



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Food and feed safety, innovation
Animal nutrition, veterinary medicines

**EC Workshop with EMA:
Data collection on consumption of veterinary antimicrobials in Europe – achievements,
challenges and way forward
Brussels, 26.04.2017**

Summary report of the workshop's outcome

In response to Commission request, the European Medicines Agency (EMA) started in 2010 the ESVAC project (European Surveillance of Veterinary Antimicrobial Consumption) to collect data on use of antimicrobials in animals in the EU.

Currently, 30 European countries are voluntarily reporting annual sales data. Inspired by the ESVAC blueprint, the Commission proposal for a new Regulation on veterinary medicinal products provides for compulsory collection of data on sales and use of veterinary antimicrobials. ESVAC is already focusing on the systems and procedures necessary to manage this proposed requirement. This includes the draft "Guidance on provision of data on antimicrobial use by animal species from national data collection systems" which was published by EMA on 24 March 2017 for a 6-month consultation period.

DG SANTE organised a workshop with EMA on 26 April 2017 to bring together all relevant parties to expose the benefits of collecting data on antimicrobial consumption (sales and use per species), and to discuss the implementation at national level of schemes for collection of those data, including collection at farm level. The workshop was also intended to provide a technical input to the Commission and EMA with a view of proposed new legal provisions.

The workshop was attended by more than 100 participants from the EU institutions, EMA, Member State authorities, private sector (including EU-level associations) and non-governmental organisations.

Discussions were mainly focused on future steps in data collection on consumption of veterinary antimicrobials, in particular on the recently published draft EMA guidance on data collection by animal species. The main preliminary views expressed by participants are summarised below:

- There is a general consensus on the need to collect data on antimicrobial use by animal species, and on the benefits of such data collection.
- Objectives/goals of data collection by animal species should be clearly defined and input from Member States is needed for this. For example, these objectives would be:
 - to provide for comparison between data on antimicrobial use and data on antimicrobial resistance (AMR; derived from AMR monitoring in animals and food in accordance with EU legislation),
 - to provide for assessment of effectiveness of measures taken at local (farm) level e.g. measures to improve farm management and animal husbandry.

- In order to promote the start of harmonised data collection by animal species and to facilitate Member States' participation, a pragmatic and gradual approach should be taken by setting the minimum (initial) requirements. This would include a minimum set of animal species with a possibility to cover also other species – for countries which decide to do so.
- Pragmatic approach also means to maintain the current system for data collection on sales of veterinary antimicrobials which is functioning well and provides harmonised data over time (while a system for data collection on use by animal species might take some time before being setup, especially to cover for all relevant animal species).
- Data collection on use by animal species should allow for careful comparisons, in particular between reporting countries. While such comparisons are to be kept in mind as one of the ultimate objectives, they should not be considered as a priority at initial stages of implementing data collection system by animal species.
- Exchange of experience on data collection by animal species between Member States is very important for the development of national systems and should be reflected in the EMA guidance document.
- As data by animal species are expected to originate from various sources (e.g. farm records, veterinary prescriptions, pharmacy books), a clarification may be needed on interpretation of these data in particular at the EU level.
- The risk of misinterpretation or even abuse of published data on antimicrobial use by animal species is of concern and should be addressed as it might have negative impacts on trade or public perception.

Overall, the workshop has successfully gathered the preliminary views on future steps in data collection on consumption of veterinary antimicrobials. Final formal views on the recently published draft EMA guidance on data collection by animal species are expected to be received by EMA during the public consultation period which will expire on 24 September 2017.