

Amsterdam, 11 November 2024 Doc. Ref: EMA/109302/2024 Human Medicines Division

Public call for expression of interest for experts to become members of the European Medicines Agency's scientific advisory groups

1. Background

The Committee for Human Medicinal Products (CHMP) is the European Medicines Agency's (EMA) committee responsible for human medicines and plays a vital role in the authorisation of medicines in the European Union (EU).

The CHMP relies on scientific advisory groups (SAGs) to provide independent recommendations on scientific or technical matters related to medicinal products under evaluation at EMA. For matters that fall outside the expertise of the established SAGs, the CHMP establishes ad hoc expert groups.

SAGs play a key role and are established in the following clinical specialties:

- Scientific Advisory Group on Cardiovascular Issues
- Scientific Advisory Group on Neurology
- Scientific Advisory Group on Oncology
- Scientific Advisory Group on Vaccines
- Scientific Advisory Group on Infectious Diseases

With this public call for expression of interest, EMA is inviting applications from interested experts with clinical/technical expertise in the fields listed below. The experts will be considered for appointment as core members for the respective SAGs by EMA's CHMP.

2. Eligibility criteria

Experts expressing their interest to become core members of a SAG must have:

- a university degree, and
- demonstrated professional experience of European therapeutic practices and/or research, and
- demonstrated clinical (adult and/or paediatric) or other expertise relevant for a SAG in one
 or more of the following fields:
- Scientific Advisory Group on Cardiovascular Issues: General cardiologists. Also cardiologists with specific experience in: cardiomyopathy; anticoagulation; lipidology; heart failure; arrhythmia and experts with experience in treating patients with overlapping aspects of health such as cardiovascular disease, kidney diseases, obesity and diabetes.



- 2. **Scientific Advisory Group on Neurology**: Any clinical aspects of neurology and particular expertise on Alzheimer Disease, Parkinson's Disease, Amyotrophic Lateral Sclerosis, Duchenne Muscular Dystrophy.
- 3. **Scientific Advisory Group on Oncology**: Any clinical aspects of oncology and haematological malignancies;
- 4. **Scientific Advisory Group on Vaccines**: Any clinical aspects of vaccines; non-clinical assessment of immunogenicity and/or efficacy; immunology; epidemiology and/or demonstrated expertise in clinical trials methodology and/or biostatistics.
- 5. **Scientific Advisory Group on Infectious Diseases**: Any clinical aspects of fungal, bacterial, viral and/or parasitic diseases/infections; clinical microbiology (for viral and non-viral infections); epidemiology; non-clinical aspects (particularly in vitro and in vivo primary pharmacology), and modeling and simulation (exposure- response relationships).

Members of any EMA Scientific Committees, EMA staff or staff of the National Competent Authorities in the European Union or experts from non-EEA countries are not eligible to become core members of a SAG.

Core members of the SAGs cannot, during any time of their mandate, be employees of a pharmaceutical company, have financial interests in a pharmaceutical company (such as shares, fees, honoraria or patents), provide general consultancy to a pharmaceutical company (individual product(s) consultancy is allowed but may lead to restrictions on participation depending on the topic under discussion), hold a general strategic advisory role for a pharmaceutical company (individual product(s) strategic advisory role is allowed but may lead to restrictions) or be involved in the repurposing of a medicinal product where the core member's organization is the champion of the repurposing. Any prohibited interests will need to be removed or stopped before an appointment is possible. Any other declared interest may lead to restrictions on participation to a particular meeting depending on the topic under discussion. The declaration of interests of core members of the SAGs will be evaluated against the EMA policy on the handling of competing interests of scientific committees' members and experts in place at the time of appointment and involvement in each meeting. Please note that this policy (EMA/136878/2022) is currently undergoing revision¹.

3. Application procedure

Interested individuals are invited to submit by email their application to the EMA using the following address: <u>SAG.public.call@ema.europa.eu</u>

An application will be deemed admissible only when it is received by the EMA by the below mentioned deadline and when it includes the documents referred to below. All documents submitted by applicants should be duly completed.

Each application must include the following documents:

- A letter of motivation including a statement which SAG the application is for
- A curriculum vitae (CV) including a list of publications
- A declaration of interests ('DoI') form on the basis of the standard EMA DoI form for experts and committee members which is attached to this call.

¹ News item: Handling of competing interests: revised rules for committee members and experts: https://www.ema.europa.eu/en/news/handling-competing-interests-revised-rules-committee-members-experts

Optionally, one letter of recommendation can be included in the application.

Deadline for application:

The applications must be received by EMA by 15 December 2024, 23:59 CET

4. Appointment and rules of procedure

The appointment of core members will follow the principles laid out in the Mandate, objectives and rules of procedure for the SAGs and ad-hoc experts.

The CHMP will aim to appoint between 8 and 14 members per SAG for their clinical/technical expertise and independence in the field of interest. The number of appointed core members may vary per therapeutic SAG. SAG members will be nominated for a period of 3 years.

The appointed core members of the SAGs shall commit to active participation in the activities of the group, including attendance of the meetings of the SAG. Core members should be prepared to contribute to the scientific discussions and to review the documents received in preparation for and in follow-up to the meeting. The expected number of meetings varies between 2-7 per year, depending on the therapeutic area and have an average duration of 5 hours. Should a core member fail to attend a minimum of 50% of the meetings on a yearly basis, replacement of the member will be considered by the CHMP.

Appointed core members will be notified and their appointment officialised through their inclusion as experts in the EMA Experts Management Tool. Applicants who have not been appointed for the core group will also be notified.

Work undertaken by core members will be remunerated subject to conditions laid out on the EMA website (<u>Procurement</u>). The vast majority of the meetings are expected to take place remotely. When meetings are in-person, reimbursement of expenses in terms of accommodation, daily allowance and travel costs will be applied according to EMA's reimbursement rules (<u>Rules of reimbursement</u>).

The details of the rules of procedure and operation of the SAGs are outlined in the Mandate, objectives and rules of procedure for the scientific advisory groups (SAGs) and ad-hoc experts groups (EMA/117014/2010).

5. Data privacy statement

All personal data provided by applicants will be processed in compliance with Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data. This applies in particular to the confidentiality and security of such data. The submission of personal data by applicants will be collected by the Agency for the sole purpose of selecting candidates with particular experience and knowledge for appointment as SAG core members. Such data will be used in this specific context only and accessed by staff members with defined responsibilities within the concerned division only.

Please see the **EMA** general data privacy statement for additional information.