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Position paper

10 August 2020

AnimalhealthEurope comments to the EMA advice to the European Commission on Good Distribution Practices for veterinary medicinal products

Implementing Act of Regulation 2019/6 article 99 (6)

Background

Article 99(6) 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 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 advice 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 medicinal products but taking into account the specificities of the veterinary field which is fully supported.
- 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.

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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.

AnimalhealthEurope appreciates that risk-based assessment has been introduced throughout the document, which will allow maximum flexibility and building systems that are adapted to the needs, size and resources of the VMP sector. However, please note that implementation of these GDPs will require significant effort and resources in organisations where there has been no current alignment with the human health GDP guidelines.

Therefore, the implementing act should include an implementation period, starting after the implementing act is published, to facilitate the transition and adoption of the GDP regulations for veterinary medicinal products.

Specific considerations

In preparation of this implementing act AnimalhealthEurope requests that the following points are considered:

- Flexibility to use manual or computerised systems for the storage operations and management of stocks and either physical separation or separation by computer systems are allowed which is welcome. However, the draft provides the following examples that according to our analysis are not in line with the general provision above:
    - In chap. 3.2 §4: "*Products pending a decision as to their disposition or products that have been removed from saleable stock should be segregated physically and electronically, if an electronic system is available*."

  In the implementing act this sentence should be amended to read: "Products pending a decision as to their disposition or products that have been removed from saleable stock should be segregated physically ~~and~~ **or** electronically, if an electronic system is available."

  Rationale: It is AnimalhealthEurope's understanding that this sentence is addressing the general situation of products pending decision e.g. products in quarantine awaiting approval. In this general case, the standard procedure needs to be applied i.e. the stock could be either physically **or** electronically segregated. The example provided on returned products is therefore inappropriate and should be removed. In human GDP, the wording here is "OR". We therefore understand that that this is simply a typo. We also would like to refer here to the statement made in "Recommendations" section of this document: "*Therefore, it is essential that the future Implementing Act does not introduce any requirements more stringent than the corresponding GDP guidance for the human sector*.". In addition, if materials do have to be physically and electronically segregated this would have a massive impact on current warehousing operations.

  On the other hand, the sentence commencing by "*Any product suspected of falsification and falsified veterinary medicinal products found in the supply chain, expired products, recalled products and rejected products*.." is focusing on classes of products that could be potentially problematic and should be treated carefully. Here, the request to segregate these products from the sealable stock is sound and acceptable.

    - In chapter 5.5, §6: "*Veterinary medicinal products that are nearing their expiry date/shelf life should be separated immediately from saleable stock physically and electronically, if an electronic system is available*. "

  This sentence should be amended in the implementing act to read: "Veterinary medicinal products that are nearing their expiry date/shelf life should be separated immediately from saleable stock physically ~~and~~ **or** electronically, if an electronic system is available. "

Rationale: as above.

- In chapter 5.1 § 2: "*All veterinary medicinal products placed on the Union market by a wholesale distributor must be covered by a Union or national marketing authorisation or by a permission to place on the market by national legislation*"

  This sentence does not include specific allowances for certain classes of veterinary medicinal products (VMPs) as contemplated by the Regulation 2019/6, e.g.:

  - Immunologicals according to article 110 (2) and (3);
  - VMPs according to article 112 (2), 113 (2) and 114 (4).

  Consequently, we conclude that these products are not seen as "placed on the Union market". However, if this is not the case, then we urge the Commission to modify this sentence in order to include these specific allowances. Please find a proposal below:

  Proposal: "All veterinary medicinal products placed on the Union market by a wholesale distributor must be covered by a Union or national marketing authorisation or by a permission to place on the market by national legislation, **with the exception of those VMPs where a derogation to hold a marketing authorisation is set out in Regulation 2019/6."**

- In chapter 5.3: There is the obligation for the wholesale distributor to ensure they supply VMPs only to persons who are themselves in possession of a wholesale distribution authorisation or "*…who are authorised or entitled to supply veterinary medicinal products to the public or otherwise authorised to procure veterinary medicinal products from a distributor in accordance with national law.*" In §2 it is stated that checks and periodic rechecks should be performed.

  Whereas the number of wholesalers is limited, the number of veterinarians or other persons authorised to procure VMPs in the individual member states might be significantly higher. Whereas the check of legitimisation is necessary and possible in the uptake of activities, periodic re-check cannot be performed as no databases exist to check validity of permissions once issued without need for renewal. This in addition would represent a big amount of administrative burden. So, for this type of customer, re-check should not be requested.

- In chapter 5.8: The details required in the delivery note are very numerous and going beyond what is requested in the human guidance. This should be simplified to keep what is useful and relevant for product integrity and/or quality.

  Please modify the following sentence in the implementing act to read:

  "For all supplies, a document (e.g. delivery note) must be enclosed stating **at least** the date; name and pharmaceutical form of the veterinary medicinal product, ~~*strength*~~ batch number **at least for products bearing the safety features;** ~~*expiry date*~~, quantity supplied ~~*stating pack size and number of packs*~~**;** name and address of the supplier, name and delivery address of the consignee (actual physical storage premises, if different), ~~*unique number to allow identification of the delivery order*~~, **and** applicable transport and storage conditions ~~*and additional requirement specified by national legislation*~~ **or alternatively to the elements above, any relevant data for ensuring product integrity and quality of the product.**"

- In chapter 9.2: There is a number of companies that have validated transport conditions and demonstrated stability of VMPs (including vaccines) for certain transport conditions going beyond the normal storage conditions, such as temperature exceeding 25°C for a certain period of time (e.g. 30 degrees for 24 hours or similar); stability of vaccines outside of cooling conditions for a certain period of time (e.g. 24 hours). Therefore, it is important to differentiate between storage conditions and transportation conditions.

  Proposal: The sentence: "*The required storage conditions for veterinary medicinal products should be maintained during transportation within the defined limits as described on the*

outer packaging by the manufacturers and by the marketing authorisation holder.” should be replaced in the implementing act by:

“The appropriate transport conditions /defined limits should be maintained during transportation to safeguard the quality of veterinary medicinal products.”
Or alternatively:
“During transportation the appropriate/defined transport conditions should be met in order to safeguard the quality of veterinary medicinal products.”

- In chapter 9.4
§ 3: The same rationale as for chapter 9.2 is valid. Please modify the following sentence to read in the implementing act:
“*For temperature-sensitive veterinary medicinal products, qualified equipment, such as thermal packaging, temperature-controlled containers or temperature-controlled vehicles, should be used to ensure correct transport conditions are maintained between the manufacturer, wholesale distributor and customer,* **unless stability of the product has been demonstrated with other transport conditions.**”

  §5: In the following sentence “*If requested, customers should be provided with information to demonstrate that products have complied with the temperature storage conditions*” this possibility for the customer to request information, will result in a systematic request of information which will dramatically increase the administrative burden given the significantly higher number of customers than in human sector (i.e. veterinarians and other persons authorised to procure veterinary medicinal products in the individual member states). In addition, this possibility is already contemplated in chap. 6 complaints where any deviation should be investigated for quality impact and communicated & discussed with the customer.

  Please do not include this sentence in the implementing act.