14 March 2023
EMA/CHMP/127687/2023
Translational Sciences Office
Human Medicines Division

Mandate, objective and rules of procedure for the Non-Clinical and New Approach Methodologies European Specialised Expert Community

1. Mandate and objective

The European Specialised Expert Communities (ESECs) are groups of experts with special knowledge and/or strong interest in certain areas of expertise that support the European Regulatory Network. ESECs also offer opportunities for experts to establish links with other experts across the community to the different working parties and committees.

The objective of the Non-Clinical and New Approach Methodologies European Specialised Expert Community (NC NAMs ESEC) is to provide a platform of information sharing and communication on the topics that are of relevance to the community and to support the delivery of the non-clinical domain workplan.

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. international collaboration). Members of the ESEC shall share their knowledge related to non-clinical (NC) and new approach methodologies (NAMs) to facilitate the evaluation of product-related procedures and the regulatory acceptance of alternative methods within the regulatory framework for human and veterinary medicinal products. It is not within the mandate of the ESEC 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. Individual ESEC experts may be called upon to support specific tactical and operational activities (e.g. drafting of guidance documents, providing scientific input to procedures, development of training for the EU regulatory network).

The Non-clinical Working Party (NcWP) and the 3Rs Working Party (3RsWP) of the non-clinical domain will provide oversight and leadership to the NC NAMs ESEC.

2. Composition and rules of participation

The NC NAMs ESEC is composed of experts who are assessors working for a National Competent Authority, members of EMA working parties and members from academia in institutions/universities with a special interest or expertise in the area of non-clinical and new approach methodologies.

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

The experts can be nominated by committee members (Committee for Human Medicinal Products [CHMP], Committee for Veterinary Medicinal Products [CVMP], Paediatric Committee [PDCO], Committee for Advanced Therapies [CAT], and Committee for Orphan Medicinal Products [COMP]), Scientific Advice Working Party (SAWP) members or by EMA. Members of the 3RsWP, NcWP and Veterinary Safety Working Party (SWP-V) are automatically appointed by CHMP and CVMP.

To be part of the ESEC, the experts need to be included in the European expert database and will need to provide a CV and a declaration of interest (DoI) in line with the EMA policy on handling of competing interests of scientific committees' members and experts. Any expert who is included in the European expert database can be proposed to be part of the NC NAMs ESEC at any time. However, experts who have current direct interests in the pharmaceutical industry, i.e. current employment, current involvement in repurposing as champion, current consultancy (except consultancy for individual products), current strategic advisory role (except strategic advisory role for individual products) or current financial interests, will be excluded from ESEC membership.

The appointment of the NC NAMs ESEC members is agreed by the 3RsWP or the NcWP of the non-clinical domain and presented to the CHMP for adoption.

3. Rules of procedures

3.1. Confidentiality arrangements

As a general principle, information about scientific evaluations or other regulatory procedures will be disseminated through the ESEC only after the regulatory procedure at stake is completed. 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 database that is in the public domain.

3.2. Virtual platform

The ESEC is supported by an IT platform 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 responsible WPs together with the scientific secretariat will provide information on initiatives that are available to the wider community and on upcoming events (such as EU NTC training, webinars, stakeholders' workshops and symposium, studies, projects) that may be organised by the EMA or by other stakeholders.

Depending on the topic and on the strategic, operational, and tactical goals of the WPs as set out in the workplan, the webinars can be organised specifically for the ESEC members or can be open to the public, in which case no confidential information shall be shared or confidential topics are deemed to be 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 WP chair and the scientific secretariat supporting the NC NAMs ESEC

The responsibilities of the WP Chair 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 CHMP adoption;
- To maintain membership and access to the ESEC workspace, and ensure access to the ESEC workspace is given only to members with up-to-date DoIs (providing an updated DoI is the responsibility of the expert);
- To agree on the content of the information to be shared with the ESEC;
- To identify gaps in the expertise of the ESEC and coordinate the calls for expression of interest of experts when needed;
- To review the functioning of the ESEC from time to time and propose a potential revision of the rules of procedures to the non-clinical domain governance based on the experience gained.