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Veterinary medicines division

Mandate, objectives and rules of procedure for the Environmental Risk Assessment European Specialised Expert Community

1. Mandate and objective

The European Specialised Expert Community (ESEC) is a community of experts with specialist knowledge and/or strong interest in the area of the ESEC that are part of the European Regulatory Network.

ESECs offer the opportunity for experts to establish links with other experts across the community, to the different Working Parties, Committees, and across multinational assessment teams. It is not within the mandate of the ESEC as an entity to initiate or contribute in any way to any regulatory action/advice/decision on product-related activities nor to comment or advise on the need for specific guidelines.

The objective of the Environmental Risk Assessment European Specialised Expert Community (ERA ESEC) is to provide **a platform of information sharing and communication** on the topics that are of relevance to the community, in order for its members to gain and further optimise their knowledge relevant to the evaluation of product-related procedures within the regulatory framework. The ESEC also functions as a pool of experts to support the delivery of relevant activities of the ERA Working Party (ERAWP) and the Non-clinical Working Party (NcWP) workplans and to provide input on all matters relating directly or indirectly to the environmental risk assessment of medicines.

The information shared will include, for example, critical regulatory actions from the Committees of the European Medicines Agency (EMA), as well as important developments outside the regulatory network (e.g. Water Framework Directive watch list). Members of the ESEC shall share their knowledge related to ERA to facilitate the implementation and application of the regulatory framework for veterinary and human medicinal products. Individual ESEC experts may be called upon to support specific strategic and/or operational activities outside of the ESEC (including drafting of guidelines or guidance documents, providing scientific input to procedures, development of training for the EU regulatory network).

The ERAWP/NcWP will provide oversight and leadership to the ERA ESEC.

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2. Composition and rules of participation

2.1. Membership

The ESEC is composed of experts that are assessors working for a National Competent Authority, members of EMA working parties or European institutions such as EFSA, ECHA, EEA and ECDC, with a special interest or expertise in ERA and members from academia in institutions/universities with expertise relevant for the ESEC.

The experts will need to be nominated by a committee member/alternate. Members of the ERAWP, NcWP and Veterinary Scientific Advice Working Party (SAWP-V) are automatically appointed and will get access to the IT platform (Microsoft Teams) dedicated to the ERA ESEC in view of their membership.

To be part of the ESEC, the expert needs to be included in the European experts list (via registration in the EMA experts management Tool) and will need 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. Experts that have current direct interests in the pharmaceutical industry, i.e. current employment, current involvement in repurposing as champion, current consultancy on individual or cross medicinal products, current strategic advisory role for individual or cross medicinal products, or current financial interests, will be excluded from ESEC membership.

The appointment of the ESEC member will be agreed by the ERAWP/NcWP leadership and a list of new memberships will be presented to the CVMP for adoption and to CHMP for endorsement.

2.2. Benefits and responsibilities

Members of the ERA ESEC will benefit from:

- Access to a discussion forum focussed specifically on ERA
- Opportunities to join drafting groups and operational expert groups aimed at supporting the work of the ERAWP, NcWP and committees
- Privileged access to the agendas and minutes of the ERAWP meetings
- Access to information as agreed to be circulated by the WP chairs and secretariats
- Access to training on relevant topics provided via the EU-NTC platform

Members of the ERA ESEC will be expected to contribute to the work of the ERAWP and NcWP as follows (based on their experience and expertise):

- Volunteer for drafting groups and operational expert groups
- Contribute to the delivery of training
- Share information relevant to the workplans and objectives of ERA in the veterinary and human domains, for example, topic areas that would benefit from training or guidance

3. Rules of procedure

3.1. Confidentiality arrangements

The information disseminated in the ESEC will be shared under the EMA confidentiality undertaking that the experts signed with their declaration of interest before being included in the European expert list that is in the public domain.

3.2. Virtual platform

The ESEC is supported by an IT platform (Microsoft Teams) with collaborative tools, and access will be given to all its members. It will provide a function to list contacts and experts by topics.

3.3. Organisation of events (webinars/external stakeholders workshops/symposium)

The ERAWP/NcWP together with the EMA secretariat will provide information on initiatives that will be available to the wider community and of upcoming events that may be organised by EMA or by other stakeholders (such as EU-NTC training, webinars, stakeholders workshops and symposium). Reference is made to the Internal Guidance event organisation S-CS (Event Organization Guidance S-CS).

Depending on the topic and on the strategic, operational, and tactical goals of the CVMP/ERAWP/NcWP as set out in their workplans, webinars can be organised specifically for ESEC members or can be open to the public, in which case no confidential information will be shared or confidential topics discussed. It is expected that the ESEC will contribute to the development and organisation of the programme for the events and trainings.

3.4. Responsibilities of the ERAWP/NcWP chairs and the scientific secretariat supporting the ERA ESEC

The responsibilities of the ERAWP/NcWP Chair (or delegate) in conjunction with the EMA secretariat are outlined as follows:

- To be responsible for the efficient conduct of the business of the ESEC.
- To agree on the ESEC membership and constitution of the ESEC for further CVMP and CHMP adoption.
- To maintain membership and access to the ESEC workspace as well as ensuring that access to the ESEC workspace is given only to members with up-to-date DoIs (providing an updated DoI is the responsibility of the experts).
- To agree on the content of the information to be shared with the ESEC.
- To support calls for expressions of interest in joining the ESEC, particularly if expertise in a particular area is perceived to be lacking by the WPs.
- To review the functioning of the ESEC from time to time and propose a potential revision of the rules of procedures to the veterinary domain governance based on the experience gained rules which are adopted by CVMP and endorsed by CHMP.

4. One health approach

The ERA ESEC aims to function as a multidisciplinary and interagency collaborative network to support the implementation of the "One Health" approach in the area of environmental risk assessment, with the goal to proactively share information between experts across domains and to help identify and address the multiple environmental challenges facing the EU in the areas of human, animal, plant and ecosystem health related to the use of medicines.

The One Health approach is widely recognised at international level and its growing relevance is also evident in the EU, as reflected in many of the ambitious goals contained under the multiple strategies and legal frameworks of the European Commission. The ERA ESEC community will support the priorities for One Health action as stated in the joint statement "Cross-agency knowledge for One Health action" published by the EU ENVI Agencies, as one of the outputs of the Cross-agency One Health Task Force.