EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

Brussels,
SANTE/E5/CS/mcd ares (2019)4599820

Sent by e-mail only

Dear Prof Rasi,

Subject: Implementing measures under Article Art 106(6) of Regulation (EU) 2019/6 on veterinary medicinal products[1] regarding rules on oral administration

On 7th January 2019, the new Regulation on veterinary medicinal products ('VMP Regulation') and the new Regulation (EU) 2019/4 on medicated feed[2] were published.

They will start applying 3 years from their entry into force, i.e. from 28th January 2022.

The new Regulation (EU) 2019/4 on medicated feed establishes stringent rules for the incorporation of VMPs into medicated feed and its subsequent oral use in animals.

According to Article 106(6) of the VMP Regulation, the Commission shall adopt a delegated act to establish rules on oral administration. It is highly desirable that this act can be adopted by the date of application of the VMP Regulations to ensure good practise of oral administration for the safe and effective use of VMPs and to avoid a shift away from the medicated feed route, for which the new and strict rules apply from 28. January 2022 on, to direct oral VMP administration if there are no similar rules in place for them.

In order to have consistent rules in place for VMPs administered via all oral routes, I would like to ask you to provide us with the Agency's scientific problem analysis and recommendations to ensure a safe and efficient oral administration of VMPs via routes other than medicated feed, by taking into account the following:

[1] 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.

[2] 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.

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- to ensure 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, mixing of a veterinary medicinal product into the ordinary feed by the farmer or top dressing of the feed offered to the animal in a feeding device with a VMP (solid or as an emulsion); this issue should address the borderline between the medication with medicated feed and with VMPs via the alternative oral routes,
- proper administration and compliance with the dosage in the veterinary prescription of the veterinary medicinal products which are to be administered orally must be ensured for a safe and efficacious treatment for all animals, in particular for antimicrobials; in this context, a matching of posology, number of animals to be treated and the pack size of the VMP should be ascertained,
- the summary of the product characteristics for veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed,
- differentiate between the categories of VMPs according to their risk,
- special production and use conditions for different species, such as fish,
- the provisions in the Medicated Feed Regulation concern the manufacturing including compositional requirements, including potential incompatibilities of the VMP with feed additives or biocides used for the feeding equipment, homogenous incorporation, cross contamination (Articles 4-7, Annex I) and safe use of medicated feed for farmed animals and pets. Thus, adequate measures for the oral routes other than medicated feed should address over-dosage and under-dosage, unintended administration to non-target animals, the risk of cross-contamination of the feed, residues in the feeding devices and water supply system, and release of those products into the environment.
- involving EFSA and their knowledge on feed, including with respect to cross contamination to achieve similar standards for all oral routes.

Relevant excerpts from the VMP Regulation are included in Annex I for your convenience.

We would kindly ask for your contribution by the end of April 2020.

We would also ask that the Agency update our services on the main progress of its work on a monthly basis.We would like to thank you for your collaboration.

Yours sincerely,

Anne Bucher

Encl.: Annex I

Annex I

Relevant excerpts from the VMP Regulation.

Recital 14

To ensure the proper administration and appropriate dosing of certain veterinary medicinal products which are to be administered orally in feed or drinking water to animals, especially in the case of treatment of groups of animals, such administration should be properly described in the product information. Additional instructions for cleaning the equipment used for administration of those products should be set out to avoid cross-contamination and reduce antimicrobial resistance. In order to improve 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 manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food-producing animals, the Commission should, where necessary, adopt delegated acts. The Commission should take into account scientific recommendations of the European Medicines Agency, established by Regulation (EC) No 726/2004 (‘the Agency’), for example concerning measures to minimise over-dosage or under-dosage, unintended administration to non-target animals, the risk of cross-contamination and dissemination of those products in the environment.

Article 106

Use of medicinal products

1. Veterinary medicinal products shall be used in accordance with the terms of the marketing authorisation.

(…)

4. Member States may, if duly justified, decide that a veterinary medicinal product shall be administered only by a veterinarian.

(…)

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.