*Disclaimer: The following document is intended to support a discussion with the national competent authorities. It has not been adopted by the Commission and therefore does not contain the official position of the European Commission.*

| **Delegated Act under article 106(6) of the Veterinary Medicines Regulation** |
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| ***Article 106*** <br> ***Use of medicinal products*** <br> ***…*** <br> **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.** |

## 1. The Context

Regulation (EU) 2019/6 on veterinary medicinal products[1] (hereafter "Veterinary Medicines Regulation") requires the Commission to adopt delegated acts in accordance with Article 106(6) establishing 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.

On 1 July 2019 the European Commission requested the European Medicines Agency ('the Agency') to provide a scientific problem analysis and recommendations to ensure the safe and efficient oral administration of veterinary medicinal products via routes other than medicated feed.

The Committee for Medicinal Products for Veterinary Use (CVMP) adopted the scientific advice on 16 July 2020[2] and the Agency provided its advice to the Commission on 28 August 2020 (link).

## 2. Scope and definitions

Article 106(6) of the Veterinary Medicines Regulation limits the scope of the delegated acts to be adopted to supplement this article to veterinary medicinal products authorised and

[1] Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L4, 7.01.2019, p.43

[2] 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.

prescribed for oral administration via routes other than medicated feed, such as mixing of a veterinary medicinal product with water for drinking or into feed and administered by the animal keeper to food-producing animals.

The administration of veterinary medicines to non-food-producing animals, as well as veterinary medicinal products not being administered orally are out of scope of the empowerment given to the Commission under the Veterinary Medicines Regulation.

In the light of the scope of Article 106(6) of the Veterinary Medicines Regulation, the rules to ensure the effective and safe use can cover **all types of veterinary medicinal products** authorised and prescribed for oral administration via routes other than medicated feed (e.g. vaccines or pharmaceutical products other than antimicrobials).

For discussion:

*Some veterinary medicinal products are directly administered via oral route resulting in individual applications (e.g. oral pastes or drench applications with individual dosage devices), for which the risks for not to be used properly are lower.*

*Do you agree to limit the measures of the future delegated act to the administration of veterinary medicinal products by means of mixing in the water for drinking or feed (as proposed in the scientific advice)?.*

For discussion:

***Article on scope***

*1. This Regulation shall apply to:*

*a) Veterinarians prescribing or administering oral veterinary medicinal products to food-producing animals by routes other than medicated feed;*

*b) Animal keepers administering oral veterinary medicinal products to food-producing animals via routes other than medicated feed.*

***Article on definitions***

1*. For the purposes of this Regulation, the following definitions apply:*

*a) The definitions of 'feed' as laid down in point 4 of Article 3 of Regulation (EC) No 178/2002[3];*

*b) The definition of 'feed additives' as laid down in point (a) of Article 2(2) of Regulation (EC) No 1831/2003[4];*

[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

*c) The definition of 'veterinary medicinal products' as laid down in point 1 of Article 4 of Regulation (EU) 2019/6;*

*d) The definition of 'medicated feed' as laid down in point (c) of Article 3(2) of Regulation (EU) 2019/4;*

*e) The definition of 'non-targeted feed' as laid down in point (a) of Article 3(2) of Regulation (EU) 2019/4;*

*f) The definition of 'biocidal product' as laid down in point (a) of Article 3(1) of Regulation (EU) 528/2012;*

*2. The following definitions also apply:*

*a) 'Cross-contamination' means contamination of a non-target feed or drinking water with a veterinary medicinal product, originating primarily from the previous use of a veterinary medicinal product in the relevant farm facilities or equipment;*

*b) 'top dressing' means the administration of a veterinary medicinal product by application onto the surface of the feed immediately prior to the feeding of the animals;*

*c) 'Homogeneity' means the appropriate, homogeneous dispersion of all ingredients in the same mixture, including those of lower inclusion;*

*d) 'Flushing': means a procedure for cleaning the distribution line of feed, consisting in passing a feed grade product through the distribution line a determined number of times.*

## 3. Obligations of the veterinarian

Veterinarians play a pivotal role to ensure the proper administration and appropriate dosing of veterinary medicinal products that are to be administered orally in feed or in drinking water. A key function for the veterinarian is to prescribe the most appropriate treatment, taking into account all the relevant elements and to provide the animal keeper with clear instructions on the use of the oral veterinary medicinal product.

One of the recommendations of EMA's scientific advice was to restrict the veterinary prescription for oral antimicrobial veterinary medicinal products to a single antimicrobial veterinary medicinal product. Such restriction already exists for medicated feed containing

[4] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

antimicrobial substances[5]. Taking into account that the reduction of the risk of developing antimicrobial resistance is one of the main objectives of the Veterinary Medicines Regulation, a similar provision for the prescription of oral veterinary medicinal products other than medicated feed should be considered.

Another recommendation is to limit the prescription and use of oral powders and granules administered to terrestrial animals via solid feed to individual animals only. In case of treatment of individual animals, the uptake of the feed with the adequate dose of the medication can be better ensured and controlled. The advice indicates that for treatment by means of top-dressing of groups of animals (that compete for the feed), it cannot be ensured that all animals will actually receive the correct dose, as the homogeneity of the mixture cannot be guaranteed and animals might intentionally take up more or less of the medication.

However, several Member States as well as stakeholders (FVE, AhE and AccessVetMed) did provide comments on this specific recommendation of the Agency stating that some technological advancements in oral application via solid feed had not been taken into account in the advice. According to these comments, modern standardized equipment is available ensuring adequate dosing of the veterinary medicinal product mixed into the feed when administered to a greater number of animals. According to these Member States and stakeholders, mixing into feed using appropriate technologies/equipment should remain an option for the prescription of the treatment of groups of animals. Only the use of veterinary medicinal products administered via top dressing should be restricted to individual animals.

The decision on whether or not the administration of oral powders and granules to terrestrial animals via solid feed is to be limited to individual animals only, is crucial for the further elaboration of the rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products for oral administration and impacts to a great extend the potential obligations to be put on veterinarians, farmers and the requirements for the equipment.

For discussion:

*a. Should the administration to **terrestrial animals** of oral powders or granules via solid feed be limited to individual animals (i.e. top dressing)?*

*b. Should oral powders and granules be allowed for the treatment of groups of **terrestrial animals** in case homogeneity in feed can be guaranteed by appropriate equipment at farm?*

*c. Possible use in aquaculture?*

[5] Article 16(9) Regulation (EU) No 2019/4, states that the veterinarian shall not prescribe medicated feed with more than one veterinary medicinal product containing antimicrobial(s).

For discussion:

***Article on obligations of the veterinarian***

*1. Veterinarians shall ensure that when deciding on the therapy to treat animals, the most appropriate oral route of administration is selected to ensure the effective and safe use of veterinary medicinal products taking the following into account:*

*a) The specific diagnosis;*

*b) The availability of appropriate veterinary medicinal products;*

*c) The good practice to have, whenever possible, a targeted individual treatment of the animal(s);*

*d) The number of animals to be treated;*

*e) The amount of feed or drinking water to be used;*

*f) The properties of the veterinary medicinal product and the characteristics of the feed or drinking water, including mixability, compatible particle sizes, solubility, possible interaction or inactivation of the veterinary medicinal product, presence of additives or biocidal products in the feed or drinking water that might impact the efficacy or safety of the veterinary medicinal product;*

*g) The facilities and equipment present at the farm (e.g. mixing and dosing equipment, type of feed presentation equipment and storage premises) and their maintenance conditions;*

*h) The relevant expertise and skills of the staff on the farm for the correct storage, preparation and administration of the veterinary medicinal product, including the ability to use the necessary equipment and/or dosing devices.*

*2. The veterinarian shall prescribe veterinary medicinal products to be administered by means of top dressing on the feed only for the treatment of individual animals and that are individually fed.*

*3. The veterinarian shall prescribe and, where relevant, dispense oral veterinary medicinal products to be administered by mixing of the veterinary medicinal product into the feed or drinking water in the most appropriate packaging volume taking into account the number of animals to be treated.*

*4. The veterinarian shall prescribe oral veterinary medicinal products to be administered by mixing of the veterinary medicinal product into the feed or drinking water only for the treatment of groups of animals in case the facilities/equipment at the farm do guarantee a homogeneous mixing into the feed/drinking water and a targeted distribution of the veterinary medicinal product to the group of animals concerned is ensured.*

*5. The veterinarian shall not prescribe more than one antimicrobial veterinary medicinal product to be administrated orally for the treatment of the same group of animals. By way of derogation, the simultaneous treatment with more than one antimicrobial veterinary medicinal product may be allowed provided that it is duly justified on the basis of a full diagnostic investigation, including bacterial culture and antimicrobial susceptibility testing.*

*6. The veterinarian shall inform the animal keeper of the required dose, the dose interval and the duration of treatment and shall provide instructions on the use of the oral veterinary medicinal products and the preparation of the mixture of the veterinary medicinal product and the feed or drinking water.*

*7. Veterinarians shall determine the amount of the veterinary medicinal product and the amount of feed or drinking water to be used in accordance with the product authorisation, taking into account the properties of the veterinary medicinal product and the expected feed or drinking water intake of the animals.*

## 4. Obligations of the animal keeper

Together with veterinarians, animal keepers also play a key role in order to ensure the proper administration and appropriate dosing of veterinary medicinal products administered orally in feed or drinking water. Therefore, rules should also be established for animal keepers to ensure effective and safe use of these products.

For discussion:

*Which obligations should animal keepers administrating veterinary medicinal products for oral administration via routes other than medicated feed comply with?*

***Article on obligations of the animal keeper***

*1. The animal keeper shall use veterinary medicinal products only in accordance with the veterinary prescription and the instructions provided by the veterinarian.*

*2. The animal keeper shall ensure that only the animals identified in the veterinary prescription receive the veterinary medicinal product prescribed.*

*3. The animal keeper is responsible for ensuring the proper storage, preparation, administration and disposal of veterinary medicinal products.*

*4. The animal keeper is responsible for ensuring the proper use, maintenance and cleaning of the equipment and/or dosing devices used for the administration of the veterinary medicinal products to be administrated in feed or drinking water.*

*5. The animal keeper is responsible to ensure that he/she, or any person administering veterinary medicinal products under his or her supervision, has had the necessary training with regards to paragraphs 3 and 4 of this Article.*

*6. The animal keeper shall take the necessary measures to avoid cross-contamination of unmedicated feed or drinking water from feed or water containing a veterinary medicinal product.*

*7. The animal keeper shall ensure that the equipment used for the mixing of the veterinary medicinal product in the feed or drinking water and the facilities used for the distribution of the medication to the animals are properly maintained.*

*8. Any other obligations for the animal keeper?*

## 5. Requirements for the equipment

Requirements should be set for the equipment used for mixing oral powders and granules administered via feed and drinking water in order to ensure homogeneity.

For discussion:

***Article on requirements for the equipment***

*1. All scales and metering devices used for the preparation of the mixing of the veterinary medicinal product shall correspond to the range of weights or volumes to be measured and shall be calibrated.*

*2. The equipment used for mixing shall correspond to the range of weights or volumes being mixed and shall allow, where relevant, the preparation of homogeneous mixtures and dilutions.*

*3. The equipment shall be designed in a way that medication via feed or drinking water is supplied to the target animals only.*

*4. The equipment used for the mixing of the veterinary medicinal product in feed or drinking water and the distribution of feed or drinking water to the animals shall be designed, built and placed in such a way that contamination of untreated feed or drinking water is minimized and a thorough cleaning is ensured.*

*5. Any other requirements (e.g. certification of equipment)?*

***Article on requirements for cleaning of the equipment***

*1. The feeding equipment and watering systems shall be cleaned thoroughly after each course of treatment to prevent any build-up of hazards.*

*2. Where necessary, all or some parts of the feeding equipment involved in the process must be flushed after the production of a feed containing a veterinary medicinal product, in order to reduce cross-contamination and the unintended treatment of animals.*

*3. After use, the flushing material shall be identified, managed and stored in such a way to not affect the safety of the feed administrated after the treatment.*

*4. Watering systems shall be cleaned and disinfected when necessary to avoid the development of biofilms.*

*5. Any other requirements?*

## 6. Concomitant use of other substances

Concomitant administration of oral veterinary medicinal products with other substances such as biocidal products, stability enhancers, feed additives or other substances may affect the stability, efficacy or safety of the veterinary medicinal product. This may result in treatment failures and/or increase the risk of development of antimicrobial resistance.

According to the Agency's advice, potential interactions between commonly used biocidal products 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 of the veterinary medicinal products.

For discussion:

***Article on concomitant use of feed-additives***

*1. Feed additives and veterinary medicinal products can only be used simultaneously in feed or drinking water if no interactions are indicated in the summary of product characteristics of the veterinary medicinal product.*

*2. Veterinary medicinal products that have a coccidiostatic or histomonostatic active substance shall not be used in feed containing feed additives authorised as a coccidiostat or a histomonostat with a maximum content.*

*3. Where the active substance in the veterinary medicinal product is the same as a substance in a feed additive contained in the feed concerned, the total content of that active substance in the feed cannot exceed the maximum content set out in the veterinary prescription.*

***Article on concomitant use of biocides, solubility enhancers or other substances***

*Biocidal products, solubility enhancers or other substances such as colouring agents can only be used simultaneously with veterinary medicinal products in drinking water or liquid feed if the absence of interactions negatively impacting the efficacy or the safety is indicated in the summary of product characteristics of the veterinary medicinal product concerned.*

## 7. Date of application

The Veterinary Medicines Regulation does not provide for a date for the entry into application of the Delegated Acts to be adopted under Article 106(6) of the Veterinary medicines Regulation.

Veterinarians, animal keepers and Competent Authorities should be given sufficient time to take the necessary measures to adapt to the future requirements.

*For discussion:*

*Member States are invited to provide their views the time needed between the publication and the entry into application of the future delegated act on oral administration.*