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: **Report on the format of the data to be collected on antimicrobial medicinal products used in animals (Article 57(4))**

Preamble

On 1st July 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 June 2020.

On 8th July 2020, 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 publication of the EMA advice and recommendations, which are basically addressed to the EU National Competent Authorities, and as such it will not make comments to it. EGGVP is glad to see that the document provides the required level of detail for the setup of national reporting, and that precise definition is given for all the terms used in the data reporting, which shall ensure the desired level of data quality and harmonisation within the Member States.
- It is acknowledged that the advice is limited to the reporting from Member States to the EMA, and that the data collection from data providers to national systems is not in the scope of this advice. Nevertheless, EGGVP would like to highlight the importance that national collection systems are harmonised to the most extent possible so as to ensure homogeneity, avoid

distortions and reduce unnecessary burden at industry level. Nowadays, national collection systems do impose an excessive administrative burden to data providers. For the case of marketing authorisation holders, ESVAC reporting to the national competent authorities is laborious and repetitive, and data is not collected uniformly (divergent formularies, timings and requirements which make processing and preparing data significantly time consuming, etc.). Harmonised and single procedures for data providers, with entry of the required sales / use data only once in the relevant EU database, are supported.