



9 March 2021  
EMA/235015/2015 Rev.2<sup>1</sup>  
Veterinary Medicines Division

## ESVAC sales Expert Advisory Group

Terms of reference 2021 - 2022

### 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 veterinary medicinal products (VMPs), as well as estimates on consumption in the major animal 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) managed 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, in a standardised and harmonised manner, data on the consumption of antimicrobial VMPs from participating countries from the European Union/European Economic Area (EU/EEA) in order to inform risk profiling and risk assessments and to identify risk management priorities to contain the risk from development of antimicrobial resistance at the EU/EEA level.

The current ESVAC activity should be aligned with and prepare the implementation of the requirements of Article 57 of the Regulation (EU) 2019/6 for Veterinary Medicinal Products. This implies that further work, including the governance of the activity in reference to collection and reporting of data on antimicrobial VMPs, should be defined according to the obligations of the Member States and the Agency laid down in Regulation (EU) 2019/6.

### 2. Objectives of the ESVAC sales project

The main tasks of the ESVAC sales project are:

- to provide continuous surveillance of overall sales of antimicrobial VMPs in the participating European countries in a standardised and harmonised manner;
- to record animal population data that are accessible from Eurostat and TRACES or from national statistics, according to specified requirements;

---

<sup>1</sup> This revision concerns clarification on the new period the mandate is covering, additional areas for which advice from the ESVAC sales Expert Advisory Group will be required, and updated list of members.



- to publish an annual report on the volume of sales of antimicrobial VMPs in the participating European countries, including overall changes and trends over time;
- to provide publicly accessible information on sales of antimicrobial VMPs via the ESVAC interactive database.

### **3. ESVAC sales and animal population data management**

To maintain and facilitate reporting of sales of antimicrobial VMPs and animal population data in a harmonised and standardised manner, the following activities are coordinated by EMA:

- the validation and quality check of the sales data submitted through the ESVAC web-based application;
- the validation of data on animal population following the revision by the participating countries of the reference statistics from Eurostat and TRACES;
- the analysis of the trends of overall sales of antimicrobial VMPs and by administration routes, pharmaceutical forms and antimicrobial classes/subclasses, both across participating countries and years;
- the preparation and publication of the annual ESVAC report on sales of antimicrobial VMPs;
- the publication of the core graphs and tables of the ESVAC annual sales reports in the publicly accessible ESVAC interactive database.

### **4. Terms of reference ESVAC sales Expert Advisory Group**

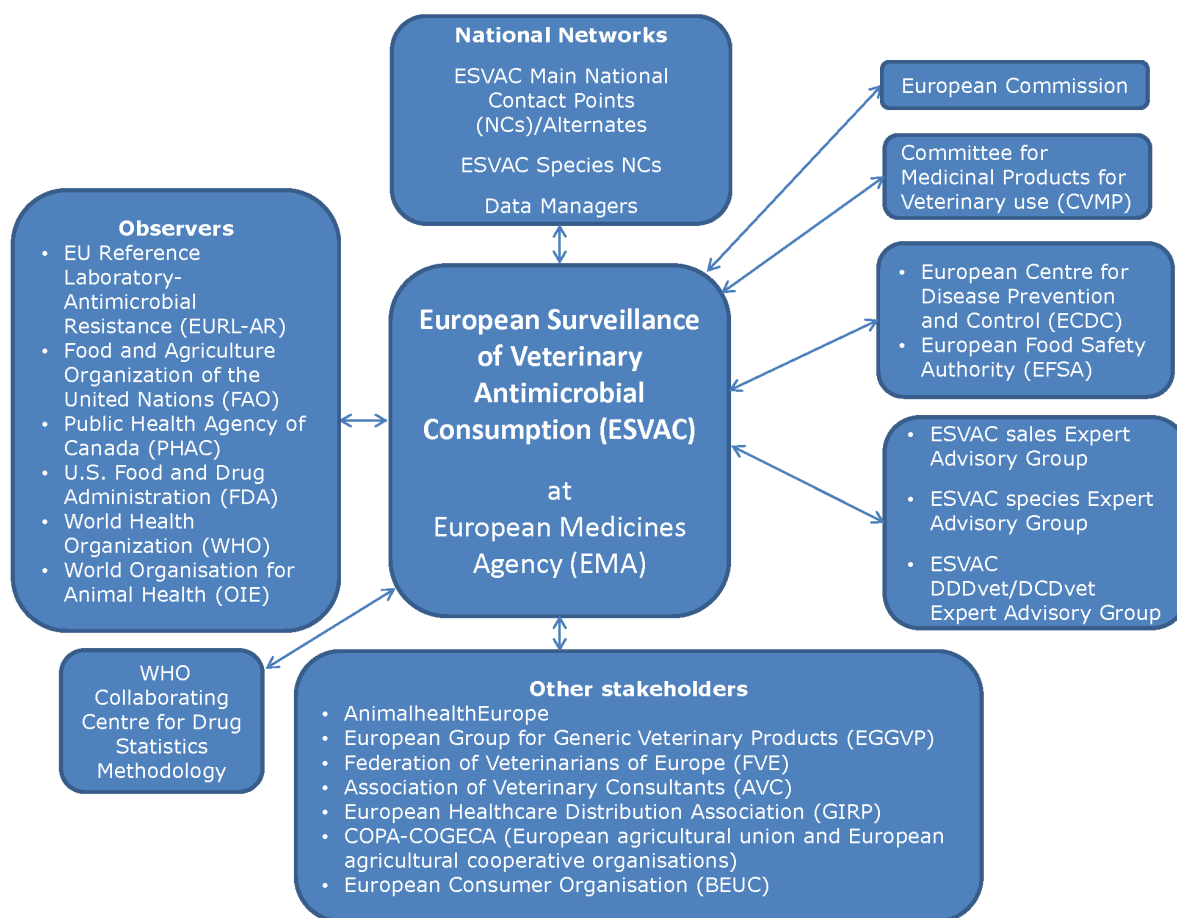
The ESVAC sales Expert Advisory Group supports the ESVAC team in discussions on technical, epidemiological and other scientific aspects of surveillance of sales of antimicrobial VMPs and in making suggestions to the ESVAC network in order to further develop the project and improve its effectiveness.

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

- collection and analysis of data;
- further development of the ESVAC sales data reporting protocol;
- further development of the denominator for reporting of sales data;
- further development of indicators for reporting sales data;
- preparation of annual reports;
- planning of annual ESVAC network meetings;
- preparation for reporting of sales and use of antimicrobial VMPs in line with Article 57 of the Regulation (EU) 2019/6;
- 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 of the ESVAC sales Expert Advisory Group

The ESVAC sales Expert Advisory Group is composed of 8 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.

Membership of the ESVAC sales Expert Advisory Group will be by invitation from the EMA and cannot be delegated to others. EMA will nominate a chair of the ESVAC sales Expert Advisory Group.

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.

Members of the ESVAC species Expert Advisory Group or members from the ESVAC Network might be invited as observers to the ESVAC sales Expert Advisory Group meetings on an ad hoc basis, when considered necessary. Other co-opted members can be considered if necessary.

## 6. Meetings

The ESVAC sales Expert Advisory Group will have physical meetings approximately once per year in connection to the ESVAC annual network meeting, if possible, and virtual meetings 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)<sup>2</sup> apply.

## 7. Duration of activity

The appointment of members of the ESVAC sales Expert Advisory Group will be for a period of two years. The mandate of the ESVAC sales Expert Advisory group is expected to be deactivated as soon as the new oversight on managing the obligations of Member States and the EMA laid down in Article 57 of Regulation (EU) 2019/6 has been established.

## 8. Members (2021 – 2022)

- Kari Grave (Chair)
- Spyridon Farlopoulos
- Christina Greko
- Iva Gruden Zdunić
- Katariina Kivilahti-Mäntylä
- Laura Mie Jensen
- Gérard Moulin
- Lucie Pokludová

---

<sup>2</sup> Available on the EMA public web page:  
[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2011/03/WC500104214.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500104214.pdf)