EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Terms of reference

For the placement of Liaison Officials at the US Food and Drug Administration and the European Medicine Agency

Introduction and background

In September 2009, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) established Terms of Reference (ToR) regarding the assignment of a Liaison Official from FDA at EMA's headquarters in London and a Liaison Official from EMA at FDA's headquarters in the Washington metropolitan area. Following two years of experience, and in accordance with the original terms, it is proposed to revise and extend these ToRs.

The original Terms of Reference were in effect for two years on a pilot basis. According to the original ToR, EMA and FDA were required to evaluate the program and determine whether to continue it beyond this first two-year timeframe, and, if so, whether to make any changes in these Terms of Reference. The revised Terms of Reference outlined below introduce changes taking into account experience gained during these first two years.

They may be revised as needed and at the latest after a further period of two years from the date of adoption of the revised terms.

Terms of reference[1]

These Terms of Reference do not constitute a binding agreement under international or other law, but rather outline the intentions of EMA and FDA regarding the assignment of liaison placements.

This assignment of Liaison Officials is based on reciprocity. The length of the term of placement of an individual Liaison Official is determined by the internal rules of the home agency.

The Liaison officials serve as primary focal points between EMA and FDA, and will specifically identify areas for further regulatory and scientific collaboration within the framework of annual work plans and the confidentiality arrangements established between both agencies. The liaison officials work under the oversight of the host agency and the liaison activities will be overseen by both the home and the host agency.

[1] As revised following two years of experience.

The Liaison Officials take part, as appropriate, in the host agency's work; however, they will play no policy-making or operational role, and each host agency has the right to circumscribe the work of the liaison to conform to legal, regulatory, or policy requirements at their discretion.

The tasks of the Liaison Officials include, but are not limited to, the following:

- to be a ready source of knowledge for the host agency about the practices and procedures of the home agency;
- to be a ready source of knowledge for the host agency about contemporary issues on which the home agency focuses;
- to facilitate regulatory and scientific cooperation between the host and home agencies;
- to work with colleagues in the host agency on topics of mutual interest;
- to provide an external resource to the host agency for issues that have impact and interest in the international context;
- to participate in appropriate internal project meetings, and to travel to external meetings, with the provision that the Liaison Officials shall not represent themselves or be represented as employees of or spokespersons for the host agency;
- to provide perspective on medicinal product safety, efficacy, and quality and other relevant public health issues, as requested; and
- other activities to be decided upon in advance by host and home agency.

The host agency will provide the Liaison Official with a suitable work station as well as the agency administrative and IT support necessary to conduct his or her assignments. The host agency will pay for travel costs and per diem for all duty travel undertaken by the Liaison Official at the request of the host agency, as part of host-agency tasks the liaison performs, (only if specifically requested by the host agency in accordance with written instructions) in accordance with the terms and policies of the host agency. The home agency will pay for all travel costs and per diem for all duty travel undertaken by the Liaison Officers at the direction of the home agency, in accordance with the terms and policies of the home agency.

In performing all activities, the Liaison Officials must follow all security procedures and other relevant rules of the host agency, unless otherwise specified in the administrative arrangements that govern these Liaison Officials.

Furthermore, the Liaison Officials are not employees of the host agency, and, as such, will work under the following restrictions:

- to work in accordance with a job description/scope of activities document agreed by the host and home agencies and under the oversight of the host agency;
- no financial or contract responsibilities for the host agency;
- no formal policy-coordination, administrative, or management tasks for the host agency;
- no access to the host agency building(s) outside working hours, unless accompanied by authorized staff of the host agency, unless the host agency so permits;
- no remote access to the internal information-technology network of the host agency, unless specifically authorized by the host agency;
- access to information and data (as outlined in the confidentiality arrangements between EMA and FDA), but the host agency reserves the right to restrict or limit such access at its discretion;

- communication of host agency confidential documents/information only with the express permission of the host agency;
- no travel alone on behalf of the host agency;
- no travel to represent the host agency;
- no ability to enter into commitments (financial or programmatic) for the host agency; and
- no authority to negotiate on behalf of the host agency.

The host agency reserves the right to exclude participation and/or to restrict access of the liaison official at its discretion.

The host and home agencies and the liaison official must ensure, through appropriate supervision, oversight, and access arrangements that there is no conflict of interest in relation to the officials' duties during the placement period.

In addition, the Liaison Official shall be required:

- To follow the applicable tax obligations of the host country in relation to their status;
- To accept the host agency's code of conduct, to complete any required declaration of interests, and to update this when necessary or at least annually;
- To comply with the legal provisions for personal injury applicable in the host country as per their legal status in the host country;
- To participate in any training considered by the host agency to be necessary to allow them to fulfil their assignments, e.g. health and safety, host agency IT policies, etc.;
- To refrain from engaging in outside activities, paid or unpaid, without prior authorization from the host agency and the home agency for the duration of the placement;
- To refrain from any action or behaviour which might reflect adversely on his/her position.

The following "Administrative Arrangements" are incorporated by reference into these "Terms of Reference".

Administrative arrangements

EMA and FDA (the "host agencies") establish the following administrative arrangements regarding the reciprocal assignments for Liaison Officials:

1. Purpose

a. Each agency has decided to assign a Liaison Official to the other agency. The Liaison Officials will remain employees of their home agency for all purposes.

2. Scope of work

a. The Liaison Official shall assist the staff of the host and home agency and carry out the duties of the position in the context of the Terms of Reference, an annual work programme, a scope of activities or job description document, including specified oversight arrangements agreed by the two agencies, based on the professional knowledge and experience of the liaison official.

b. The Liaison Official and the host agency must make every effort to avoid any conflicts-of-interest, or the appearance of such conflicts, in relation to the work of the Liaison Official at the host agency.

c. The Liaison Official may work in any field in which his/her services are deemed necessary, relevant, or helpful, provided there is no conflict with the interest of the host or home agency.

d. This and all other arrangements for this assignment shall not be construed in any manner as a waiver of any immunities or privileges as contained in the Vienna Convention on Diplomatic Relations, and/or any other treaty or agreement in force between the Government of the United States of America and the Government of the United Kingdom, or the European Commission.

3. Specific arrangements

a. The host agency will provide the Liaison Official with a suitable work station as well as agency administrative and IT support.

b. The home agency will provide salary, living compensation, and other support, according to the home agency's policies for the placement of staff overseas.

c. The home agency will provide all necessary social security payments and/or illness insurance during the term of the placement.

d. Liaison Officials may take leave in compliance with the policies and procedures of their home agency.

e. If a Liaison Official is ill, he/she must notify his/her co-coordinator in the host agency immediately; if absent for more than three days because of illness, he/she must send a medical certification to his/her co-coordinator, to indicate the probable length of absence and/or fitness to return to work, as appropriate.

f. The home agency agrees to pay, in full, all costs and expenses for the Liaison Official whom it sends to the host agency, including relocation expenses, residential quarters, residential furnishings, and related expenses, unless otherwise indicated.

4. Duration, extension and termination of this arrangement

a. The original arrangement became effective upon the assignment of the first of the liaisons, and continued for two (2) years. EMA and FDA have now positively evaluated the pilot program, and, decide to extend the arrangement by another two years, with future options for two-year extensions upon mutual decision.

The duration of an assignment of an individual Liaison Official will be covered by the home agency's internal rules.

b. By mutual consent, the host agencies may amend, extend, or terminate this arrangement, with reasonable notice. Either host agency should declare, in writing, the desire for such amendment, extension, or termination at least two months in advance of the desired effective date of the action. In exceptional circumstances, the host agencies may request that a specific assignment be terminated immediately.

5. Special rules, regulations and polices

a. Liaison Officials shall not represent themselves as or be represented as an employee of their host agency. Liaison Officials will not enter into commitments, financial or programmatic, nor shall they negotiate, on behalf of their host agency.

b. The FDA Liaison Official is subject to the U.S. Federal statutory and regulatory provisions that govern ethical and other standards of conduct, conflict-of-interest, suitability, security, and limitations on political activity (18 U.S.C. 203, 205,208, and 209,5 CFR 73 and 5 CFR 1635); and to any applicable U.S. State and local Government statutory and regulatory provisions.

c. The FDA Liaison Official will be under the full authority and direction of the U.S. Ambassador to the United Kingdom, and will be excused from work on such days that the U.S. Embassy in London is closed for business. It is acknowledged that day-to-day work assignments will be coordinated by the home and host agency.

d. The U.S. Federal tort claims statutes and any other Federal tort liability statutes shall apply to the FDA Liaison Official.

e. The EMA official remains subject to the relevant rules set by the Staff Regulations and Conditions of employment of the other servants of the European Communities and to additional rules and special provisions which the EMA may consider to adopt to further regulate the attachment of its staff to non EU regulatory authorities.

Declaration of absence of conflicts of interest and confidentiality understanding

No conflicts of interest

I, the undersigned, declare that, to the best of my knowledge, neither I, nor any member of my immediate family, have any interests (pecuniary or otherwise) that could reasonably be construed as having any influence on the proper and objective performance by me of my assignments with [name of host agency].

I confirm that, if I discover during the performance of my tasks that such interests exist, I will immediately and truthfully declare it to my co-coordinator at my host agency, and I will discontinue further performance of my tasks.

Confidentiality understanding

I commit to exercise the greatest discretion with regard to all confidential facts and information that come to my knowledge in the course of, or in connection with, the performance of my tasks. To the extent permitted under relevant U.S. Federal, British, and European Community law, as appropriate, I commit not to disclose in any manner whatsoever to any unauthorized person any confidential document or information not already made public. I will not make any use of information given to me other than that required for the performance of my assigned tasks.

To the extent permitted under relevant U.S. Federal, British, and European Community law, as appropriate, I will not disclose in any legal proceedings information of which I may have knowledge because of my tasks, without permission of [name of host agency]. It is my understanding that FDA and EMA intend to refuse such permission only where the interests of the [name of host agency] so require, and such refusal would not entail criminal consequences for the undersigned.

After termination of my assignment, I will continue to be bound, to the extent permitted under relevant U.S. Federal, British, and European Community law, as appropriate, to the above confidentiality provisions when dealing with information shared in reliance on these confidentiality provisions until such information has become public.

I acknowledge the Confidentiality Arrangements in effect between EMA and FDA, and I will be bound by those provisions in the performance of my duties, and after my appointment as a liaison official has terminated.