



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 April 2016
EMA/351418/2015
Veterinary Medicines Division

ESVAC DDDvet and DCDvet Expert Advisory Group

Terms of reference 2015 - 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 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 will be established for these three work streams.

2. Objectives of establishing DDDvet and DCDvet

The objectives are to establish standardised units of measurement for EU/EEA veterinary antimicrobial agents for the analysis of consumption data by species, in order to take into account differences in dosing (daily dosing and length of treatment) for the various antimicrobials when reporting consumption data. The DDDvet and DCDvet values might also be implemented in countries outside the EU/EEA area.



3. Task of ESVAC – DDDvet and DCDvet

The tasks of the ESVAC team for establishing and maintaining lists of DDDvet and DCDvet are:

- to assign ESVAC DDDvet and DCDvet according to the principles on assignment of defined daily dose for animals (DDDvet) and defined course dose for animals (DCDvet);
- to publish lists of DDDvet and DCDvet values;
- to amend and maintain lists of DDDvet and DCDvet values to ensure comprehensive coverage of antimicrobials used within the EU/EEA;
- to revise lists of DDDvet and DCDvet values as required;
- to revise the principles on assignment of DDDvet and DCDvet as required.

4. Terms of reference ESVAC DDDvet and DCDvet Expert Advisory Group

The ESVAC DDDvet and DCDvet Expert Advisory Group will support the ESVAC team:

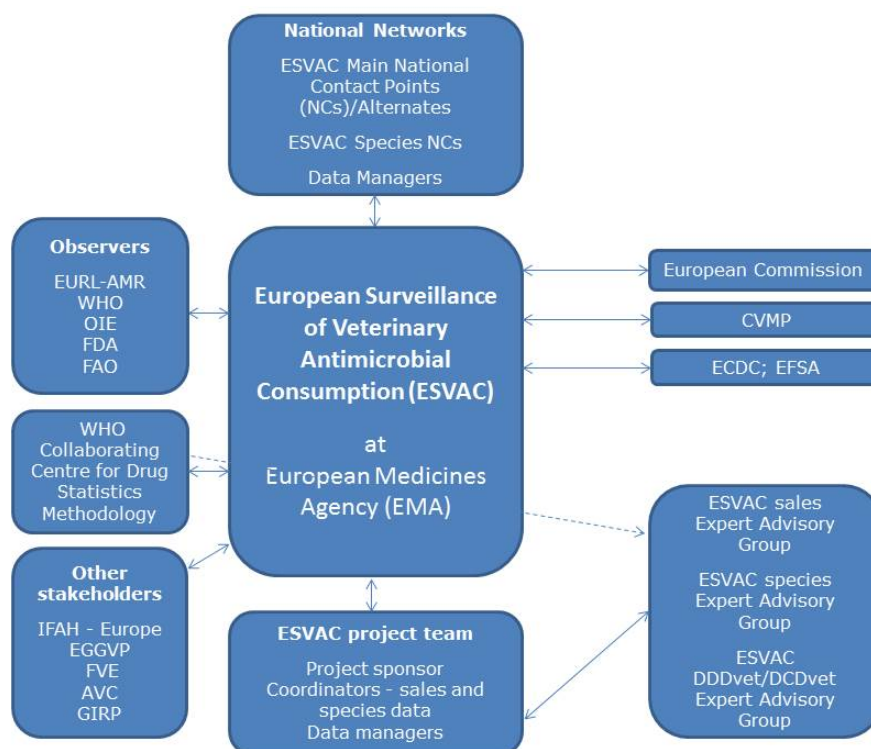
- in discussions on technical, epidemiological and other scientific aspects of establishing, updating and revising the lists of DDDvet and DCDvet values;
- in communication of the DDDvet and DCDvet system to EU/EEA countries and other stakeholders.

The ESVAC DDDvet and DCDvet Expert Advisory Group will specifically provide advice to the ESVAC team:

- on assignment of DDDvet and DCDvet values;
- on revision of the principles on assignment of DDDvet and DCDvet as required;
- in order to improve the DDDvet and DCDvet system;
- on development of appropriate indicators for reporting species data;
- on other activities as required.

The ESVAC DDDvet and DCDvet 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 units Expert Advisory Group

The ESVAC DDDvet and DCDvet Expert Advisory Group is composed of 5 to 6 ESVAC main National Contact Points (ESVAC main NCs) or their alternates and a representative from the WHO Collaborating Centre for Drug Statistics Methodology. The experts should to the extent possible have experience in the assignment of technical units of measurement such as DDDvet and DCDvet and also in the use of such units for the analysis and reporting of data on veterinary antimicrobial consumption.

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

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

6. Meetings

The ESVAC DDDvet and DCDvet 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.

7. Duration of activity

The appointment of members of the ESVAC DDDvet and DCDvet 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 DDDvet and DCDvet Expert Advisory Group members should be replaced during the next nomination period.

8. Members (2015 – 2017)

- Inge van Geijlswijk
- Kari Grave (Chair)
- Christina Greko
- Irene Litleskare
- Gérard Moulin
- Cedric Müntener