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FEFAC comments on

the EMA Advice on implementing measures under Article 106(6) of Regulation (EU) 2019/6: problem analysis and recommendations to ensure a safe and efficient administration of oral administration via other routes than medicated feed

Veterinary medicinal substances may be orally administered to animals in different forms, in particular in the form of medicated feed, oral powder added to solid feed or soluble powder delivered via drinking water.

FEFAC represents the suppliers of compound feed and premixtures to livestock farmers. The primary objective of feed manufacturers is to provide farmers with high quality feed to maintain their animals in an optimal physiological status that allows them to cope with pathogens. Manufacturing and delivering medicated feed is a side activity for a compound feed manufacturer and a service to farmers.

As rightly pointed in the EMA advice page 13, “all the available pharmaceutical forms and routes of administration of a veterinary medicinal product are considered useful and should be taken into account within a certain production system…. the choice of the most appropriate administration method to be used in a given situation should remain with the prescribing veterinarian”. We believe however that the constraints put on the feed manufacturers, if maximum limits for antibiotic residues in feed as a result of carry-over are set following the EFSA draft methodology, compound feed manufacturer will no longer be in a technical possibility to produce medicated feed. This means that there is a clear responsibility for public authorities to ensure that farmers who cannot use medicated feed can still administrate veterinary medicines to their animals in conditions as safe as via medicated feed to avoid in particular that the use of antimicrobials via top dressing or drinking water contributes to increase the AMR risk. In this sense, the development of good practices for the on-farm oral administration of veterinary medicines via top dressing and drinking water is critical.

As pointed also by EMA page 13, the choice of the most appropriate administration method is to be left to the veterinarian, “who has knowledge of the particular farm concerned, of its equipment and of the possible therapeutic alternatives”. In our opinion, this means that veterinarians should have the tools to evaluate the relevance and efficiency of the available equipment. This means that veterinarians should be regularly trained on how to perform an audit of the facilities and equipment of the farm or should be able to rely on an audit performed by a third party. This could be considered in the framework of the promotion of the Agricultural Knowledge and Innovation Systems (AKIS) as key initiative laid down in the Farm to Fork communication. It might also be useful in the case of top dressing, to define acceptability criteria, e.g. on homogeneity as is foreseen for medicated feed; this could stimulate innovation in top dressing technology, thus avoiding a de facto ban on group administration of VMPs via top dressing as recommended by EMA.

It should also be stressed that the advice delivered by EMA should differentiate, both in terms of risk assessment and recommendations for risk management, the case of administration of antimicrobials vs. other veterinary drugs, considering the primary concern is antimicrobial resistance.

We do believe that farmer organisations should be involved in the drafting of the guidelines to the attention of farmers. The expertise of feed manufacturers may be useful as well and FEFAC is willing to provide its technical input.

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