Fédération Européenne pour la Santé Animale et la Sécurité Sanitaire
(European Federation of Animal Health Services, FESASS)

Date: **12 December 2019**

Note to: **Dr Christian SIEBERT, Head of Unit for Animal Nutrition and Veterinary Medicines, Health and Food Safety Directorate General, European Commission**

Subject: **FESASS comments on EMA advice on implementing measures under Article 57(3) of Regulation 2019/6 – requirements for collection of data on antimicrobial medicinal products used in animals**

FESASS thanks the Unit for Animal Nutrition and Veterinary Medicines for the opportunity to comment on the key issues for the implementation of Regulation (EU) 2019/6 on VMPs. Our organisations manage animal health on a daily basis with farmers, in partnership with veterinarians and competent authorities. It is essential being involved in the design of the new regulatory framework in order to ensure its feasibility and effectiveness.

Our federation welcome with great interest the work already made on data collection (EMA/CVMP/131097/2019). With regard to data collection on usage, there are already different systems in place in some Member States. For instance, in Germany there are two systems, one industry driven (QS) and one state driven (DIMDI AMV). Data is collected for fattening animals (cattle, pigs, chicken, and turkey). Discussion is ongoing for years if breeding animals and cows should be included. In our opinion the risk from the breeding units for human health is very low. In that regard, we would like to ask for clarification, that the term "all categories" in the recommendation (page 5 above in the cited document) refers to the categories as defined in the annex of CID 2013/652 (which does not include all categories).

For us it is very important to take into account both farm animals and companion animals. The collection of data on dogs and cats might be more complex and burdensome, but there is undeniably a risk for human health due to the close contact of companion animals and their owners. Again using the German example, there are 1.8 million breeding sows, 4.1 million dairy and 0.7 million suckler cows, but approximately 15 million cats and 9.4 million dogs. Furthermore, companion animals are likely to be treated with highly critical antibiotics and we would assume that they are a – so far completely neglected – considerable risk factor. Also, as opposed to most of the farm animals in European Union, they are usually roaming free and have plenty of chances for exchange between "holdings". So, for FESASS companion animals should move up on the priority list.

We welcome the possibility to report data for species, that are only present in low numbers, under "any other food-producing animal species". If however, as mentioned on page 18, data on these animal population are not available, how exactly can this be done? The EMA advice clearly explains the methodological challenges when using Eurostat data. As we are using this data, too, we know that sometimes data for a particular MS are not available, reported with a lag of one year of changed afterwards. Do we then need to adapt the results of the sales and use data collection as well?

With regard to the draft delegated regulation dealing with data collection, we hope that stakeholders will have the text available to them in good time. We must be able to consult our members in order to make an effective contribution within an acceptable time frame to the development of this project.

And finally a last and more general remark: The overarching objective is to reduce antimicrobial resistances, and in that regard the statistics on these resistances are even more important. Use data, and to an even lesser extent, sales data can only be an auxiliary means to in order to achieve well-founded conclusions on the development of resistances and the public health risks involved. Any evidence, that can be deducted from the collection of data on sales and usage per species to confirm or rule out these presumed link would be highly welcome.

Contact details:

Fédération Européenne pour la Santé Animale et la Securité Sanitaire (FESASS)
Place du Nouveau Marché aux Grains, 21
1000 Bruxelles
Tel +32 2 759 44 07

Alain C. CANTALOUBE
Secrétaire Général de la FESASS