



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 May 2017
EMA/196621/2015
Veterinary Medicines Division

ESVAC species Expert Advisory Group

Terms of reference 2016 – 2017

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 overall sales data, establishing and maintaining lists of defined daily doses for animals (DDDvet) and defined course doses for animals (DCDvet) and providing guidance for collection of harmonised and standardised data on antimicrobial use by species. Separate Expert Advisory Groups have been established for these three work streams.

2. Objectives of work stream

The objective of ESVAC in the area of monitoring antimicrobial use by species is to foster and facilitate the collection of harmonised and standardised data in the EU/EEA countries on the use of antimicrobials by species by providing guidance for collecting antimicrobial use data in pigs, poultry (broilers and turkeys) and cattle. These data should eventually allow for an integrated analysis with data on the use of antimicrobials in humans and on resistance in animals, humans and food.



3. Role of ESVAC – collection of data by species

The role of the ESVAC team is to:

- develop, in conjunction with the ESVAC species Expert Advisory Group, guidance and documents related to this guidance, including testing of these if considered necessary, for collection of data on use of antimicrobial agents by species at national level in the EU/EEA countries;
- suggest, in conjunction with the ESVAC species Expert Advisory Group, appropriate indicators for reporting of the data;
- stimulate EU/EEA countries to collect data on use of antimicrobial agents by species.

4. Terms of reference ESVAC species Expert Advisory Group

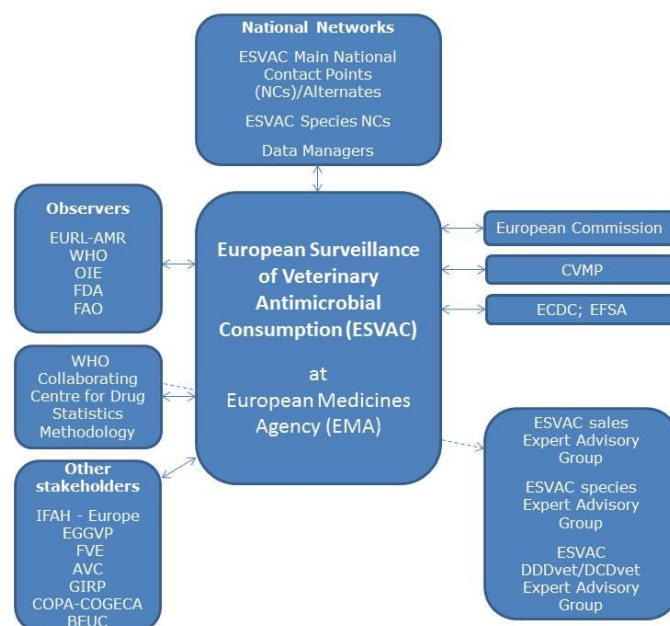
The ESVAC species Expert Advisory Group will guide the ESVAC team in discussions on technical, epidemiological and other scientific aspects of surveillance of use of veterinary antimicrobials by species.

It will specifically provide advice to the ESVAC team on:

- development of guidance and documents related to this guidance for data collection on antimicrobial use by species;
- how to stimulate data collection in more EU/EEA countries;
- development of appropriate indicators which are feasible and useful for analysing and reporting use data by species;
- preparation of reports from trials;
- other activities as required.

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

Figure 1. ESVAC Project organization



5. Composition ESVAC species Expert Advisory Group

The ESVAC species Expert Advisory Group is composed of a limited number of experts (5 to 6) from the ESVAC species National Contact Points (NCs) network or external institutions. The experts should i) have experience in collecting data on consumption of antimicrobials in pigs, poultry and/or cattle, ii) to the extent possible geographically represent the different areas of the EU, and iii) to the extent possible represent different types of species data collection systems (continuous, cross-sectional, etc.).

Membership of the ESVAC species Expert Advisory Group will be by invitation from the ESVAC team. The Agency will nominate a chair of the ESVAC species Expert Advisory Group. As participation in the ESVAC species Expert Advisory Group is based on individual expertise it cannot be delegated to others. The ESVAC network of main NCs and of species NCs 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 species Expert Advisory Group meetings.

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

6. Meetings

The ESVAC species Expert Advisory Group will mainly have 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/327935/2010¹) apply when data is shared with the ESVAC species Expert Advisory Group to aid discussion.

7. Duration of activity

The appointment of members of the ESVAC species Expert Advisory Group will be for a period of one year, which could be extended to two or three years. In order to make use of the expertise from other Member States and also to ensure the continuity in the group, at least one third of the ESVAC species Expert Advisory Group members should be replaced during the next nomination period.

8. Members (2016 – 2017)

- Fraser Broadfoot
- Claire Chauvin (Chair)
- Dick Heederik
- Henriette Helin-Soilevaara
- Miguel A. Moreno
- Lucie Pokludová

¹ http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500104214.pdf