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Mandate, objectives, and rules of procedure for the European Specialised Expert Community (ESEC) for Methodology

MANDATE AND OBJECTIVE

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

The objective of the Methodology ESEC comprise three main goals:

1. To provide a community that will contribute to the delivery of the workplan of the Methodology Domain.
2. To provide a forum for the interaction with stakeholders.
3. To provide a platform for knowledge transfer, information sharing and communication.

Members of the Methodology ESEC are invited to contribute with their specific expertise to the delivery of the Methodology Working Party (MWP) workplan which will include drafting of guidance documents, providing scientific input to procedures related to the evaluation of medicinal products or development of training for the EU regulatory network.

The Methodology ESEC shall also provide a forum for the interaction with external stakeholders (e.g. international regulators, industry associations, patient or healthcare representatives) mainly on general topics which are not directly related to on-going assessments as these are covered by dedicated cluster meetings.

The Methodology ESEC will provide a forum for knowledge transfer and training opportunities. Members of the Methodology ESEC shall gain and further optimise their knowledge in the evaluation of product-related procedures within the regulatory framework. 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.

As a general principle, all communication within the Methodology ESEC should be transparent and available to all Methodology ESEC members. However, in some cases, a Specialised Interest Area (SIA) within the Methodology ESEC may function as a content group that facilitates the dissemination of information on very specific scientific topics. SIAs prove particularly useful when the ESEC comprises of members with a broad range of expertise in various scientific and medical areas. Methodology ESEC members can express interest in certain SIAs to receive communication tailored to those specific topics.

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The Methodology Working Party will provide oversight and leadership to the Methodology ESEC. Individual ESEC experts may be invited to support the evaluation of products as part of a temporary or standing Operational Expert Group (OEG) or the drafting of guidelines as part of multidisciplinary temporary drafting groups. The Methodology ESEC also offers opportunities 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 scope of the Methodology ESEC to initiate any regulatory action/decision on product-related activities.

The Methodology Working Party together with the EMA scientific secretariat will provide information on initiatives that will be available to the wider community and of upcoming events that may be organised by the EMA or by other stakeholders (such as EU NTC training, webinars, stakeholders' workshops and symposium, studies and projects).

Depending on the topic and on the strategic, operational, and tactical goals of the Methodology Working Party as set out in its workplan, webinars can be organised specifically for Methodology ESEC members or can be open to the public. It is expected that the Methodology ESEC will contribute to the development and organisation of the programme for the events and trainings.

COMPOSITION AND RULES OF PARTICIPATION

Membership

The Methodology ESEC is composed of experts that are assessors working for a National Competent Authority, members of EMA Committees or working parties with a special interest or expertise in the relevant field, EMA Scientific staff, and members from academia in institutions/universities with expertise relevant for the Methodology ESEC. Additional expertise can be invited to join the Methodology ESEC on an as needed basis. The experts should be nominated by Committee member (COMP, PDCO, PRAC, CAT, CVMP and CHMP), Scientific Advice Working Party (SAWP) member or by EMA. Committee and SAWP members, members of the Methodology Working Party and of standing OEGs can request access to the Methodology ESEC automatically.

To be part of the ESEC, the expert needs to be included in the European expert list, for which he/she 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 (except if consultancy for individual products), current strategic advisory role (except if strategic advisory role for individual products) or current financial interests, would be excluded from ESEC membership.

The appointment of the Methodology ESEC member will be agreed by the Methodology Working Party leadership and a list of new memberships will be presented to the CHMP for adoption. Members can be part of several ESECs.

The list of existing Methodology ESEC members shall be publicly available and revised regularly by CHMP and amended as needed.

Confidentiality arrangements

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

RULES OF PROCEDURES

Virtual platform

The Methodology ESEC is supported by a modern IT platform with collaborative tools and access will be given to all its members. It will provide a function to list contacts and experts matching the Methodology ESEC structure.

In certain cases, Specialised Interest Areas (SIAs) within the Methodology ESEC can serve as a content group that helps target sharing of information on very specific scientific topics. Methodology ESEC members can indicate interest in certain SIAs to receive targeted communication on related topics and can also express interest in taking a leading role in a SIA by shaping and coordinating activities.

Responsibilities of the Methodology Working Party Chair(s) and the scientific secretariat supporting the ESEC

The responsibilities of the Methodology Working Party Chair(s) in conjunction with the WP secretariat are outlined as follows:

- To be responsible for the efficient conduct of the business of the Methodology ESEC;
- To agree on the Methodology ESEC membership and constitution of the Methodology ESEC;
- To maintain membership and access to the Methodology ESEC workspace, and ensure access to the Methodology ESEC workspace is given only to members with up-to-date DoIs (providing an updated DoIs is the responsibility of the experts);
- To agree on the content of the information to be shared with the Methodology ESEC;
- To identify gaps in the expertise of the Methodology ESEC and coordinate the expression of interest of experts when needed;
- To review the functioning of the Methodology ESEC on a regular basis and propose a potential revision of the rules of procedures to the Domain governance based on the experience gained.