



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

18 March 2015  
EMA/449474/2013  
Executive Director

## EMA policy on visiting experts

POLICY/0077

Status: Final/ Public

Effective date: 18 March 2015

Review date: 18 March 2017

Supersedes: Rules governing participation by visiting experts at EMEA, 18 October 1999

### 1. Introduction and purpose

At EMA there are three categories of person who are employees of external bodies while they may either visit, work at or are assigned temporarily to the Agency:

- Seconded National Expert
- Liaison Official
- Visiting Expert

These employees of external bodies remain throughout an employee of that body.

This policy applies to a visiting expert who undertakes a visit that takes place at the European Medicines Agency (EMA). This policy shall be published on the EMA public website.

### 2. Scope

This policy applies only to visiting experts. The visit shall be for the purpose of training (for the person or their institution), to assist the EMA, information gathering, or exchange with EMA or other collaborative purposes within the mission, role, and responsibilities of the Agency.

The policy does not apply to Scientific Committee member and experts who participate in EMA activities as a member or expert or observer of a specific Committee, Working Party, or Ad-hoc expert group meeting or similar.



### 3. Definitions

Coordinator: the EMA staff member who liaises with and assists the visiting expert while the visiting expert is at EMA.

EMA: European Medicines Agency

EU: European Union

External body: a public institution (EU or non-EU), other academic or non-commercial body.

Liaison Official: an employee of a medicines regulator such as the FDA or PMDA who is assigned to EMA to represent that body. The assignment is governed by specific Terms of Reference between EMA and the body concerned. The liaison official serves as a primary focal point and to identify areas for further regulatory and scientific collaboration within the framework of annual work plans and the Terms of Reference established between the two agencies. Throughout the assignment period the liaison official remains an employee of the other regulatory body and does not report to or act on behalf of the EMA.

Participating institution or employing institution: body that employs the visiting expert

Seconded National Expert: an employee of an EU national or other public body who is seconded to EMA to foster the exchange of professional experience and knowledge. The person remains an employee of the seconding body while undertaking specific responsibilities at EMA akin to that of a staff member. Normally, the secondment to the Agency is between six months to two years. EMA has specific implementing rules on seconded national experts.

Visiting Expert: A visiting expert will visit the EMA for a period of time for training (for the person or their institution), to help the EMA, for information gathering, or exchange with EMA or other collaborative purposes within the mission, role, and responsibilities of the Agency. A visiting expert works in a national competent authority (EU or non-EU) or other institution (EU or non-EU) or academic body (EU or non-EU). Visiting experts are not seconded national experts or liaison officials. Visiting experts can be EU or non-EU nationals, and attend EMA for a short pre-defined period of time.

### 4. Policy statement

#### ***4.1 Preparatory steps - Applications***

Requests may be initiated by the Head of the participating institution or by the Executive Director of the EMA. Applications from the participating institution should include:

the name of the proposed visiting expert, details of the scope of the visit, its expected duration and a CV of the proposed visiting expert.

Applications should be sent for the attention of the Executive Director whose office will send a copy of the application to both the Head of International Affairs and Head of Administration (Division A). The proposed visiting expert shall be copied in all information exchanges between the participating institution and the Agency.

#### ***4.2 Selection process***

International Affairs, having received an application, coordinates examination of whether a proposed visiting expert can be accommodated with the division/department concerned.

The elements that determine whether an application can be accepted are:

- Nature of the participating institution/body
- Profile of the visiting expert
- Purpose, objectives and scope of the visit
- Added value of collaboration for EMA
- Timing proposed
- Duration proposed
- Workload of the department(s)/division(s) involved with the visiting expert programme
- Resources to interact with and to support appropriately the visiting expert.

The elements above are not an exclusive list of aspects to be taken into account. Other considerations may apply.

The Executive Director examines proposals on visiting experts in consultation with the Head of International Affairs and the Head of Division concerned. Based on a proposal from International Affairs, the Executive Director, at his/her discretion, decides whether an application can be accepted. If agreement is given for the visiting expert, International Affairs informs the division/department. International Affairs prepares the acceptance letter to the participating institution and the visiting expert for signature by the Executive Director. The Executive Director may delegate signature of this acceptance letter. A copy of the acceptance letter is sent to the Head of Human Resources (HR) and Head of Infrastructure Services.

### ***4.3 Programme***

Once a visiting expert proposal is agreed by the Executive Director, the receiving division appoints a co-ordinator who establishes a draft programme for the visit based on the objectives and scope. The receiving division prepares the programme for the visiting expert in consultation with International Affairs and the latter ensures that other services are consulted as appropriate to the case. In the case of visiting experts from EU institutions, the EU Institutional Liaison Officer is consulted.

### ***4.4 Length of a visit***

Visits can be, normally, for five working days and up to six months. The period is fixed at the outset in the acceptance letter between the EMA and the employer of the visiting expert. A minimum of one month's notice shall apply from acceptance by EMA of the programme of the visit and the start date.

### ***4.5 Administrative matters***

A visiting expert does not have the status of an EMA staff member. A temporary agent or contract staff or other contract under the Staff Regulations may not be accorded to a visiting expert in the year of or following the end of the visit unless he/she is successful in an EMA external selection procedure that has been advertised in accordance with the applicable implementing rules in force.

The employing institution is responsible for full compliance with UK visa regulations, application for and provision of all documents required by the UK authorities in order to allow the visiting expert to enter the UK. The employing institution is responsible for arranging and providing suitable travel and or health insurance during the full period of the visit. EMA is not responsible for any social security payments or medical insurance during the visit. The salary of a visiting expert is the responsibility of the employing institution. The expenses of the visiting expert during the visit are the responsibility of

the employing institution. Visiting experts are responsible for any taxes due by virtue of the laws in force in the State concerned.

#### ***4.6 Organisation***

The co-ordinator of the receiving department/division shall contact HR Department and Infrastructure Department for practical logistical issues and shall liaise with these departments giving each of them due advance notice of the start date of the visit.

Visiting experts, in line with the scope of the programme approved, may attend meetings on subjects of interest to them, receive documentation, and participate in the work of the division/department to which they are attached. They should consult their co-ordinator or, if appropriate, International Affairs on any action they propose to take on their own initiative relating to EMA activities. They shall not have access to the EMA electronic repository of documents.

Visiting experts shall not undertake missions on behalf of EMA. Where a visiting expert undertakes a mission for their participating institution that institution shall pay the related costs and expenses and the visiting expert is responsible to make all the relevant arrangements for this mission. The visiting expert shall notify their co-ordinator of the dates of their absence on mission.

Visiting experts are required to follow EMA policies. They are bound by all the other administrative rules applicable to them. Therefore, they must, in particular, follow the EMA Code of Conduct, provide a declaration of interest, and sign a Confidentiality Declaration to ensure that the interests of the EMA are fully safeguarded. A declaration of interest is provided by the visiting expert within one week of the start of the visit which is reviewed by the co-ordinator who shall assign a risk level as required and notify HR accordingly.

Visiting experts must exercise the greatest confidentiality and discretion with regard to all facts and information coming to their knowledge in the course of their visit. 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 visit.

#### ***4.7 Leave and illness***

A visiting expert may only take leave in agreement with his employing institution and shall notify his co-ordinator of the leave days. If a visiting expert is ill, he/she must notify his/her co-ordinator immediately. The Agency does not require any medical certificate to be submitted to it. Any health related matters shall be handled between the visiting expert and his/her employment entity. A visiting 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.

#### ***4.8 Expenses grant***

Exceptionally and in the specific interest of EMA, and after express written agreement with the employing institution, a visiting expert may be paid an expenses grant, subject to budget availability. These grants shall be a maximum of £120 per calendar day.

Exceptionally, in the specific interest of EMA, and after express written agreement with the employing institution, visiting experts whose place of residence at the beginning of the visit is not London, UK and which is more than 50 kms from the EMA, may be reimbursed their travel expenses at the beginning and the end of the visit (journey from/to their place of residence as stated on the letter of acceptance sent to them by the EMA). A change of address is not allowed once the decision to award a visit is taken.

Expenses are calculated on the basis of the most economic route by rail (economy class) for journeys within the UK. For journeys originating outside the UK, travel expenses from the place of residence to London may be reimbursed on the basis of the shortest air route (economy class). Expenses for the inward and the return journey are reimbursed on presentation of the relevant travel documents. If transport other than rail or air is used, reimbursement is based on the economy class rail fare.

The EMA may, exceptionally, seek a contribution from the participating institution for logistical or office related expenses.

#### **4.9 Termination of a visit**

The visit ends when the period for which it was awarded expires. The visit may be ended earlier in the interests of the EMA, if the visiting expert's employer requires or for any other sufficient cause.

If the conduct of the visiting expert does not prove satisfactory, if there is a breach of the obligations with which visiting experts are required to comply, the EMA, after hearing the visiting expert, may at any moment decide to terminate the visit.

#### **4.10 Personal Data protection**

The purpose of processing the personal data submitted by a participating institution is to manage the application with a view of a possible visiting expert programme at the Agency.

The Agency does not make public the names of individual applicants to be a visiting expert. However, for the purposes of examination of the application and related planning purposes, members of the Agency's management team will have access to a visiting expert's individual profile.

International Affairs in its internal communications instructs the recipients to treat the CV of a visiting expert with due confidentiality. This individual profile/CV and declaration of interest is kept in confidence by HR and the relevant Division or Department. The profile and declaration of interest is held for two years by HR following conclusion of the visiting expert period after which time it is destroyed. On conclusion of the visiting expert period, HR instructs the relevant Division or Department and/or co-ordinator to destroy the CV that may be held by these parties.

On instruction from HR, where a visiting expert application is not approved, the CV of the person is destroyed at once when EMA has decided that the visit is not proceeding.

The personal information requested in the context of a visiting expert application will be processed in line with Regulation (EC) N°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.

A Data Protection Notice shall be sent to the visiting expert informing him/her of the processing of his/her personal data, jointly with a hyper link to the EMA Privacy Policy ([http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general\\_content\\_000516.jsp&mid=WC0b0ac05805faa0b](http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid=WC0b0ac05805faa0b)).

## **5. Related documents**

Executive Director Decision laying down rules on the secondment of national experts to the Agency, 1 August 2013 (EMA/267306/2013).

## **6. Changes since last revision**

Rules governing participation by visiting experts at the EMEA, 18 October 1999 are superseded.

13 March 2015

Signature on File

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