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Position paper

10 August 2020

AnimalhealthEurope comments to the EMA advice to the European Commission on Good Distribution Practice for active substances used as starting materials in veterinary medicinal products

Implementing Act of Regulation 2019/6 article 95 (8)

Background

Article 95(8) of the new veterinary legislation Regulation 2019/6 requires that "the Commission shall, by means of implementing acts, adopt measures on good distribution practice for active substances used as starting material in veterinary medicinal products". The European Commission requested expert advice from the EMA prior to the drafting of these implementing acts. The EMA advice was published at the beginning of July 2020 for public consultation.

General considerations

AnimalhealthEurope would like to thank the EMA expert group for their considerations on this topic and the Commission for the opportunity to provide comments on this document.

As a general principle, AnimalhealthEurope would like to recommend to not include detailed requirements in the implementing acts as experience shows an implementing act cannot be easily or quickly changed in response to potential amendments to these details; changing a guideline will be easier and faster if the details need to be updated in the future.

To ensure the details can be adapted when required, the detailed conditions and documentation requirements should be published in guidelines and not in the implementing act.

AnimalhealthEurope very much appreciates that the Agency when preparing this advice took the following points into consideration (with reference to the EMA document, § background and § considerations and rationale for the recommendations):

- The similarities but also the potential differences between the requirements towards GDP for human and for veterinary medicinal products.
- The Agency advise the European Commission to follow the principles of GDP for human active substances but taking into account the specificities of the veterinary field.
- It is essential that the future Implementing Act does not introduce any requirements more stringent than the corresponding GDP guidance for the human sector.
- It is suggested to not deviate significantly from the human side in order to avoid unnecessary administrative burden to experts dealing with inspections generally common to both sectors. On the other hand, it is recognised this could be necessary when there are practical needs that dictate otherwise. This modulation is fully supported by AnimalhealthEurope.

  In addition, we would like to add that it would be highly beneficial that inspections in GMP and GDP areas on the veterinary domain should be carried out by persons who have sufficient knowledge/training on the needs and specificities of the veterinary sector.

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Specific considerations

Chapter 1. Scope, §1:

"The measures proposed in this advice for good distribution practice apply to import and distribution of active substances used as starting materials in veterinary medicinal products, as defined in Article 95 (1) of Regulation (EU) 2019/6 on veterinary medicinal products."

It should be made clear in the implementing act that the guidelines should apply directly to active substances used as starting materials in veterinary medicinal products imported from non-EU countries from the point of receipt of the active substance on EU soil and onwards.