**EGGVP comments** as regards the **EMA scientific recommendations** on delegated and implementing acts as part of the implementation of the new veterinary medicines Regulation 2019/6

# Subject: **Requirements for the collection of data on antimicrobial medicinal products used in animals (Article 57(3))**

## Preamble

On 6 February 2019 the European Commission sent a request to the European Medicines Agency (EMA) for scientific recommendations on specific requirements for the collection of data on antimicrobial medicinal products used in animals.

The Committee for Medicinal Products for Veterinary Use (CVMP) adopted the scientific recommendation which was sent to the European Commission on 30 August 2019.

On 18 September 2019, the European Commission (DG Sante) contacted EGGVP with a kind request for written comments as regards the EMA advice, in the context of a targeted stakeholder consultation.

EGGVP highly values this consultation and the opportunity to share its views on this topic; we thank DG Sante for the initiative.

## EGGVP general comments

- EGGVP welcomes the EMA advice and recommendations, which provide a practical framework and time plan.
- EGGVP is glad to see that the role of the ESVAC system is reinforced. The EGGVP members are marketing authorisation holders with extensive experience as **sales data** providers in the framework of ESVAC. Our organisation has firmly supported ESVAC data collection and reporting since its implementation and over the years, as a valuable tool to improve transparency and as a fundamental step to perform risk assessment.

- EGGVP also welcomes the big steps in the new veterinary regulation so as to collect **use data** to the most extent possible. Although EGGVP acknowledges the limitations in some Member States to implement (semi) automated continuous data collection systems, it is regrettable that no timeframe or expected deadline are provided in the document for all Member States to implement such systems.

  EMA recommendations suggest collecting stratification sales data as an interim measure for these Member States unable to implement (semi) automated continuous data collection systems at present; but again there is no indication of how long this interim measure should last.

  EGGVP fears that, without a timeframe indication, it may be a disincentive to move to a fully operational use-collection system.

  EGGVP would like to point again that collecting stratification sales data is the less accurate method because marketing authorization holders deliver data based on assumptions (estimation according to knowledge on the use of the drug in the different animal species and total number of animals per species in the country). EGGVP fully supports collection of sales data for other purposes (e.g. validation), but it cannot be seen as an indicator of use.

- EMA recommendations are mainly addressed to Member States, who shall put in place the appropriate national collection system (sales and use). The document provides general recommendations for the setup of these national collection systems, but no details are provided on how these national systems will be run and data collected, which is of concern for data providers. It is very important the collection systems are harmonised to the most extent possible so as to ensure homogeneity and avoid distortions:

  - Clarification and precise definition is needed for all the terms used in the data collection. If these terms are not well exactly defined, it may lead to wrong interpretation and disharmonisation in the different member states.

  - Clarity and standardisation of exactly what is being measured (doses/ treatment courses/ weight of active etc.) are required. Any programme of data collection must deliver reliable, accurate information that is fit for purpose.

  - National collection systems should not impose excessive and unnecessary burden to data providers. For the case of marketing authorisation holders, today ESVAC reporting is laborious and repetitive, and data is not collected uniformly (divergent formularies, timings and requirements which make processing and preparing data significantly time consuming). Simple and pragmatic use, with entry of data only once in the relevant EU database (Union Product Database) are supported.