EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Oncology and Haematology Office
Human Medicines Division

Mandate, objectives and rules of procedure for the Oncology European Specialised Expert Communities (ESEC)

1. MANDATE AND OBJECTIVE

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

The objective of the ESEC is to provide a platform of information sharing and communication on the topics that are of relevance to the above referred community of experts in order for its members to 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 (e.g. new treatment guidelines). It is not within the manate 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.

A designated working party (in this case the Oncology WP) will provide oversight and leadership to the ESEC. Individual ESEC experts may be called upon to support the drafting of guidelines as needed. ESECs also offer opportunities for experts to establish links with other experts across the community, to the different Working Parties, Committees, and across multinational assessment teams. The ESEC may also be associated to a SAG (in this case the Oncology SAG).

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 with a special interest or expertise in oncology and members from academia in institutions/universities with expertise relevant for the ESEC. The experts will need to be nominated by a Committee member (COMP, PDCO, PRAC, CAT and CHMP). Committee members/alternates and members of the Oncology working party and the SAG-Oncology are

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automatically appointed by CHMP and will get access to the Oncology ESEC teams' platform in view of their membership.

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 ESEC member will be agreed by the Oncology Working Party and a list of new memberships will be 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 list that is in the public domain.

3.2. Virtual platform

The ESEC is supported by an IT platform (e.g. 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 Oncology WP together with the 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, projects). Reference is made to the Internal Guidance event organisation S-CS (https://docs.eudra.org/webtop/drl/objectId/090142b2837a8fbc).

Depending on the topic and on the strategic, operational, and tactical goals of the WP 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 are deemed to 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 Oncology WP chair and the scientific secretariat supporting the Oncology ESEC

The responsibilities of the Oncology 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 the ESEC workspace, and ensure access to the 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 ESEC;
- To identify gaps in the expertise of the ESEC and coordinate the 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 clinical domain governance based on the experience gained, rules which are adopted by CHMP.