EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

Mandate, objectives and rules of procedure for the novel therapies & technologies 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 novel therapies and technologies, 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 novel therapies and technologies European Specialised Expert Community (NTs 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 novel therapies Working Party (NTWP) workplans, and to provide input on all matters relating directly or indirectly to novel therapies and technologies.

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. Biotech Act). Members of the ESEC shall share their knowledge related to novel therapies and technologies to facilitate the implementation and application of the regulatory framework for veterinary 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 NTWP, with input from the SAWP-V, will provide oversight and leadership to the NTs 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 and ECDC, with a special interest or expertise in novel therapies and technologies, and members from academia in institutions/universities with expertise relevant for the ESEC.

The experts will need to be nominated by a committee member/alternates (CVMP or CHMP), novel therapies working party (NTWP), Veterinary Scientific Advice Working Party (SAWP-V), or by EMA. Members of the NTWP, SAWP-V, Quality Innovation group (QIG) and Committee of advanced therapies (CAT) are automatically appointed and will get access to the IT platform (Microsoft Teams) dedicated to the NTs 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 NTWP 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 NTs ESEC will benefit from:

- Access to a discussion forum focussed specifically on novel therapies
- Opportunities to join drafting groups and operational expert groups aimed at supporting the work of the NTWP, and other working parties and committees
- 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 NTs ESEC will be expected to contribute to the work of the NTWP 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 NTWP in the veterinary, 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 NTWP 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/NTWP 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 NTWP chairs and the scientific secretariat supporting the veterinary NTs ESEC

The responsibilities of the NTWP 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 adoption and CHMP endorsement.
- 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.