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Position paper

18 October 2019

AnimalhealthEurope comments to the Scientific recommendation on the revision of Annex II to Regulation (EU) 2019/6 on veterinary medicinal products

EMA Advice on implementing measures under Article 146(2) of Regulation (EU) 2019/6 on veterinary medicinal products

1. General Comments

AnimalhealthEurope is supportive of the legal basis given to the ESVAC project and welcomes the opportunity to provide input.

We believe that focus, accuracy and attention should be given to the collection of sales and use data for medically important antibiotics and we fully support this.

According to tables 2 and 3 of the EMA Advice a very large expansion of the ESVAC programme is proposed with only very limited efforts made to prioritise and ensure the effort (administrative burden) in data collection and analysis is justified by the risks involved.

Proposals are made for where member states may voluntarily require sales, or sales and use data. But is the voluntary nature of this is also relevant to the stakeholders in those countries who decide they wish to collect such information? Furthermore, the delegated act should only set out mandatory requirements.

In various places reference is made to reviewing and modifying the approach e.g. "inclusion of additional animal species", "other substances or classes of antimicrobials". Since the delegated act will define the "types of antimicrobial medicinal products used in animals for which data will be collected" then such changes should only be made following an update of the delegated act.

Table 3 indicates that by 2030 use data should be collected for dogs and cats. However, the wording of the Regulation refers to "animals which are kept or bred". In this context it is understood this does not relate to household pets, but instead to specifically animals kept in groups for business purposes e.g. cattery or kennels. The delegated act should not go beyond what the Regulation requires and should furthermore focus on the priority areas.

Specific Comments:

Page Number	Comment
6, (para. 11)	Reference is made to the source of sales data, with marketing

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	authorisation holders (MAH) named as one source. This should be changed. With the Union Product Database and the future requirement for information to be entered by MAHs on sales volumes, this should be used as the source rather than requiring specific and additional information returns from MAHs.
25 6.2.1)	This section highlights some member states have experience in implementing data capture, for example from prescription data. The following is an important learning from this: Within the delegated act and concerning the rules on the methods of gathering use data, the following pre-requisite should be added - that the MS when putting in place data collection systems to have the responsibility to: - fully test the system before use is mandatory - to ensure the design does not disrupt or slow down usual prescribing procedures.