EGGVP comments as regards the **EMA scientific recommendations** on delegated and implementing acts as part of the implementation of the new veterinary medicines Regulation 2019/6

Subject: **Administration of VMPs via oral route (other than medicated feed (Article 106 (6))**

Preamble

On 1st July 2019 the European Commission sent a request to the European Medicines Agency for scientific recommendations on the administration of veterinary medicines via oral route (other than medicated feed.

The Committee for Medicinal Products for Veterinary Use (CVMP) adopted the scientific recommendation which was sent to the European Commission on 31 August 2020.

On 26 November 2020, the European Commission (DG SANTE) contacted EGGVP with a kind request for written comments as regards the EMA advice, in the context of a targeted stakeholder consultation.

EGGVP highly values this consultation and the opportunity to share its views on this topic, and thanks DG SANTE for the initiative.

EGGVP comments

EGGVP fully supports implementation of a legal framework which ensures a safe and efficient use of veterinary medicinal products administered orally via routes other than medicated feed, so that the needs for animal and public health in the Union are covered.

EGGVP comments on the European Medicines Agency's scientific recommendations on the administration of veterinary medicines via oral route (other than medicated feed) are:

Pack size

Registering smaller pack sizes is an increasing requirement from authorities, not allowing the registration of larger packs. While this is of course needed and getting more important, it is

sometimes not easy to determine the smallest pack size needed (as regards to the promotion of prudent use of antibiotics) because of huge differences in farm size between EU countries.

Therefore, the EMA proposal for "Adequate pack sizes" is welcome in principle. However, manufacturers of veterinary medicines can have difficulties to manufacture a wide variety of pack sizes. Therefore, harmonized criteria from Member States on what is "adequate" should be established to allow time and preparation and ensure predictability for marketing authorisation holders. "Adequate" should mean that presentations are suitable for all Member States, adapted to reality of Europe, and not to national requirements from individual territories.

It is also not clear if potential new pack size rules would be applicable only to new marketing authorisations approved after the coming into effect of Regulation 2019/6, or if these would also be applicable to existing marketing authorisations. If the later would be confirmed, how will these affect the existing marketing authorisations? More details on the conditions seem to be needed for appropriate implementation.

Restrictions to individual treatment only

EMA recommends that *"the use of oral powders, granules or similar pharmaceutical forms administered to terrestrial animals via solid feed shall be restricted to individual animals only. This includes veterinary medicinal products administered via top dressing".*

This statement is based on the well-known assumptions: inhomogeneous mixing in the feed → no reliable dose intake by the sick animal (under- and overdoses) → increased resistance development

It is necessary that rules for the administration of such veterinary medicines via oral route are equivalent / similar to those for medicated feed as set up by Regulation 2019/4; this shall ensure a safe and reliable treatment of the animals, especially with antimicrobial substances and with the aim to prevent the risk of development of antimicrobial resistance. In EGGVP's view, if required homogeneity levels can be proved to be consistent and equivalent to those for medicated feed (Regulation 2019/4), then the use of oral powders, granules or similar pharmaceutical forms administered to terrestrial animals via solid feed shall not be restricted to individual animals only.

Modern technologies have been recently developed and also recent studies show that a highly homogeneous distribution of the veterinary medicine into the feed for these products is possible. As such, even the last animal receiving the feed still gets an adequate amount of the medication – see Appendix.

It would be important to keep the possibility of group treatment, at the discretion of the veterinary prescriber. Although water medication is the preferred option for groups of animals, mixing into the feed could be a good solution when it is not possible for some veterinary medicines, for the reasons i.e.:

- Insufficient water-solubility of the active substance - There are active substances with poor solubility per se as e.g. benzimidazoles. Other active substances may precipitate in e.g. hard drinking water and block the nipple drinkers, so that the animals do not receive the vital drinking water.
- Worse palatability via liquid administration - A bitter taste is noted in drinking water easily, but may be covered with other flavours in the feed.

Concomitant use of biocides

EMA recommendation: "*Potential interactions between commonly used biocides and veterinary medicinal products administered via drinking water should be assessed and appropriate guidance regarding interactions and incompatibilities should be provided in the product information.*"

EGGVP would recommend provision of further details / more elaborate guidance to allow a consistent and practical implementation. The current text is too wide open and not implementable, and we see a need to be precise with regards of what would be tested, i.e. for which (groups of) veterinary medicines and combinations with biocides, since testing every possible combination would not be feasible.

Solubility enhancers

More information would be needed on the process for testing and approval of solubility enhancers, i.e. It is not clear if it would be applicable only to new marketing authorisations approved after the coming into effect of Regulation 2019/6, or if these would also be applicable to existing marketing authorisations. If the later would be confirmed, how will these affect the existing marketing authorisations? More details on the conditions seem to be needed for appropriate implementation.

Appendix

Example of dosing device: This device doses the drug into the feed stream. It meets the requirements of the DIN standards for dosage systems and DIN-tested technology for the application via feed as well as drinking water on the German market.

- Mediput
- DIL - Report No 2322 Project No 2013/08

Study results: *Blutspiegel von Antibiotika bei Verwendung eines handelsüblichen Medikamentendosierer für Trockenfutteranlagen*
Axel Wehrend, Peter Latell, Fritz Rupert Ungemach

- View results