



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Donation of EMA assets no. EMA/2014/28/IS

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Donation of EMA assets no. EMA/2014/28/IS

1. Title of the invitation for expression of interest

This document contains the Specifications for the Donation of EMA assets procedure no. EMA/2014/28/IS.

2. Objectives and context of the invitation for expression of interest

The European Medicines Agency ("the Agency") is a decentralised body of the European Union based in Canary Wharf in the Docklands area of London (E14). Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency was established in 1995 and operates under Council Regulation No 726/2004 to provide a system for the authorisation of medicinal products. The Agency is an Agency of the European Union and has its own legal personality. The Agency's budget is subject to checks and audits by the Court of Auditors.

The Agency is responsible for the scientific evaluation of applications for European marketing authorisation for medicinal products (centralised procedure). Under the centralised procedure, companies submit a single marketing authorisation application to the Agency. Once granted by the European Commission, a centralised marketing authorisation is valid in all European Union and EEA-EFTA states. The safety of medicines is monitored constantly by the Agency through a pharmacovigilance network.

The Agency also gives scientific advice and protocol assistance to companies for the development of new medicinal products. It published guidelines on quality, safety and efficacy testing requirements. A dedicated office provides special assistance to small and medium-sized enterprises (SMEs). Seven scientific committees, composed of members of all EU and EEA-EFTA states, some including patients' and doctors' representatives, conduct the main scientific work of the Agency.

Further information about the work of the Agency can be obtained on its website:
<http://www.ema.europa.eu>.

The Agency will shortly relocate to its new premises and will vacate its premises at Westferry Circus in Canary Wharf. As a result, the Agency will have a number of items, furniture, fittings and office equipment and stationery that it no longer requires and in line with its environmental and social commitment it wishes to offer them for donation to registered charities and local authorities.

3. Subject of the donation

The Agency considers that it will offer for donation a number of items of furniture and office equipment and stationery which will be available for collection approximately from August 2014. The Agency expects to dispense with all items no later than the beginning of October 2014.

The items being offered are listed in the Catalogue in Annex I of this document. The items are being offered as detailed in the Catalogue on an 'as seen' basis (i.e. the Agency is unable to give any warranty as to the quality or condition of items). The Catalogue will be updated throughout the procedure as more information becomes available; please see Point 5 below.

Registered charities and local authorities are invited to express their interest for the items listed as per the guidance provided in this document.

This invitation does not constitute any obligation on the part of the Agency. The Agency's obligation commences only upon signature of a donation agreement with the successful charity or local authority.

The Agency reserves the right not to proceed with the donation of items at any time without providing a reason and without paying any compensation before a donation agreement is concluded.

4. Participation in the procedure

Expressions of interests for donation will only be accepted from registered charities and local authorities.

5. Estimated volume

The items and respective indicative quantities are being offered as detailed in the Catalogue in Annex I on an 'as seen' basis.

The Agency reserves the right throughout this procedure to update the list of items (including indicative quantities available) in the Catalogue in Annex I in line with its relocation and disposal requirements. Following each update the Agency will publish the updated version of the Catalogue on its external website with the date of the recent update. Interested parties are therefore encouraged to regularly monitor the Agency's external website for future updates. Should an update of the Catalogue affect an expression of interest already submitted by a registered charity or local authority, the parties concerned will be informed accordingly and will be given an opportunity to revise their expression of interest.

6. Cost associated with the expression of interest

The Agency will not reimburse any cost incurred in the preparation and submission of expressions of interest.

Note that successful registered charities and local authorities will have to collect the items and transport them at their own costs. This may involve collection of the items from the various locations within the Agency's demised premises at Westferry Circus and dismantling of furniture in some cases e.g. desking. All related costs shall be borne by the charity or local authority.

7. Health and Safety

Successful registered charities and local authorities with whom the Agency will conclude a donation agreement will be responsible for its staff or agents collecting the items from the Agency's premises and for their compliance with all relevant UK health and safety.

8. Information visit

The Agency will allow registered charities and local authorities to inspect the items being offered at the Agency's premises at 7 Westferry Circus as of 1 August 2014.

It is to be noted that as the items are located throughout the premises, it may not be possible to view all items in their entirety. Registered charities and local authorities wishing to attend an information

visit with the intention to inspect the items are advised to contact Enrico Palider by e-mail at donation@ema.europa.eu or by phone on 020 7523 7707 clearly indicating items they wish to inspect. In addition, interested parties should provide their contact details (including names of visitors, e-mail address and telephone number) to arrange a visit. For operational reasons a maximum of three people per registered charity and local authority will be allowed to attend a visit. Persons attending the visit will be provided with precise logistical details in due time.

9. Selection criteria

The items will be donated (subject to signature of donation agreement) to registered charities and local authorities complying with all the conditions stated in this document and providing all the required supporting documentation.

The selection of registered charities and local authorities to whom a donation agreement will be offered will be at the Agency's discretion, taking into consideration one or more of the following factors:

- order in which the parties submitted their expressions of interest;
- volume of items covered by the expression of interest;

10. Submission of expressions of interests

Before submitting an expression of interest, registered charities and local authorities should consider an information visit to physically inspect the items being offered (see point 8 for further details).

Registered charities and local authorities wishing to express their interest may submit the documents listed below either electronically or by post or courier service.

Documents to be submitted:

- A cover letter on the official letter headed paper signed by the authorised representative of the registered charity or local authority indicating the following:
 - the name and registered business address including telephone number, e-mail address and website address, if applicable;
 - the name and contact details of the person whom may be contacted with any queries regarding this expression of interest;
 - the name and the position of the person(s) authorised to sign the donation agreement on behalf of the charity or local authority;
- A completed and signed expression of interest application annexed to this document (Annex II) clearly specifying items (incl. Catalogue reference) and respective quantities to which this expression of interest relates;

Electronic submission

Scanned copies of the above listed documents should be submitted by e-mail to: donation@ema.europa.eu

The date of submission of expression of interest shall be the date expression of interest is received by e-mail.

Submission by post or by courier service

The above listed documents should be sent to the following address:

Enrico Palider
Infrastructure Services Department
European Medicines Agency
Donation EMA/2014/28/IS
30 Churchill Place
Canary Wharf
London E14 5EU

The date of submission of expression of interest shall be the day the Agency receives the expression of interest by post or by the courier service.

11. Donation agreement details

Selected charities and local authorities will be notified of the Agency's decision on the items which will be donated to them. This notification of the offer of donation will stipulate a deadline by which the selected charity or local authority will have to agree with the Agency on a mutually acceptable collection date. Failure to agree on a collection date within the stipulated deadline, as well as failure to collect the items on the agreed collection date may result in the offer of donation being revoked.

Charities and local authorities are reminded that they will have to arrange for collection and transportation of the items from the Agency's premises at their own cost (see point 6 for further details).

A copy of the donation agreement will be sent electronically to the selected charities and local authorities for their signature by an authorised representative. Once signed, the charity or local authority can send to the Agency two signed originals of the donation agreement by post or by courier service or it can send a scanned version of the signed donation agreement electronically to the Agency. E-mail address and postal address are same as those indicated in point 10 of these Specifications. The Agency may request a letter of authority for the nominated signatory. On collection, the representative of the charity or local authority collecting the items on their behalf will be required to countersign the document by way of receipt. A draft donation agreement is attached to this document as Annex III.

12. Data protection

Processing your reply to this invitation may involve the recording and processing of personal data (such as names, addresses). Such data will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the European Union institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions and any personal data requested are required to evaluate your submission in accordance with the specifications of this invitation and will be processed solely for that purpose and, if necessary, for any other relevant purposes which may be specified by the Agency. Details concerning the processing of your personal data are available on the privacy statement on the Agency's website at:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/12/WC500136168.pdf

13. Access, inspections and audits

You are informed that for the purposes of safeguarding the financial interest of the European Union, your personal data may be transferred to internal audit services, to the Court of Auditors, to the Financial Irregularities Panel and/or to the European Anti-Fraud Office (OLAF).

Data of economic operators which are in one of the situations referred to in Articles 106, 107, 109(1)(b) and 109(2)(a) of the general Financial Regulation¹ may be included in a central database and communicated to the designated persons of the European Commission, other institutions, agencies, authorities and bodies mentioned in Article 108 (1) and (2) of the general Financial Regulation. This refers as well to the persons with powers of representation, decision making or control over the said economic operators. Any party entered into the database has the right to be informed of the data concerning it upon request to the Agency. The Agency will obtain the requested information from the accounting officer of the European Commission. The privacy statement for the central database of the European Commission is available at:

http://ec.europa.eu/budget/library/explained/management/protecting/privacy_statement_ced_en.pdf

Annexes

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¹ Council Regulation (EC, Euratom) N° 996/2012 of 25 October 2012.