17 December 2024
Executive Director
EMA/55453/2022

Policy on visiting and collaborating experts involved in the activities of the European Medicines Agency

POLICY/0083
Status: Public
Effective date: 1 January 2025
Review date: 31 December 2027
Supersedes: Policy 0077 on visiting experts (EMA/449474/2013) and Policy 0080 on the use of expertise for specific tasks to be undertaken by the Agency (EMA/219979/2016)

1. Introduction and purpose

The European Medicines Agency (EMA or the Agency) has at its disposal experts who serve as members or contribute to the activities of the EMA scientific committees, working parties, scientific advisory groups and other bodies[1] in particular with regards to the authorisation and supervision of medicinal products for human and veterinary use or who perform inspections on behalf of EMA. They can be nominated by a Member State, the European Commission or by EMA.

However, other situations may arise where EMA needs of the use of services of 'collaborating experts' for the fulfilment of another specific task (e.g. to collaborate in identifying and tackling important research questions) in the context of the EMA's mandate and remit and in its interest.

In addition, the EMA also hosts 'visiting experts', who will visit and be involved in EMA work for the purpose of training (for the person or their institution), to assist the EMA, for information gathering, or exchange of knowledge with EMA or other purposes within the mandate, role, and responsibilities of the Agency.

The purpose of this policy is to describe the arrangements put in place governing the use of such collaborating experts and visiting experts.

[1] such as the Emergency Task Force (ETF), the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and the Executive Steering Group on Shortages and Safety of Medical Devices (MDSSG)

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2. Scope

This policy applies only to:

- Collaborating Experts.
- Visiting Experts.

This policy does not apply to:

- Members or experts of EMA's scientific committees, working parties, scientific advisory groups, and other bodies. The rules governing the use of those experts are set out under the website of the Agency and, in particular, Policy 0044.
- External experts remunerated in accordance with Article 237 of the Financial Regulation applicable to the general EU budget.[2]
- Seconded national experts who are governed by the Decision of the Executive Director on rules governing the secondment of national experts to the EMA (EMA/194397/2022).
- Consultants and contractors engaged following a procurement procedure.
- Liaison officials from other international regulators, whose assignment in EMA comes under the specific agreement with their employing international organisation.
- Other ad hoc short visits to the EMA without a specific assignment.

3. Definitions

Assignment: Specific task agreed between EMA and a visiting or collaborating expert;

Collaborating expert: An individual, who on the basis of acquired expertise/knowledge, has been invited by EMA to perform a specific task within a pre-defined project within EMA's mandate and remit, and is a paid employee from an EU or non-EU, public or academic organisation (e.g. national competent authority, international regulator, research institutions or international organisations), or a post graduate student within such organisations. In exceptional cases, an individual can be invited from outside these organisations;

EMA entity: Group of people under the supervision of a manager at EMA. This can be an office, service, task force, department, advisory function;

EMA mentor: Assigned EMA staff member who is the primary contact of the collaborating or visiting expert, facilitates their engagement across EMA, supervises their activities and, where relevant, reviews the progress and completion of their assigned tasks;

Employing organisation: Organisation to which the visiting or collaborating expert is affiliated to;

Visiting expert: An individual who is assigned temporarily by the employing organisation for training (for the person or their organisation), information gathering or exchange of knowledge/best practices with EMA or other purposes within the mandate or remit of the Agency, and is an employee of an EU or non-EU public or academic organisation (e.g. national competent authority, international regulator[3], research institutions or international organisations) or a student within such organisations. The duration of such assignments would normally not be less than 5 days.

[2] The remunerated external experts shall provide opinions and/or advice to the Agency or any of its committees, working parties and other groups for the discharge of specific tasks for which they are responsible. These experts are selected following call(s) for expression of interest to establish pool(s) of remunerated external experts.
[3] Including staff taking part of Fellowship programmes.

4. Policy statement

4.1. Initiating process

The initiating process is flexible and it can be undertaken either by the Head of an EMA entity or by the employing organisation of an expert or by an individual expert.

In order to facilitate a selection of a collaborating expert and identify the required competence, calls for expression of interest may be prepared and published on EMA's careers website. Ad hoc engagement of a specific collaborating expert without such a call may also be considered if their particular expertise is deemed required for the purpose of a specific project.

Visiting expert placements do not require external publication.

When considering the engagement of a visiting or collaborating expert, the following (non-exhaustive) list of elements should be taken into account:

- details of the scope and purpose of the assignment (including deliverables);
- nature of task (within the mandate and remit of EMA);
- expected duration;
- added value for EMA and expert;
- any costs involved for EMA related to reimbursement of travel related or meeting attendance expenses;
- resources and workload of the EMA entity involved with the expert;
- the details of the organisation(s) which employs the expert (if applicable);
- the identification of any competing interests that the expert may have.

4.2. Selection and internal decision making process

The selection of an expert, where relevant, will take into account the following elements:

- CV of the proposed expert;
- identification of the required competence, and
- the absence of any competing interest which could affect or could be reasonably perceived as affecting their impartiality.

Proposals to engage a collaborating expert will be approved by the Head of Regulatory Science and innovation Task Force.

Proposals to engage a visiting expert will be approved by the:

- Head of International Affairs for visiting experts from a non-EU/EEA national competent authorities;
- Head of Institutional and Policy for visiting experts from EU institutions and Agencies;
- Head of the receiving EMA entity for all other visiting experts.

All selected experts will subsequently also be approved by the Executive Director.

4.3. Acceptance letter

The terms of engagement of the collaborating and visiting experts are set out in an acceptance letter which will include the following elements, as applicable:

- the task to be performed, including the ultimate objectives and deliverable(s);
- EMA will retain all copyrights on the deliverable(s), unless otherwise specified;
- the start, time frame and end dates of the task;
- information if the task should be undertaken remotely and/or at the EMA premises;
- the frequency of visits to EMA;
- the name of the EMA mentor.

4.4. Supervision and assigned tasks or programme

The receiving EMA entity appoints a mentor for either type of expert. The mentor will supervise and assist experts during their assignment at the Agency.

Collaborating expert will undertake the assigned tasks, supervised by the EMA mentor. Regular reviews of the collaborating expert's work will be undertaken by the EMA mentor to ensure that the assigned task is performed as planned. At the end of the timeframe for conducting the task the EMA mentor will review the agreed deliverable(s) and confirm that the task has been performed as agreed.

The EMA mentor prepares a draft programme for the visiting expert based on the agreed tasks, objectives and deliverables, as applicable in consultation with International Affairs or the Institutional and Policy Department, and other relevant EMA entities, as appropriate to the case.

4.5. Duration

The duration of the assignment will be stated in the acceptance letter between the Agency and the expert. It may vary between five working days to six calendar months with possible extensions.

A collaborating expert may have his/her assignment extended in line with the acceptance letter provisions. It is of utmost importance to seek formal extension of the collaborating expert's assignment in due course to ensure their status remains the same (working for a public organisation/academia) and that their organisation agrees with the collaboration.

4.6. Termination

The assignment of the visiting or collaborating expert ends when the period for which it was assigned in the acceptance letter expires. The assignment may be ended earlier in the interest of the EMA, at the request of the expert's employer or for any other sufficient cause. If the work performed by the expert does not prove satisfactory, if there is a breach of the terms of engagement, EMA, after providing the concerned expert an opportunity to submit observations, may at any moment decide to terminate the assignment.

4.7. Competing interests, confidentiality and other obligations

Visiting and collaborating experts must ensure that they have no interests in the pharmaceutical or medical device industry which could affect or could be reasonably perceived as affecting their impartiality. In particular, they must adhere to the relevant EMA's rules on the handling competing interests[4].

Following the selection of the expert, a declaration of interest must be completed and the Head of the organisational entity where the expert will be assigned must review the declaration, assign an interest level and possible mitigation actions, as required, prior to the start of the assignment.

Visiting and collaborating experts must exercise the greatest confidentiality and discretion regarding all facts and information coming to their knowledge in the course of their assignment. They must not, in any manner whatsoever, disclose to any unauthorised person any document or information that has not already been made public. They continue to be bound by this obligation after the end of their assignment.

During the course of their assignment, visiting and collaborating experts should also follow the principles set forth in the EMA code of conduct.

4.8. Access to EMA building and information (IT) systems

The access to EMA premises is granted as defined in EMA's Internal guidance on Access Control to Agency premises.

Visiting experts and collaborating experts have reduced access to EMA information systems based on a need-to-know basis. If required, the receiving EMA entity will decide on the access granted to EMA systems and the access request is handled by the mentor.

4.9. Meetings outside the EMA

Visiting experts shall not attend meetings outside of EMA on behalf of the Agency. Where a visiting expert attends an external meeting on behalf of their employing organisation that organisation shall pay the related costs and expenses and the visiting expert is responsible to make all the relevant arrangements for this trip. The visiting expert shall notify their mentor of the dates of their absence related to an external meeting.

In exceptional circumstances related to his/her assignment, a collaborating expert may be requested to attend a specific meeting outside of EMA. In such cases, Policy 0029 on Representing the Agency and Scientific Committees at external events or in professional bodies should be considered by the collaborating expert, where relevant. The costs related to that meeting will be covered according to the EMA rules for reimbursement of expenses for delegates attending meetings.

4.10. Leave/illness

Visiting and collaborating experts shall notify their mentor of planned leave days authorised by their employing organisation. In case of sickness, they must notify their mentor immediately. The Agency does not require any medical certificate to be submitted. Any health-related matters, as well as other forms of leave, shall be handled between the expert concerned and their employing organisation. An expert may be exceptionally required to have a medical examination at the EMA's official medical centre in the interest of the service and to protect public health.

[4] Decision of the European Medicines Agency (EMA) On rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the European Medicines Agency and candidates before recruitment https://www.ema.europa.eu/documents/other/decision-european-medicines-agency-rules-relating-articles-11-11a-13-staff-regulations-concerning_en.pdf)

4.11. Administrative status

Visiting experts and collaborating experts are not EMA staff members. All aspects related to finding and arranging accommodation, legal obligations to enter or to stay in the Netherlands, social security, taxation matters, travel, health insurance or other applicable insurance will be the responsibility of the expert and their /employing organisation.

4.12. Financial arrangements

The salary of a visiting or collaborating expert is the responsibility of the employing organisation.

Collaborating experts attending physical meetings, including on-site collaboration days at EMA or, exceptionally at other destinations designated by EMA, will have the costs (hotel, travel and DSA) related to these meetings covered by EMA according to the rules for reimbursement of expenses for delegates attending meetings.

The expenses of the visiting expert during the assignment are the responsibility of the employing organisation.

4.13. Data protection

All personal data related to visiting and collaborating experts will be processed in accordance with Regulation (EU) 2018/1725 on the protection of natural persons about the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

Details concerning the processing of the personal data are available on the Agency's website at: https://www.ema.europa.eu/en/about-us/legal/general- privacy-statement.

On behalf of EMA, the Head of Administration and Corporate Management Division is appointed as 'Internal Controller' to ensure the lawful conduct of processing of personal data regarding visiting and collaborating experts. The internal controller may be contacted at datacontroller.administration@ema.europa.eu

5. Related documents

The European Medicines Agency Code of Conduct

Policy on publications by EMA staff and EMA scientific committee members on EMA's work (Policy 0015)

Policy on representing the Agency and scientific committees at external events or in professional bodies (Policy 0029)

EMA careers webpage on Collaborating Experts

Fellowships

6. Changes since the last revision

This policy supersedes Policy 0077 on visiting experts (EMA/449474/2013) and Policy 0080 on the use of expertise for specific tasks to be undertaken by the Agency (EMA/219979/2016).

In addition to the merging of the content of the previous policies, changes are introduced in the initiation, selection and decision steps of the process for recruiting collaborating and visiting experts as well as the financial arrangements.

Amsterdam,

[Signature on file]

Emer Cooke
Executive Director