Concept paper on the reporting of antimicrobial sales and use in animals at the EU level

Draft

Agreed by European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) ad hoc expert group on revision of indicators and denominator (written approval) | October 2020
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Adopted by ESVAC network via written procedure for release for consultation | 4 November 2020
Start of public consultation | 12 November 2020
End of consultation (deadline for comments) | 31 January 2021

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1. Introduction

As outlined in the Article 57 of the Regulation (EU) 2019/6, a mandatory reporting of the sales and on the use of antimicrobial medicinal products used in animals is required to enable the direct or indirect evaluation of the use of such products in food-producing animals. The Article 57 states that, the European Medicines Agency (EMA) shall cooperate with Member States and with other European Union agencies to analyse antimicrobial sales and use data and shall publish an annual report. It is requested that the EMA should take into account those data when adopting any relevant guidelines and recommendations.

The EMA advice on implementing measures under Article 57(3) of the Regulation (EU) 2019/6 on veterinary medicinal products – “Report on specific requirements for the collection on antimicrobial medicinal products used in animals” (EMA/CVMP/131097/2019) - recommends conducting a scientific assessment on different denominators and indicators for analysing use data.
2. Problem statement

In the context of the Regulation (EU) 2019/6 and its future delegated and implementing acts, there is a need to further develop standards, amongst others, in terms of the denominator and main indicators for the reporting of veterinary antimicrobial sales and use data.

The work performed in the ESVAC project constitutes a good basis for the development of such guidance.

When reporting data on antimicrobial sales and on use by animal species it is necessary to take into account data relating to the animal population that could potentially be treated with antimicrobials. The methodology for calculation of the current ESVAC sales denominator - the population correction unit (PCU) - has now been in place for several years. ESVAC participating countries have indicated that this denominator for sales data reporting, i.e. including animal categories to be included and weights of animals used for calculation of the sales PCU, should be revisited.

The EMA advice on implementing measures under Article 57(3) of the Regulation (EU) 2019/6 on veterinary medicinal products includes, amongst others, recommendations for denominators and indicators for reporting of the data. The advice also recommends conducting a scientific assessment of different denominators for reporting of use data.

Of note is that, until an assessment of different denominators and indicators has been conducted, the PCU will continue to be used as a denominator when reporting sales data.

Assessment and proposals for the denominator for sales and use data is considered as a priority task. This assessment should take into account international guidelines and recent publications worldwide concerning the reporting of antimicrobial consumption in animals.

Recommendations on the main indicators to present quantification of antimicrobial sales and use data are also to be established. The effects on the presentation of the quantification of antimicrobial sales data should be evaluated.

The overall assessment of the denominator and main indicators should provide key recommendations for description of sales and use data by country, at EU level, by animal species, as appropriate.

Finally, it is necessary to determine activities to accommodate the recommendations resulting from this review exercise of indicators and denominators for reporting antimicrobial sales and use in animals at the EU level.

3. Discussion (on the problem statement)

To enable development of the guideline the following elements needs to be prepared:

- Assessment of the current denominator used for reporting ESVAC sales data;
- Assessment of a suitable denominator and main indicators for describing antimicrobial use data by animal species, including assessment of applicability of PCU for reporting use data;
- Proposals for indicators for reporting antimicrobial sales;
- Proposals for ESVAC sales denominator and use data denominator per animal species;
- Proposals for indicators for reporting antimicrobial use data in animal species, prioritising according to the requirements of the Reg. 2019/6;
• Assessment of the tasks for the EMA and Member States to accommodate the recommendations for the analysis of antimicrobial use data at European level.

The guideline should take into consideration the impact on the work performed within the ESVAC activity in consideration of analysis of antimicrobial consumption in animals at European level.

4. Recommendation

It is recommended to draft a guideline for presenting antimicrobial sales data and use data of antimicrobial medicinal products used in animals in Europe.

The objectives of this guideline are:

1. To assess adequate denominators and indicators of antimicrobial consumption at EU level;
2. To define the methodology, including animal categories and weights assigned, of the denominator to be used for sales and use data;
3. To recommend denominator(s) and indicator(s) that should be used for reporting on sales and on the use of antimicrobial medicinal products used in animals at European level to guaranty the fulfilment of the requirements and obligations set by the Article 57 of the Regulation 2019/6.

5. Proposed timetable

The concept paper will be released for consultation in November 2020. The deadline for comments is January 2021.

The draft guideline for public consultation is intended to be released by June 2021. The deadline for comments will be September 2021. The expected date for adoption of the guideline is December 2021.

6. Resource requirements for preparation

The guideline will be prepared by the ESVAC Denominator and Indicators Review Ad Hoc Expert Group in collaboration with the ESVAC secretariat. Virtual meetings will be held every 4 weeks (or as required).

7. Impact assessment (anticipated)

To describe the reporting of data on antimicrobial sales and use in a harmonised manner, as noted in the recital 50 and as per requirements of Article 57 of Regulation (EU) 2019/6. To assist Member States and EMA providing standards for quantifying antimicrobial consumption in animals in Europe. To perform necessary analysis of antimicrobial sales and use at European level as per requirements of Article 57 of Regulation (EU) 2019/6.

8. Interested parties

Veterinarians, policy makers, veterinary medicine authorities, national competent authorities responsible for collection and analysis of antimicrobial sales and use data, organisations liable for developing policies for antimicrobial consumption reduction, offices for animal population statistics etc.
9. References to literature, guidelines, etc.

AACTING, 2019. 'Guidelines for collection, analysis and reporting of farm-level antimicrobial use, in the scope of antimicrobial stewardship',

ECDC/EFSA/EMA, 2017. 'Joint Scientific Opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals',

EMA, 2018a. 'Guidance on collection and provision of national data on antimicrobial use by animal species/categories (EMA/489035/2016)',

EMA/CVMP, 2019. 'Advice on implementing measures under Article 57(3) of Regulation (EU) 2019/6 on veterinary medicinal products - Report on specific requirements for the collection of data on antimicrobial medicinal products used in animals (EMA/CVMP/131097/2019)',

FDA, 2017. 'FDA's Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, Using a Biomass Denominator',
https://www.fda.gov/media/106826/download;