

5 May 2021 EMA/170106/2019EMA/170106/2019 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 Products
- Scientific Advisory Group on Anti-infective Products
- Scientific Advisory Group on HIV / Viral Diseases
- Scientific Advisory Group on Neurology
- Inter-Committee Scientific Advisory Group on Oncology
- Scientific Advisory Group on Vaccines

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 possible 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:



- 1. Scientific Advisory Group on Cardiovascular Products: Any clinical aspects of cardiology diagnosis/prevention/treatment; anticoagulation; lipidology;
- 2. Scientific Advisory Group on Anti-infective Products: Any clinical aspects of fungal and bacterial diseases; clinical microbiology (non-viral infections); epidemiology; non-clinical aspects (particularly *in vitro* and *in vivo* primary pharmacology), and modeling and simulation (exposure-response relationships).
- 3. Scientific Advisory Group on HIV / Viral Diseases: Any clinical aspects of viral diseases; viral infections; clinical microbiology with expertise in virology; non-clinical aspects (particularly *in vitro* and *in vivo* primary pharmacology).
- 4. Scientific Advisory Group on Neurology: Any clinical aspects of neurology;
- 5. Inter-Committee Scientific Advisory Group on Oncology: Any clinical aspects of oncology and haematological malignancies;
- 6. Scientific Advisory Group on Vaccines: Any clinical aspects of vaccines; nonclinical assessment of immunogenicity and/or efficacy; immunology; and/or demonstrated expertise in clinical trials methodology and/or biostatistics relevant for a SAG.

Members of any EMA Scientific Committees, EMA staff or staff of the European National Competent Authorities are not eligible to become SAG members.

Experts from non-EEA countries may be appointed by the CHMP as core member if a justification on the lack of expertise in the EEA for this particular scientific area is accepted.

Core members of the SAG cannot during any time of their mandate be employees of a pharmaceutical company, have financial interests in a pharmaceutical company (such as shares or honoraria), provide cross-product consultancy to a pharmaceutical company (individual product consultancy is allowed but may lead to restrictions on participation depending on the topic under discussion) or hold a cross-product strategic advisory role for a pharmaceutical company (individual product strategic advisory role is allowed but may lead to restrictions). Any prohibited interests will need to be removed or stopped before an appointment is possible and may lead to restricted participation depending on the topic under discussion. For details see, EMA policy on the handling of competing interests of scientific committees' members and experts (EMA/MB/89351/2020)

# 3. Application procedure

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

An application will be deemed admissible only if it is sent by 4 June 2021 and 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. Please download the form on your computer using the 'Download' button and view the form in Adobe Acrobat Reader.

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

#### Deadline for application:

• The applications must be sent by 23.59 CET on 4 June 2021.

### 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.

Twelve core members per SAG will be selected for their clinical/technical expertise and independence in the field of interest and will be nominated for a period of 3 years.

The appointed core members of the SAG shall commit to active participation in the activities of the group. Should a core member fail to attend for any reason more than 3 meetings in less than 2 years (or attend less than 50% of the meetings during the same period), replacement of the member will be considered by the CHMP. The expected number of meetings is between 2-7 per year, depending on the therapeutic area.

The final appointment of core members is the responsibility of the CHMP.

Appointed experts will be notified and their appointment officialised through their inclusion as experts in the public EMA European Experts Database.

Applicants who have not been appointed for the core group will also be notified.

Work undertaken by core members will be non-remunerated. Reimbursement of expenses in terms of accommodation, daily allowance and travel costs, when needed, 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