European Medicines Agency policy on the use of expertise for specific tasks to be undertaken by the Agency

POLICY/0080
Status: Public
Effective date: 5 April 2016
Review date: No later than 3 years following the effective date
Supersedes: Not applicable

1. Introduction and purpose

The European Medicines Agency (EMA) has at its disposal European experts who serve as members of the EMA scientific committees, working parties and other groups, or who perform inspections on behalf of EMA. They can be nominated by the Member States or by EMA itself. Detailed arrangements for the use of these experts have been published on the EMA website.

However, other situations may arise where EMA is in need for the use of non-remunerated services of experts not covered by the aforementioned framework, and this for the fulfilment of a specific task in the context of the EMA’s mandate and remit. The purpose of this policy is to describe the arrangements put in place governing the use of these experts.

2. Scope

The scope of this policy relates to situations which may arise where EMA has identified the need to undertake a particular activity/piece of work within its remit and in EMA’s interest, other than direct involvement in the authorisation and surveillance of medicinal products for human and veterinary use.

This policy does not apply to visiting experts which come within the scope of Policy 0077 (EMA policy on visiting experts). Likewise, this policy does not apply to seconded national experts which come within the scope of the Executive Director’s Decision dated 1 August 2013 (EMA/267306/2013). In addition, consultants and contractors following procurement procedures do not come within the scope of this policy.
3. Definitions

AF: Advisory Function.
DoI: Declaration of Interests.
EMA: European Medicines Agency.
Expert: An individual, or an employee of an EU or non-EU public or academic body, who on the basis of acquired expertise/knowledge, has been invited by EMA to perform, on a non-remunerated basis, a specific task within EMA’s mandate and remit.
EU: European Union.
SMO: Senior Medical Officer.
Supervisor: EMA staff member who will supervise the work undertaken by the expert invited by EMA to perform a specific task.

4. Policy statement

The following aspects are covered:

- Need identification.
- Internal decision-making.
- Practical arrangements.

4.1. Need identification

Although the need for the use of an expert covered by the scope of this policy can be identified by any EMA staff member, a request should be channelled through the concerned Head of Division. Likewise, the need can be identified by the Head of an AF or the SMO. Once the need has been identified a request is made to the Executive Director.

In order to allow for informed decision-making the following aspects need to be addressed in the request submitted to the Executive Director, using the attached form:

- Description of the task to be undertaken by the expert, including details on the ultimate deliverable(s), the anticipated start of the task and the timeframe for concluding the task (in terms of the availability of the agreed deliverable(s)). Such timeframe should be limited in time and be kept as minimal as possible.
- Identification of the required competence.
- Identification of the proposed expert(s) matching the required competence, including the rationale for choosing such expert(s).
- Information if the task should be performed through remote access and/or working at the EMA premises (in case of the latter, frequency of visiting the EMA premises to be stated).
- Requested access to EMA databases and systems necessary for the expert to perform the agreed task.
- Proposed EMA supervisor.
4.2. **Internal decision-making**

Decisions are made by the EMA Executive Director (or by the Deputy Executive Director if delegated for that purpose) on the basis of the information provided. Where necessary, further information/clarification may have to be obtained to allow for informed decision-making.

Elements that will determine whether the request can be accepted include:

- Task is within the mandate and remit of EMA.
- Added value of the task.
- Proposed deliverable(s).
- Proposed start of the task and the timeframe for concluding the task.
- Profile of the proposed expert(s).
- Any perceived conflict of interest the expert(s) may have.

Once a favourable decision is taken the EMA Executive Director will inform the expert on the conditions that will apply for performing the task assigned to the expert. Such conditions will stipulate amongst others:

- The task to be performed, including the ultimate deliverable(s). EMA will retain all copyrights on the deliverable(s), unless otherwise specified.
- The start and end data of the task.
- Information if the task should be undertaken remotely and/or at the EMA premises. As regards the latter, the frequency of visiting EMA.
- Information on the expert’s access to EMA databases and systems for performing the task.
- The absence of remuneration for the services to be provided, although reimbursement of reasonable expenses in terms of accommodation and travel costs can be undertaken if the expert’s place of residence is more than 50 km from the EMA premises and the expert needs to perform the activity at the EMA premises.
- The need to declare conflicts of interests and to comply with any resulting restrictions, and to confirm that confidentiality will be respected.

The expert will also be provided with the name of the EMA supervisor, including the role of such supervisor.

4.3. **Practical arrangements**

The following arrangements apply. These may be complemented with additional guidance.

- Prior to starting the assigned task the expert
  - will confirm that the conditions that will apply for performing such task will be respected;
– will provide EMA with a duly completed and signed DoI and a signed Confidentiality Undertaking¹.

• Prior to starting the assigned task the EMA supervisor will
  – review if all necessary documents have been made available, duly completed and signed;
  – review the expert’s DoI in order to identify if any restrictions should apply;
  – enter all necessary information in an internal register.

• At the start of the assigned task EMA will grant the expert the agreed access to the EMA databases and systems, and will also provide the expert with an ID pass with a black lanyard.

• The expert will undertake the assigned tasks, supervised by the EMA supervisor.

• Regular reviews of the expert’s work will be undertaken by the EMA supervisor to ensure that the assigned task is performed as planned.

• At the end of the timeframe for conducting the task the EMA supervisor will review the agreed deliverable(s) and confirm that the task has been performed as agreed.

• If the work performed by the expert does not prove satisfactory, if there is a breach of the conditions, EMA, after hearing the expert, may at any moment decide to terminate the task.

5. Related documents

Not applicable.

6. Changes since last revision

Not applicable.

5 April 2016

[Signature On File]

Guido Rasi
Executive Director

¹ The Agency processes personal data in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Further information is provided on the Agency’s website under “Privacy statement”.

Request to the Executive Director to use expertise for a specific task to be undertaken by the EMA (in accordance with EMA policy 0080)

1. Description of the task to be undertaken by the expert:
   a) Scope of the task:
   b) Ultimate deliverable(s):
   c) Anticipated start of the task:
   d) Timeframe for concluding the task:

2. Required competence:

3. Proposed expert(s) including the rationale for choosing such expert(s):

4. Task to be performed through remote access (tick as appropriate):
   Yes ☐
   No ☐

5. Task to be performed through working at the EMA premises (tick as appropriate):
   Yes ☐
   No ☐
   If yes, indicate frequency of visiting the EMA premises:

6. Access required to EMA databases and systems (tick as appropriate):
   Yes ☐
   No ☐
   If yes, indicate the EMA databases and systems:

7. Proposed EMA supervisor:

Date    Name    Signature