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Veterinary Medicines Division

Mandate, objectives and rules of procedure for the European Sales and Use of Antimicrobials for veterinary medicine Working Group (ESUAvet WG)

1. General considerations

Since September 2009, the Agency, on request of the European Commission, has coordinated and supported European countries in establishing a standardised and harmonised collection of data on the volume of sales of antimicrobial veterinary medicinal products, analysed the data, and published annual reports.

Article 57 of Regulation (EU) 2019/6 calls for the collection of relevant and comparable data on the volume of sales for and on the use of antimicrobial medicinal products in animals, which Member States shall collate and send to the Agency. The Agency shall cooperate with Member States and with other Union agencies to analyse those data and shall publish annual reports. The Agency shall consider those data when adopting any relevant guidelines and recommendations. These activities constitute a surveillance system that will provide reference data on antimicrobial consumption in animals and will form the basis for monitoring the progress of the EU and its Member States towards prudent use of antimicrobials in animals.

As mandated by Article 57 of Regulation (EU) 2019/6, the Commission adopted Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 regarding the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals, establishing the requirements for: (a) the types of antimicrobial medicinal products used in animals for which data shall be collected; (b) the quality assurance that Member States and the Agency shall put in place to ensure quality and comparability of data; and (c) the rules on the methods of gathering data on the use of the antimicrobial medicinal products used in animals and on the method of transfer of those data to the Agency. Commission Implementing Regulation (EU) 2022/209 of 16 February 2022 establishes the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals.

Furthermore, Regulation (EU) 2019/5, amending 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 the sales and use of antimicrobials in human and veterinary medicine as well as on the situation as regards antimicrobial resistance in the Union based on contributions received by Member States, taking into account the reporting requirements and

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periodicity in Article 57 of Regulation (EU) 2019/6. Such joint reporting shall be carried out at least every three years.

The ESUAvet WG is therefore established to support and advise the Agency and the CVMP on all matters related directly or indirectly 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. In addition, the ESUAvet WG constitutes a mechanism for information exchange on antimicrobial consumption data, pooling knowledge and practices and furthering cooperation with Member States in this area. It shall ensure close cooperation as well as the coordination of communications between the Agency and the competent authorities in the Member States in order to fulfil the respective legal obligations.

2. Mandate and objectives

The ESUAvet WG is established to provide strategic guidance and recommendations to the Agency and the CVMP on matters related to collection and analysis of data on the volumes of sales and on the use of antimicrobials in animals and to coordinate liaison with relevant national bodies involved in the collection and reporting of data on sales and use of antimicrobials in animals. In particular will the ESUAvet WG support the Agency to meet its obligations with regards to the surveillance and monitoring of antimicrobial sales and use in the EU. The CVMP may delegate certain tasks to the ESUAvet WG, and the WG may establish dedicated drafting groups to develop the input on certain tasks, in particular for tasks related to developing technical content.

Relevant tasks identified in the CVMP annual workplan should be included in the workplan of the ESUAvet WG.

The ESUAvet WG's remit includes, but is not limited to, the following tasks:

Scientific advice to CVMP:

- Advise the CVMP on matters related to the development, review and update of guidelines on reporting, analysis and publication of data on the volume of sales of veterinary antimicrobial products and on the use of antimicrobials in animals, when required.
- Advise the CVMP on the analysis and publication of on the volume of sales of veterinary antimicrobial products and on the use of antimicrobials, including trend analysis at EU and national level, including support to the joint reporting with the European Food Safety Authority and European Centre for Disease Prevention and Control on the sales and use of antimicrobials in human and veterinary medicine as well as on the situation as regards antimicrobial resistance in the Union.
- Provide an annual report to CVMP on key activities and outputs of the WG related to the surveillance of the volume of sales of veterinary antimicrobial products and use of antimicrobials in animals in the EU.

Strategic and operational advice to the Agency on technical matters related to the collection, reporting and analysis of data on volumes of sales and on use of antimicrobials in animals, and the development and maintenance of relevant IT systems:

- Advise on the preparation, review and update of protocols, templates and manuals for the reporting, analysis and publication of data on volumes of sales and on use of antimicrobials in animals.
- Advise on business requirements for development and maintenance of the IT platforms and tools for data reporting, analysis and presentation of results to the public.

- Facilitate scientific, technical and operational discussions, and coordinate or at least provide a link for communications between the Agency and Member States on matters related to the reporting, analysis and publication of data on volumes of sales and on the use of antimicrobials in animals.
- Contribute to the interpretation of results, review and approve draft annual reports and other joint outputs produced by the Agency based on data from the Member States, and support dissemination of the outcomes.
- Provide advice on the presentation and release of information and results on the volumes of sales of veterinary antimicrobial products and on the use of antimicrobials in animals to stakeholders and the general public.
- Facilitate appropriate coordination between the tasks of the Agency and the work of the national competent authorities in the Member States including the consultative bodies and other stakeholders concerned with the surveillance of sales and use of antimicrobials in animals. The ESUAvet WG may consult national competent authorities, consultative bodies or other interested parties regarding specific scientific expertise.

Training and best practice sharing activities:

- Facilitate training and best practice sharing on matters related to the collection and reporting of data on volumes of sales and on the use of antimicrobials in animals, also to promote harmonisation and of data collection systems.
- Promote synergies and collaboration on issues of common interest amongst Member States, and between Member States and the Agency, e.g. exchange of scientific and technical information, best practice sharing activities, training material, organisation of workshops etc.
- Contribute to identifying Member States' needs for support from the Agency in terms of scientific, technical assistance, training and best practice sharing activities.

Liaison and cooperation with other bodies:

- Provide a forum for exchange of information in the framework of international cooperation and contribute to foster cooperation and collaboration with European and other international interested parties across sectors and domains on collection, reporting, analysis and publication of data on volumes of sales and on the use of antimicrobials.
- Liaise and facilitate cooperation with interested parties and relevant stakeholders (e.g. industry associations, veterinarians, pharmacists and learned societies) with respect to data on the volumes of sales of veterinary antimicrobial products and on the use of antimicrobials in animals.
- Foster technical and scientific collaboration within and between Member States and their stakeholders with respect to data on the volumes of sales of veterinary antimicrobial products and on the use of antimicrobials in animals.

The mandate and objectives of the ESUAvet WG shall be agreed by the Agency and the CVMP. They shall be reviewed every 3 years. The Heads of Medicines Agencies will be informed.

Direct interactions between national contact points for the reporting of data on volumes of sales and on the use of antimicrobials in animals and national data managers (as set out in Article 7 of Commission Delegated Regulation (EU) 2021/578) in matters related to the fulfilling of the Member States' reporting obligations, including data quality related matters, will take place separately and are not addressed by the ESUAvet WG mandate.

3. Composition and rules of participation

Members:

The ESUAvet WG will consist of national experts nominated by the Heads of Medicines Agencies, in liaison with the CVMP and the Agency, following a call for nominations, on the basis of their relevant experience and direct involvement in antimicrobial sales and use data collection systems in animals at national level, as well as their capacity to actively contribute to the work of the WG in the area of surveillance and monitoring of antimicrobial sales and use in the EU.

There will be one representative per Member State. This nominated member will be expected to serve as an active and effective link between the Agency and the competent authorities in the Member States, and provide updates on joint activities with the Agency to relevant experts and stakeholders in their country. 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. ESUAvet WG members shall liaise with national contact points, data managers and their alternates for surveillance of sales and use of antimicrobials in animals, if necessary, and ensure that the relevant contact details are kept up to date on the Agency website.

An alternate will be also nominated for each member, to participate in cases where the main representative is unable to attend. Nominated members and alternates need to be included on the European list of experts, with relevant expertise indicated.

Member States are encouraged to appoint ESUAvet WG members and alternates who also serve as national contact point or data managers. Ideally both data collection activities on sales of veterinary antimicrobials and on use of antimicrobials in animals should be represented.

Operational activities, such as the provision of advice on specific topics or drafting of guidance documents, may require the establishment of operational expert groups. Number, scope and mode of operation of operational expert groups and activities planned for implementation will be specified in the ESUAvet WG's workplan, for endorsement by CVMP. The operational expert groups will be assembled to deliver specific tasks and will be discontinued after completion, unless a specific need is identified to maintain the group active for a longer period of time. The decision to extend the activity of operational expert groups beyond the completion of specific tasks will be considered by the ESUAvet WG and presented to CVMP for endorsement. The selection procedure to appoint experts to operational expert groups will be carried out by CVMP, through a selection committee, including the Co-chairpersons of the ESUAvet WG, following a call for nominations, which depending on the topic may be through CVMP or through CVMP and ESUAvet WG members. The selection of experts for specific groups shall be agreed by the CVMP on the basis of their expertise in the areas within the scope of the activity defined by the ESUAvet WG, as outlined in the relevant Work Plan.

Where additional experts (beyond the nominated members) need to be appointed, the selection will also be carried out by CVMP through a selection committee, following the process described for the operational expert groups.

Membership in the ESUAvet WG and its operational expert groups implies a commitment to participate actively in the work of the group and to attend the meetings of the group regularly. If a member of the ESUAvet WG does not participate in 3 consecutive meetings without reasonable justification, the secretariat, in consultation with the Co-chairpersons, will ask the Head of the nominating Agency to reconfirm her/his membership or to nominate a new member.

In case a member of an operational expert groups does not have the capability to continue contributing as required, another expert with the required expertise and capability will be appointed to

ensure timely completion of the tasks. When appointment of a new member of an operational expert group is required, the ESUAvet WG will propose a required profile for endorsement by CVMP.

Members wishing to bring additional experts should notify the secretariat in advance of the meeting, and their participation will be subject to the agreement of the Chairperson.

Observers:

Observers from accession countries, mutual recognition agreement partners and partners with a confidentially agreement may have standing invitations to participate at ESUAvet WG meetings. Observers from non-EEA countries may participate with the agreement of the chair.

Considering the global importance of the surveillance of antimicrobial sales and use, and in order to support and enhance international cooperation and collaboration in this area, representatives from relevant international organisations and expert groups will be invited as observers.

Observers will attend at the discretion of the chairperson, in line with the EMA policy on observers, and may not be involved when particular items of concern to Regulatory Authorities of the Union, product specific matters or other sensitive matters are discussed.

Specific confidentiality rules will apply to observers who are encouraged to participate freely in discussions but shall not take part in any decision-making process.

4. Meeting frequency and method of operation

The WG shall meet at least 4 times per year in accordance with the adopted workplan . The dates of the meetings shall be included in the workplan. Operational expert groups meetings will be scheduled according to the annual workplan.

Regular meetings will be scheduled either virtually or on site at EMA, however, the ESUAvet WG and its operational expert groups will conduct the majority of their business remotely by correspondence, teleconference or videoconference.

5. Rules of procedure

5.1. Chairmanship and Co-chairmanship

Meetings shall be chaired by a representative of EMA, normally the Head of Surveillance and Regulatory Support Department or her/his delegate.

The CVMP shall appoint the Co-chairperson for the group from the nominated members of the ESUAvet WG, who shall be elected for the duration of the mandate term.

Nominations should be submitted in writing to the secretariat no later than by the start of the CVMP meeting at which the election will take place.

Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

The election of the Co-chairperson shall follow the same procedure as for the election of the CVMP Chairperson, as stated in Article 3, paragraphs 1 to 4, of the Rules of Procedure of the CVMP.

In the event of resignation of the Vice-Chairperson a new election will be scheduled at the next possible date.

5.2. Responsibilities of Co-chairpersons

The Co-chairpersons are responsible for the efficient conduct of the business of the ESUAvet WG and shall in particular:

- Plan the work plan of the ESUAvet WG, together with the EMA secretariat;
- Prepare and run the ESUAvet WG meetings;
- Monitor together with the secretariat that the rules of procedure are respected;
- Ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the ESUAvet WG;
- Aim to achieve consensus on issues discussed and ensure that scientific grounds are adequately reflected;
- Ensure that ESUAvet WG members have the opportunity to express their views, take a position on issues under debate, are involved in the drafting of recommendations and that the views expressed by the members are reflected in the WG scientific considerations to the CVMP or the Agency;
- Ensure the regulatory and scientific consistency of decisions and recommendations and the scientific advice provided;
- Co-ordinate, together with the EMA secretariat, the work of the ESUAvet WG with the Agency's scientific committees, working parties and other relevant groups or stakeholders;
- Report on the activities of the ESUAvet WG to the Agency's scientific committees, working parties and other relevant groups of the Agency. The CVMP Co-chairperson will be invited to attend plenary meetings to report on the activities of the ESUAvet WG and both Co-chairpersons will coordinate to ensure liaison with the work of the CVMP;.
- Provide feedback from the ESUAvet WG discussions including divergent views and summarise the conclusions of the ESUAvet WG for the CVMP;
- The CVMP co-chairperson will deputise for the EMA co-chairperson when the latter is unable to chair, either all or part of the ESUAvet WG meeting. On such occasions the EMA co-chairperson will notify the CVMP co-chairperson as early as possible before the meeting and inform the EMA secretariat. Certain parts of ESUAvet WG meetings may routinely be chaired by the CVMP co-chairperson.

5.3. Organisation of meetings

Meeting documentation will be distributed to an agreed list of recipients drawn up by the secretariat with the agreement of the Chairpersons. Agenda and minutes of the meetings of the working group will be circulated to the CVMP.

The draft agenda for every meeting shall be circulated by the EMA secretariat, together with the related documents, in consultation with the chairpersons, at least 7 calendar days before the meeting;

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

The ESUAvet WG shall prepare and agree an annual Work Plan for endorsement by the CVMP.

Observers may participate with the agreement of the Chairpersons and the EMA. Specific confidentiality rules will apply to observers.

5.4. Operational expert groups

For specific scientific tasks, for example regarding scientific opinions or drafting guidelines, operational expert groups will be established to develop scientific advice and recommendations on matters related to the surveillance of the volume of sales of veterinary antimicrobial products and of the use of antimicrobials in animals. The operational expert groups will report exclusively to the ESUAvet WG.

The operational expert groups will generally consist of at least one ESUAvet WG member who will act as coordinator with the ESUAvet WG (more ESUAvet WG members may participate) in addition to the experts chosen for their specialist knowledge in the topic area of interest. Depending on the topic, the operational expert groups will be chaired either by one or two coordinators. These coordinators should be members of and will be nominated by the ESUAvet WG.

The coordinators have a specific role ensuring that the outcome produced by operational expert groups is of the adequate quality, fit-for-purpose and takes account of relevant advice, decisions and positions taken by the group.

The coordinators are responsible for timely (i) planning and conduct of meetings, workshops or contributions to meetings; (ii) drafting and finalising of documents, such as reflection papers, recommendations or guidelines; (iii) ensure that all potential conflicts of interests are identified and handled appropriately; as well as (iv) report on the operational expert groups' activities to the ESUAvet WG. The coordinators of operational expert groups will be supported by the EMA Secretariat.

5.5. Written procedures

With approval of the chairpersons, documents may be presented to the ESUAvet WG for adoption by written procedure. Written procedures should be restricted to matters requiring decisions between scheduled meetings;

Members may comment or raise objections within a specified time period established in agreement with the chairperson. The secretariat shall report on the outcome of the written procedure at the next meeting.

In the case of serious objections, the chairperson may suspend the written procedure and schedule discussion and adoption at the next regular meeting.

5.6. Guarantees of independence

Members of the group and experts referred to above shall not have any direct interests in the pharmaceutical industry that could affect their impartiality (except possibly 'expert witnesses'). They shall undertake to act in the public interest and in an independent manner and shall make an annual declaration of their financial interests. All indirect interests, which could relate to the pharmaceutical industry, shall be entered in a register held by the EMA, which is accessible to the public.

The specific provisions for handling declarations of interests and confidentiality undertakings as defined in the EMA policy on the handling of declarations of interests of scientific committees' members and experts, adopted by the Management Board (EMA/626261/2014) are applicable to members of the group and experts participating in the activities of the group.

5.7. Code of conduct

Members of the ESUAvet WG and experts participating in the WG or any operational expert group activities shall abide by the principles set out in the EMA Code of Conduct (EMA/385894/2012).

5.8. EMA secretariat

Under the authority of the Executive Director, the secretariat shall provide technical, scientific, and administrative support to the ESUAvet WG. This includes but is not limited to the following:

- Provide technical and scientific support to rapporteurs (guidelines), and other members of the working group;
- Provide legal, regulatory and scientific support to the working group;
- Prepare and co-ordinate the work of the ESUAvet WG in consultation with their Chairpersons, including drafting of the annual reports by EMA analysing the data sent by Member States on volumes of sales and on the use of antimicrobials in animals;
- Organise meetings and ensure timely circulation of meeting documents;
- Facilitate the necessary contacts between the ESUAvet WG, the CVMP and other bodies;
- Ensure adequate co-ordination of the work carried within the working group, the scientific Committee(s) and other concerned working parties or scientific advisory or concerned groups;
- Contribute to the overall quality assurance and assurance of scientific consistency of the documents or recommendations of the working group;
- Prepare the agenda, table of actions and summary records of meetings in consultation with the Chairpersons;
- Communicate when necessary any CVMP recommendations relevant to the working group to interested parties;
- Transmit any recommendations of the working group to the relevant body for adoption or publication as appropriate.

The Executive Director of the Agency, members of the Secretariat, and representatives of the European Commission, may attend all meetings of the working group.

5.9. Contact with interested parties

Where relevant, the ESUAvet WG and operational expert groups, when considered appropriate, will establish contacts, on an advisory basis, with parties concerned with the surveillance of sales and use of antimicrobials. This will include at least annual meetings with all relevant national contact points and data managers.

When considered appropriate, oral or written presentations by interested parties can be made or may be invited for virtual or on-site meetings and discussions.

Draft concept papers and guidelines will be subject to public consultation of all interested parties.

In any case, the ESUAvet WG shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.

Before any consultation session, interested party representatives and ESUAvet WG members will communicate to the Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the Chair and circulation by the Secretariat.

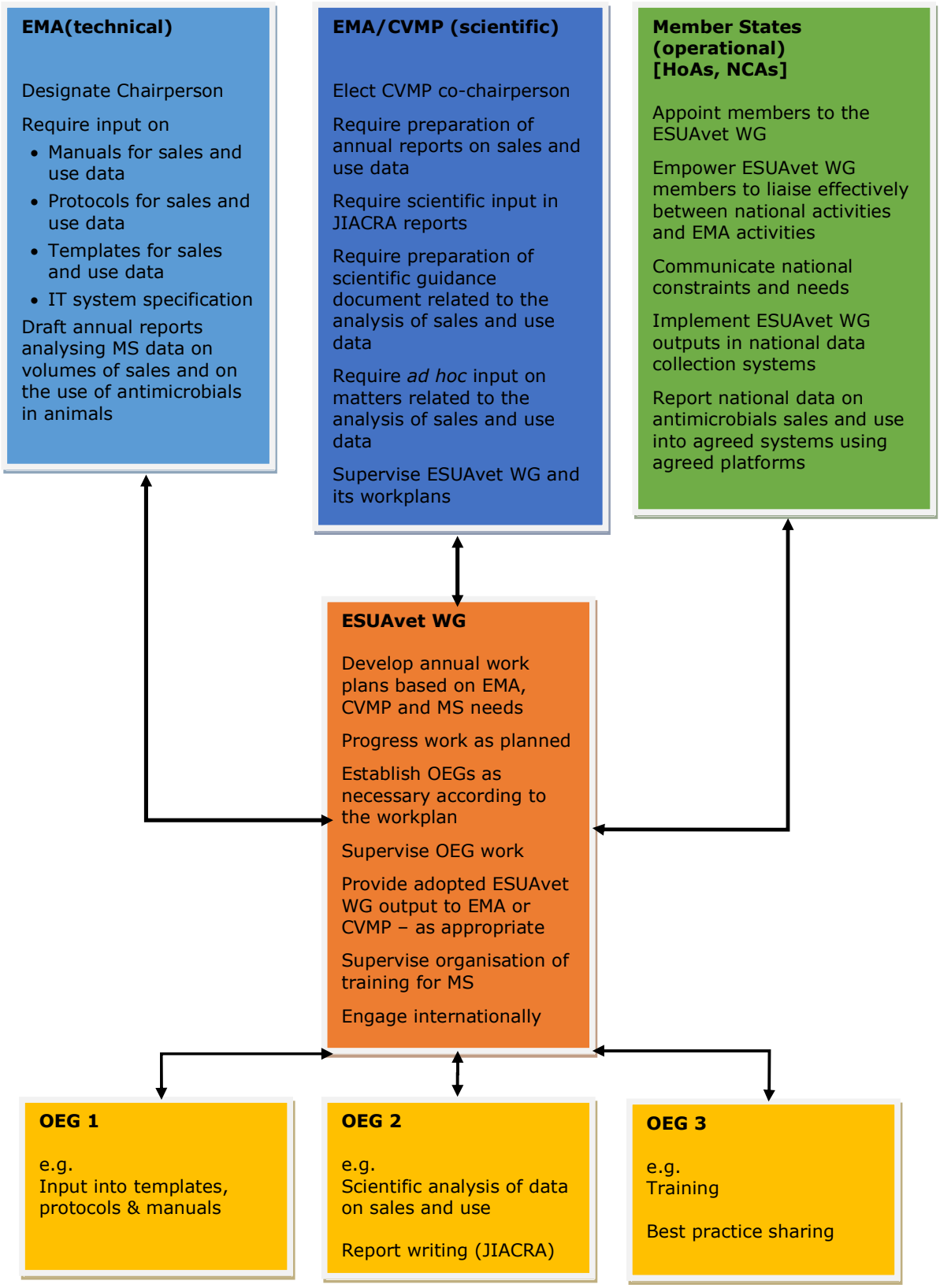
5.10. General provisions

Members of the ESUAvet WG, observers and all experts 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.

When participating in international or other fora on behalf of the CVMP or the ESUAvet WG where activities outside the Committee's remit are concerned, members shall ensure the views expressed are those of the CVMP or the ESUAvet WG and they should adhere to the principles described in the 'Policy on scientific publication and representation for European Medicines Agency's scientific committees and their members' (EMA/231477/2005 Rev. 1).

When participating in international or other fora not specifically on behalf of the WG, members shall make clear that the views expressed are their own views and not those of the WG.

Flowchart


EMA(technical)
Designate Chairperson
Require input on
Manuals for sales and use data
Protocols for sales and use data
Templates for sales and use data
IT system specification
Draft annual reports analysing MS data on volumes of sales and on the use of antimicrobials in animals
EMA/CVMP (scientific)
Elect CVMP co-chairperson
Require preparation of annual reports on sales and use data
Require scientific input in JIACRA reports
Require preparation of scientific guidance document related to the analysis of sales and use data
Require ad hoc input on matters related to the analysis of sales and use data
Supervise ESUAvet WG and its workplans
Member States (operational) [HoAs, NCAs]
Appoint members to the ESUAvet WG
Empower ESUAvet WG members to liaise effectively between national activities and EMA activities
Communicate national constraints and needs
Implement ESUAvet WG outputs in national data collection systems
Report national data on antimicrobials sales and use into agreed systems using agreed platforms
ESUAvet WG
Develop annual work plans based on EMA, CVMP and MS needs
Progress work as planned
Establish OEGs as necessary according to the workplan
Supervise OEG work
Provide adopted ESUAvet WG output to EMA or CVMP – as appropriate
Supervise organisation of training for MS
Engage internationally
OEG 1
e.g.
Input into templates, protocols & manuals
OEG 2
e.g.
Scientific analysis of data on sales and use
Report writing (JIACRA)
OEG 3
e.g.
Training
Best practice sharing