.

I would like to highlight that one of the main objectives of Regulation 2019/6 is indeed to increase availability of veterinary medicinal products and promote innovation. In this respect it contains multiple provisions to encourage the pharmaceutical industry to place new products on the EU market.

We will be pleased to continue exchanging views with you on this important matter at any future occasions.

Yours sincerely,

(e-signed)
Eva Zamora Escribano