FEDERATION OF VETERINARIANS OF EUROPE

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FVE COMMENTS on the 'Advice on implementing measures under Article 57(4) of Regulation (EU) 2019/6 on veterinary medicinal products – Report on the format of the data to be collected on antimicrobial medicinal products used in animals' (EMA/CVMP/586518/2019)

FVE welcomes the EMA advice on implementing measures under Article 57(4) of Regulation (EU) 2019/6 on veterinary medicinal products, which is technically a sound document.

It is important to strengthen the ESVAC system by ensuring a proper and easy collection of both sales and use data, which will promote and facilitate judicious and prudent use across Europe. The information considered within the presented report is towards that direction.

In order to ensure that the system is fit for purpose, implementable and transparent, FVE would like to draw your attention to the following points, i.e.

- **Scope of collection systems**
  FVE welcomes the opening of the scope to include sales and use data for all antimicrobials, i.e. antibiotics, antifungals, antivirals, antiprotozoals, antimycotics and antimycobacterials. However, we would like to reiterate that adding the collection of data on antiparasitics as well as of coccidiostats/anticoccidials and histomonostats would be very useful as well. The emerging risk of anthelmintic resistance is generally recognised[1] and all food partners agree that it is time to take action to ensure the responsible use of veterinary anthelmintics in food-producing animals.[2] Coccidiostats/anticoccidials and histomonostats containing antimicrobials should also be under veterinary prescription and their use be monitored. [3] FVE, while highlights the importance

[1] COMBAR Press Release 'Drug resistant parasites cost European livestock industry millions each year': https://www.combar-ca.eu/sites/default/files/COMBAR_press_release.pdf
[2] EPRUMA best-practice framework on the use of anthelmintics in food-producing animals https://www.epruma.eu/wp-content/uploads/2019/04/Best-practice-framework.pdf
[3] FVE position on coccodiostats : https://www.fve.org/publications/fve-position-paper-oncoccidiostats-or-anticoccidials/

for those products to become prescription medicines and enter ESVAC system, emphasises that it is of utmost importance that this transition should be done without losing the availability of these essential products.

- **Collection of accurate data**
  It is of ultimate importance to ensure the accuracy of collected data to avoid multiple insertions for the same treatment course from different sources or type of data. For example, it may be appropriate to add a requirement on the form for the collection of use data to identify the source of information. A single input point/source of the information should be ensured. The type of data provided should also avoid that an overestimation takes place. A break down into amount of active ingredient used is necessary. That way it would be easier for the national competent authority to track different submissions and avoid duplication. We note however that collection of data from different sources, e.g. from veterinarian or from the farmer, may reveal discrepancies, which should be acceptable, e.g. the prescribed quantity of a medicine is not always completely used.
  A standardised approach to data collection is very important, if we are to accurately benchmark any interventions that are made, without any negative effect on animal welfare. We share the concerns raised by the Member States and agree with the suggested 'species PCU' as denominator. Additionally we remark the importance of a harmonised approach in collection of use data in animals and humans which will allow for a more correct analysis and benchmarking of antimicrobial consumption in the future JIACRA reports.
  With regard to the collection of animal population data for all species, FVE agrees with the methodology for collection of animal population data and is satisfied that the need for identification and registration of companion animals, e.g. horses, cats and dogs, is recognised and highlighted.

- **Templates for collection of sales data and use data need to be comparable and at the same time fit for purpose.**
  We see as valid to use a similar template for the collection of sales data and use data that will allow for easy comparison and analysis of the results. In collecting data appropriately it is important that the product itself but also each package size of each antimicrobial product is reliably identifiable. This should be ensured by the appropriate set up in the UPD, e.g. via the Global Trade Item Number (GTIN). However, minor changes might need to be implemented to make the submission fit-for-purpose. For example requirements 14-17 on the template for use data is a redundancy. Provided that those values are requested via sales data there is no need to ask for them again. These data should be provided by the marketing authorisation holder and not the veterinarian or the farmer. On the other hand, the inclusion of a requirement to track the source of use data/type of data would be more appropriate
  We also note that while Member States need to report both sales and use data, it is necessary to expect a certain degree of discrepancy in quantities between the two. The reporting does not cover all aimal species for which a product

might be sold and used. In general the amount calculated via the sales figures should be higher than the reported use data. It might also be the case that not all sold product is applied in the reporting period. Therefore, it would be important to ensure that analysis considers when the reported data sound realistic and meaningful.

- **Ensure proper collection of data on off-label use of veterinary antimicrobials**
  FVE welcomes the opening of the scope to include also use data of human products used off-label in animals when necessary. We note, however, that similar attention may be required concerning the collection of data in the case of veterinary antimicrobials used off-label or in cases of cross-border prescriptions. For example, the requirement for indication of the "pharmaceutical form" within the collection of use data should be adapted to encompass the case when a veterinary product is necessary to be used via a different administration route than the one on the label to ensure treatment of a different species/indication. Therefore the option "*other forms*" should also refer to veterinary medicinal products used off-label and footnote 5 should be amended respectively.
  Further to this off-label use may be the prescription of a VMP authorised in another country, this means that sales data and use data for this product would have to be reported by different Member States. That is also of importance for cross-border prescriptions. It would be necessary to include explanatory footnotes within the "type of data" description for use data to cover such cases.

- **Support Member States to implement properly the requirements**
  FVE notes that setting up these use data systems requires an important investment by Member States. Currently only a few countries have implemented a collection system and most of them they do so far only for some species/categories of animals. It is important that the EU in collaboration with MS ensure the implementation of data collection systems without overburdening competent authorities, farmers or veterinarians. Amongst veterinarians, there are serious concerns regarding the extra bureaucracy in documenting the use and the responsibility for potential mistakes in data entry. Automated systems need to be developed without additional bureaucracy and cost for the veterinarian. Considering that such collection systems are a public good, we are of the opinion and expect that the costs should be covered by the government or society. Responsibilities need to be clearly defined and honest mistakes not be penalised.

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