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Veterinary Medicines Division

Terms of reference for the European Sales and Use of Antimicrobials for veterinary medicine (ESUAvet) network

1. Legal basis

Article 57 of Regulation (EU) 2019/6 provides for the collection of relevant and comparable data on the volume of sales and on the use of antimicrobial medicinal products in animals, which Member States must collate and submit to the European Medicines Agency (EMA, hereinafter 'the Agency' or 'EMA') in accordance with Article 57(2) of that regulation. Article 57(2) of Regulation (EU) 2019/6 further establishes certain requirements for the Agency to:

- cooperate with Member States and other Union agencies to analyse those data; and
- publish annual reports.

Commission Delegated Regulation (EU) 2021/578 supplements Article 57 of Regulation (EU) 2019/6 by setting out the scope and requirements for data collection, reporting and analysis, including obligations for both Member States and the Agency. It also provides that the Agency and Member States should organise, together and as appropriate, best-practice-sharing activities to support Member States in the development of data collection systems on antimicrobial use in animals.

These activities form the basis of a Europe-wide network of national surveillance systems, providing European reference data on antimicrobial on the volume of sales and on the use of antimicrobial medicinal products in animals. To support this work and enable coordination, exchange of expertise, and support joint technical work on surveillance methodologies and data analysis, EMA has established a framework for cooperation with all Member States, hereafter referred to as the ESUAvet network.

2. Objectives

The ESUAvet network functions as an **EMA-Member State operational and strategic network,** supporting the Agency in all matters related to the reporting, analysis and publication of data on the volume of sales of veterinary antimicrobial products and on the use of antimicrobial medicinal products in animals. It also serves as a platform for cooperation, enabling the exchange of information, the pooling of expertise and the strengthening of collaboration between Member States in this area.

The goal of the ESUAvet network is to:

- Support the Agency in fulfilling its obligation related to the analysis and publication of data on antimicrobial sales and use in animals, including contributing to the preparation, review and

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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dissemination of the annual surveillance reports referred to in Article 57(2) of Regulation (EU) 2019/6 (hereinafter 'the ESUAvet' annual reports) and related outputs, based on data submitted by Member States.

- Support the coordination and discussion of technical aspects related to the collection, validation, analysis and interpretation of antimicrobial sales and use data, including methodologies, indicators and reporting approaches.
- Facilitate coordination and exchange between the Agency and Member States, including communication with relevant national bodies involved in data reporting.
- Promote best practices and capacity building in data collection, reporting and analysis across Member States.
- Support collaboration and information exchange with EU, international and stakeholder organisations involved in antimicrobial surveillance across domains[1].

The ESUAvet network also offers opportunities to establish links with the Committees of the Agency and their Working Parties. It is not foreseen that the ESUAvet network would initiate any regulatory action/decision on specific products or groups of products.

The ESUAvet network will provide regular updates to the Committee for Veterinary Medicinal Products (CVMP) on its activities, including the ESUAvet annual surveillance reports, which are to be submitted to CVMP for endorsement to support consideration of the findings in relevant regulatory activities.

Depending on the topic and the objectives set out in its deliverables, webinars may be organised for ESUAvet network members, **national contact points** and **data managers nominated for the reporting of data**[2], or can be open to the public.

Direct interactions between **national contact points** and **national data managers** related to the fulfilment of Member States' reporting obligations, including data submission and quality matters, **are handled through dedicated operational processes**. The ESUAvet network complements these processes by facilitating coordination and discussion at EU level, including on reporting cycles, timelines, technical and analytical aspects.

The terms of reference may be reviewed and updated as needed to ensure alignment with the evolution of regulatory requirements, ESUAvet operational needs, and the broader EMA governance framework.

3. Composition and rules of participation

3.1. Composition

The ESUAvet network is composed of experts from Member States who are directly involved in the collection and reporting of antimicrobial sales and use data in animals at national level. A list of the national institutions / organisations responsible for the collection of sales and use data will be publicly available.

[1] Article 57(2), second subparagraph point (u), of Regulation (EC) No 726/2004 requires the Agency to contribute to the joint reporting with the European Food Safety Authority and European Centre for Disease Prevention and Control on antimicrobial consumption and resistance analyses in human and veterinary medicine, taking into account the reporting requirements and periodicity in Article 57 of Regulation (EU) 2019/6.
[2] As set out in Article 7 of Commission Delegated Regulation (EU) 2021/5783.

There will be one member per Member State, who acts as the main active link between the Agency and the relevant national authorities[3]. **One alternate** will also be nominated for each Member State to participate in the activities of the ESUAvet network. In the absence of the member, the alternate should ensure continuity of the respective Member State's participation and engagement in the activities of the ESUAvet network.

Member States are encouraged to appoint members and alternates who also serve as national contact points or data managers. Where these roles do not overlap, national contact points and data managers may participate in ESUAvet activities and meetings in line with Section 6.4. **Additional experts**[4] may be invited to contribute to specific topics, as appropriate. Ideally, both data collection activities — notably, on the volume of sales and on the use of antimicrobial medicinal products in animals — should be represented.

Members, alternates, nominated national contact points, data managers and additional experts need to be included in the European expert database, where they are required to provide their CV and a declaration of interest (DoI) in line with the EMA policy on handling of competing interests of scientific committees' members and experts.

Representatives of the European Commission and staff of European Union agencies may attend all meetings of the ESUAvet network and contribute as appropriate.

In addition, and where appropriate, **observers**, in line with the Agency policy on observers, may also attend all meetings of the ESUAvet network. Observers do not take part in decision-making.

3.2. Nomination

Members and alternates are nominated by Member States from the national competent authority or other public authorities responsible for collecting and reporting of antimicrobial sales and use data in animals at national level. It is understood that Member States designate their representatives in a manner that reflects expertise in the national responsibilities and arrangements in this area.

The duration of nomination is determined at national level, with continuity of representation encouraged where possible.

Member States are expected to ensure that nominations are kept up to date, so that representation in the ESUAvet network is maintained at all times.

3.3. Confidentiality arrangements

In principle, and unless mentioned otherwise, information dissemination in the ESUAvet network is covered by the EMA confidentiality undertaking that experts sign with their DoI in accordance with the EMA Policy 0044 on the handling of declarations of competing interests of scientific committees' members and experts (EMA/54457/2024). This entails *inter alia* that all relevant information disseminated in the context of the ESUAvet network must be treated on a strictly confidential basis.

[3] This is especially important for Member States where the National Competent Authorities for data collection on sales of veterinary antimicrobials and for data collection on the use of antimicrobials in animals are different.
[4] For the purpose of this document, 'additional experts' means EU/EEA experts registered in the Agency's Experts Management Tool who are not members or alternates of the ESUAvet network, nominated national contact points or data managers.

3.4. Framework of participation

All ESUAvet network members are expected to:

- Act as the main active link between the Agency and the relevant national authorities;
- Ensure that relevant contact details are kept up to date, particularly for national contact points and data managers;
- Contribute to the preparation, agreement and implementation of the ESUAvet network deliverables, supporting the activities outlined therein;
- Participate actively and regularly attend the entirety of the meetings and provide written input between meetings when needed.

If a member of the ESUAvet network is unable to participate in network activities over an extended period, the secretariat, in consultation with the co-chairpersons, may contact the relevant national competent authority to discuss ongoing representation in the network, in order to ensure continuity of business.

4. Meeting frequency

The ESUAvet network meets as required to support its work activities, with a minimum of two meetings per year involving all Member States.

Additional meetings with a subset of ESUAvet network experts may be organised, as needed, to support specific tasks within the remit of the ESUAvet network and its deliverables. This enables more focused and efficient handling of tasks, with outcomes reported back to and subsequently reviewed and endorsed by the full ESUAvet network.

5. Duration of the network

The ESUAvet network is established for an indefinite duration.

6. Working arrangements

6.1. Appointment of co-chairpersons

The network and its meetings are co-chaired by a representative of EMA from the Surveillance and Regulatory Support Department within the Veterinary Division and by a Member State co-chairperson.

The **EMA co-chairperson** is designated internally by the relevant line management within the Veterinary Division[5] for a duration determined by the Agency. The designation may be reviewed and revised, as appropriate, to reflect organisational needs and responsibilities.

Member State co-chairing is ensured on a rotating basis, **aligned with the Council Presidency**. The Member State co-chair role is fulfilled by the member of the respective Member State holding the Council Presidency, or by the alternate where necessary. The EMA co-chairperson is appointed with a view to ensure the continuity of ESUAvet activities throughout the rotating Member State co-chairing.

[5] In principle, by the Head of Service (in V-SR-AMR).

6.2. Tasks of co-chairpersons

The responsibilities of the ESUAvet network co-chairpersons, in conjunction with the ESUAvet secretariat, include:

- Overseeing the development and execution of the work of the ESUAvet network based on the priorities outlined in the respective deliverables;
- Setting up the meeting objectives and agendas;
- Co-chairing meetings, facilitating focused and inclusive discussions and achieving consensus on issues discussed by the ESUAvet network;
- Promoting participation of all members present and achieving consensus on issues discussed by the ESUAvet network during meetings;
- Ensuring the working arrangements and framework for participation are followed and ensuring appropriate management of conflicts of interest (at the beginning of each meeting);
- Reviewing the functioning of the ESUAvet network and proposing improvements where necessary;
- Reporting on ESUAvet activities to CVMP, including presenting the annual ESUAvet reports for CVMP endorsement.

6.3. Responsibilities of EMA secretariat

The EMA secretariat provides technical, scientific, coordination and administrative support to the ESUAvet network. It includes the following but is not limited to:

- Organise virtual and face-to-face meetings and ensure timely preparation (together with the co-chairpersons) and follow-up to the meetings (including drafting of the minutes);
- Track milestones, deadlines and progress against the deliverables;
- Ensure that all members and additional experts (when contributing to the meeting) have a valid DoI and that this is evaluated in accordance with EMA's policy on the handling of competing interests of scientific committees' members and experts[6];
- Contribute to the preparation, drafting, finalisation and publication of ESUAvet outputs, including collection of comments from consultations where applicable;
- Maintain membership and access to the ESUAvet network workspace, and ensure access is given only to members with up-to-date DoIs (providing updated DoIs is the responsibility of the experts).

6.4. Organisation of meetings and reporting lines

The ESUAvet network meets virtually and face-to-face as needed. Additional experts may be invited to participate in specific discussions or to listen to the meetings. Members wishing to bring additional experts should notify the secretariat at least 14 calendar days before the meeting confirming that these experts are included in the European expert database and that they have, *inter alia*, a valid declaration of interest (DoI) in accordance with EMA policies. Exceptionally, the co-chairpersons may jointly object to the participation of a proposed additional expert based on duly substantiated grounds.

[6] EMA policies are published on the following webpage: https://www.ema.europa.eu/en/about-us/how-we-work/governance-reporting/policies-procedures.

Meeting documentation will be distributed to an agreed list of recipients drawn up by the secretariat with the joint agreement of the co-chairpersons. The draft agenda for every meeting should be circulated by the EMA secretariat, together with the related documents, in consultation with the co-chairpersons, at least 7 calendar days before the meeting.

When a member of the ESUAvet network is unable to participate in a meeting or part of a meeting, or a discussion topic due to a conflict of interest, he/she must inform the secretariat in advance in writing.

Observers from international organisations with interests in the surveillance of antimicrobial consumption and resistance across the veterinary and human domains, from non-EEA regulatory agencies or bodies, and from decentralised EU agencies may also be invited to observe ESUAvet network meetings, as appropriate.

The ESUAvet network shall organise its activities through periodic deliverables, taking into account legal obligations and timelines, in particular for the preparation of the ESUAvet annual reports. Where appropriate, the deliverables may also include additional activities supporting the objectives of ESUAvet, based on identified needs and priorities.

6.5. Guarantees of independence

Members and experts are subject to EMA policies on the handling of competing interests of scientific committees' members and experts[7].

ESUAvet members and any other experts attending the meetings must declare at the beginning of each meeting any interests that may be prejudicial to their independence regarding the agenda items. This will be documented in the meeting minutes.

6.6. Code of conduct

Members and experts are subject to the principles set out in the Agency's Code of Conduct[8].

6.7. Contact with Interested Parties

Where relevant and as agreed, the ESUAvet network may establish contacts with parties interested in or involved in surveillance of sales and use of antimicrobials and antimicrobial resistance activities in the human, veterinary and environmental sectors.

Interested parties may attend ESUAvet meetings to discuss general matters or specific scientific topics as foreseen in its deliverables. No decisions should be made in the presence of interested parties.

6.8. General provisions

ESUAvet members, as well as any other participating experts and observers, shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy[9].

When participating in meetings or other fora on behalf of EMA, ESUAvet members should obtain prior agreement from EMA and ensure that the views expressed are those of EMA. When they are not

[7] Reference is made to the Procedural guidance to scientific committees' members and experts on completing the European Medicines Agency's declaration of interests in the Experts Management Tool, Section 2, for provisions applying to observers from the European Commission and from non-EU/EEA regulators.
[8] https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-conduct_en.pdf
[9] Article 76 of Regulation (EC) No 726/2004.

participating on behalf of EMA, they shall make clear that the views expressed are their own, in compliance with EMA Policy 0029.

When contributing to a scientific publication related to EMA activities, ESUAvet members must comply with EMA Policy 0015[10].

[10] EMA policies are published on the following webpage: https://www.ema.europa.eu/en/about-us/how-we-work/governance-reporting/policies-procedures.