



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2018
EMA/235015/2015-Rev.1¹
Veterinary Medicines Division

ESVAC sales Expert Advisory Group

Terms of reference 2018 - 2020

1. General considerations

The European Medicines Agency (EMA) has been mandated by the European Commission to take the lead in coordinating the collection by Member States of harmonised national sales data of antimicrobial (AM) agents for animals, as well as estimates on consumption in the major species. Collection of sales data should ensure harmonisation with data on consumption in human medicine collected within the framework of the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) funded by the European Centre for Disease Prevention and Control (ECDC).

The main aim of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) activity is to obtain harmonised and reliable data on the consumption of veterinary AM agents from all the European Union/European Economic Area (EU/EEA) countries as input for risk profiling, risk assessment and setting risk management priorities with regards to the containment of antimicrobial resistance at the EU/EEA level.

The ESVAC activity is organised into three work streams: collection of sales data, establishing and maintaining lists of defined daily doses for animals (DDDvet) and defined course doses for animals (DCDvet) and providing systems for collection of harmonised and standardised data on consumption by species. Separate expert advisory groups are established for these three work streams.

2. Objectives of ESVAC on collection of sales data

The objectives are:

- to provide continuous surveillance of harmonised data on overall sales of veterinary antimicrobials in the EU/EEA countries;
- to provide the participating EU countries with harmonised data on animal population from Eurostat and TRACES through the web based delivery system;
- to provide public access to information on sales of antimicrobials for animals via the ESVAC interactive database.

¹ Note: Revision 1 is a minor revision which refers to a new 2 year period of terms of reference, additional areas for which advice from the ESVAC sales Expert Advisory Group will be required, and updated list of members.



3. Task of ESVAC - sales data collection

To maintain and facilitate reporting of harmonised and standardised data on sales of veterinary antimicrobials, the ESVAC team ensures:

- validation and quality check of the sales data submitted through the web system;
- validation of data on animal population following revision by the participating countries of the data from Eurostat and TRACES;
- analysis of the trends in overall sales of veterinary antimicrobials and by administration routes/forms and antimicrobial class/subclass, both across participating countries and years;
- development of annual ESVAC reports on sales;
- providing public access to information on sales data published in the annual ESVAC reports of antimicrobials in animals in the participating countries through an interactive database.

4. Terms of reference ESVAC sales Expert Advisory Group

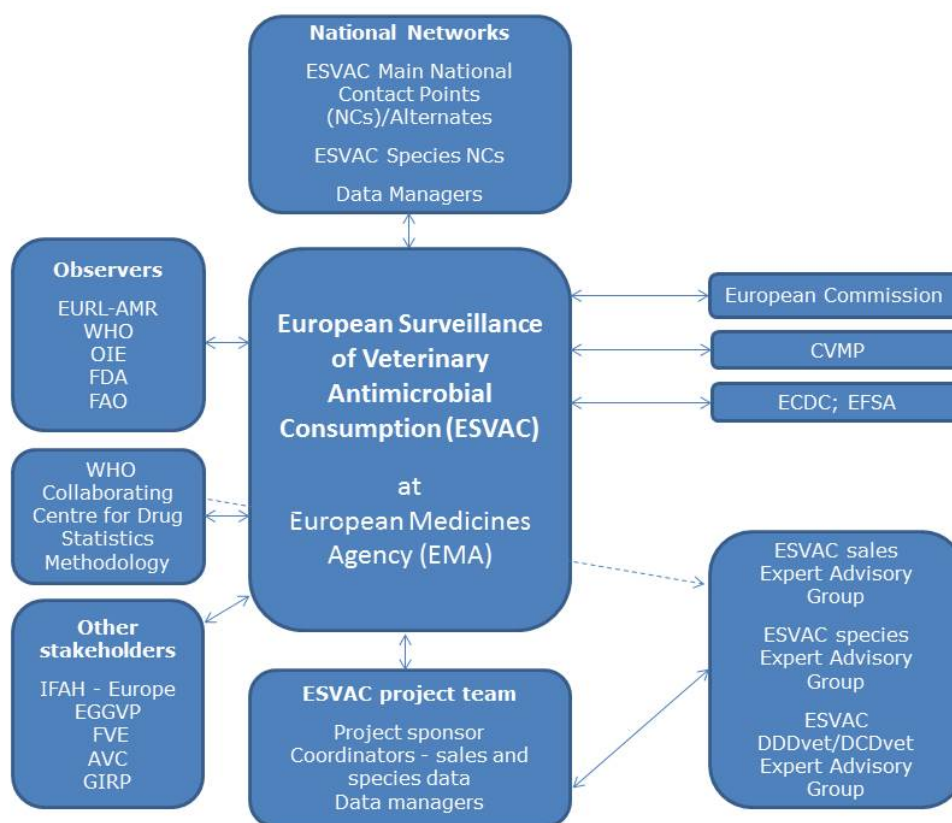
The ESVAC sales Expert Advisory Group will support the ESVAC team in discussions on technical, epidemiological and other scientific aspects of surveillance of sales of veterinary antimicrobial and in making suggestions to the ESVAC network in order to further develop the project and improve its effectiveness.

The ESVAC sales Expert Advisory Group will specifically provide advice to the ESVAC team on surveillance of overall sales data of veterinary antimicrobial agents including:

- collection and analysis of data;
- further development of the ESVAC sales protocol;
- further development of the denominator;
- further development of indicators for reporting of sales data;
- preparation of annual reports;
- planning of annual ESVAC network meetings;
- other activities as required.

The ESVAC sales Expert Advisory Group is an informal group that is integrated into the organisation of the ESVAC project as shown in the following chart.

Figure 1. ESVAC Project Organization



5. Composition ESVAC sales Expert Advisory Group

The ESVAC sales Expert Advisory Group is composed of 5 to 6 ESVAC main National Contact Point (ESVAC main NCs) or their alternates. The experts should have broad experience in collecting, analysing and reporting sales data and to the extent possible geographically represent the different areas of the EU/EEA countries and different types of data providers (MAH, wholesalers, etc.).

Membership of the ESVAC sales Expert Advisory Group will be by invitation from the ESVAC team and cannot be delegated to others. The Agency will nominate a chair of the ESVAC sales Expert Advisory Group. The ESVAC network of main NCs/alternates will be informed about the nomination.

The Commission, a member of the ECDC dealing with the ESAC-Net and a representative from the European Food Safety Authority (EFSA) may be invited as observers of the ESVAC sales Expert Advisory Group meetings.

One or two members of ESVAC species Expert Advisory Group might be invited as observers of the ESVAC sales Expert Advisory Group meetings on an ad hoc basis when considered necessary – e.g. for mutual information.

6. Meetings

The ESVAC sales Expert Advisory Group will have physical meetings approximately once per year in connection to the ESVAC annual network meeting and virtual meetings (Adobe Connect) as required. Most communications within the group will be via email or virtual meetings.

The principles for ensuring the confidentiality of data supplied to the ESVAC activity (EMA/327935/2010)² apply.

7. Duration of activity

The appointment of members of the ESVAC sales Expert Advisory Group will be for a period of two years. In order to make use of the expertise from other MSs and also to ensure the continuity in the group at least one third of the ESVAC sales Expert Advisory Group members should be replaced during the next nomination period.

8. Members (2018 – 2020)

- Kari Grave (Chair)
- Christina Greko
- Katariina Kivilahti-Mäntylä
- Laura Mie Jensen
- Gérard Moulin
- Lucie Pokludová

² Available from http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500104214.pdf