EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 February 2015
EMA/47128/2015

Dear Madam/Sir,

**Subject: Service concession in the area of pharmacovigilance training, ref. EMA/2014/35/RE [advertised in OJEU of 21/02/2015, ref. S 37]**

1. Please find enclosed the documents relating to the above-mentioned service concession. Attached to this letter you will find a "acknowledgement form". I would be grateful if you would complete and return it to me within seven days of receipt of this letter to indicate whether or not you intend to submit an application.

2. If you are interested in participating in this concession procedure, please submit one application in one original paper copy with one copy of all documents on CD-ROM. Please note only one application per applicant can be submitted (this includes only one financial offer (costing sheet)). Any applicant submitting more than one application shall be eliminated from the procedure. In case of any discrepancy the paper copy shall prevail over the copy on CD-ROM. Please submit to the following address which should be clearly marked as follows on the outer envelope:

   Dagmar Vogl
   Pharmacovigilance Department
   European Medicines Agency
   Procurement Procedure – Reference: EMA/2014/35/RE
   30 Churchill Place
   Canary Wharf
   London E14 5EU

   Please note that no application may be submitted by electronic mail. Any application submitted in such a way will be immediately eliminated from the procedure.

   Applicants should note that the Agency is unable to accept electronic signatures on the paper copy.

3. Applications must be submitted in one of the following ways:

- Either by **registered post or by courier service**, dispatched no later than **17 April 2015**, the postmark or the date of the deposit slip with the courier service serving as proof of posting date/time.
- **Or by hand delivery** to the Agency no later than 1200H on **17 April 2015**, directly or by a representative of the applicant.
- In the case where deliveries are effected by hand, the deadline to be respected shall be the date and time of **delivery** cited above and not the date of transmission/deposition by the applicant to

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

its representative. The said delivery must be effected against a dated and signed receipt given by a member of staff of the Agency or its representative.

- Please note that in the case of delivery by hand or by courier service, the envelope should be addressed as in point 2 above but delivery must be made to the following address:

  European Medicines Agency
  30 Churchill Place
  Loading Bay
  Canary Wharf
  London, E14 5EU

4. Applications must be submitted in one or more envelopes which are sealed, each enclosed inside a second sealed envelope. The following must be written on the inner envelope(s) in addition to the name and address as given in point 2 above:

| **Application** |
| --- |
| Concession Procedure – Reference: EMA/2014/35/RE |
| Attn Pharmacovigilance Department |
| **NOT TO BE OPENED BY THE INTERNAL MAIL SERVICE** |

If self-adhesive envelopes are used, they must be sealed with adhesive tape and the sender must sign across this tape.

Boxes may be used instead of envelopes if the size or weight of the application so requires.

Labels are attached to this letter which you may use for the submission of your application for both the inner and outer envelopes.

Any financial element (including costing sheet) must be submitted in separate binders or folders and on separate CD-ROM, which must be clearly labelled. Information relating to this element should be given nowhere else in the application.

All documents in electronic copy on the CD-ROM should be in either Adobe Portable Document Format (.pdf) or in standard Office 2003/7 format (i.e. doc and .xls).

In order to reduce the amount of paper submitted, the Agency requests that applications are presented in the following way:

(1) always using double-sided printing;

(2) avoiding use of unnecessary plastic folders or binders;

(3) avoiding inclusion of attachments (brochures, booklets, general publicity material etc) which are not requested by the Agency;

(4) choosing a simple and clear structure.

The technical specifications for this service concession as well as the draft concession agreement are attached to this letter. The technical specifications indicate clearly which documents are required to submit an application as well as the supporting documents which must be enclosed.

5. All applications must:

- Be signed by the applicant or his authorised representative.

- Be perfectly legible in order to avoid any doubt about terms and/or figures included.
- Include the costing sheet or other model documents as indicated in the technical specifications.

6. All applications submitted must be valid for a period of nine months from the closing date for receipt of applications during which the applicant may not modify the terms of the application in any respect.

7. The submission of an application in response to this invitation automatically implies the applicant's acceptance of all the terms and conditions stipulated in this invitation, the current technical specifications and annexes including the draft concession agreement. It also implies that the applicant renounces his own terms and conditions. This is binding on the applicant to whom the concession is awarded for the duration of the concession agreement. You are requested to confirm acceptance of the draft concession agreement and terms and conditions of this procedure as part of your response.

8. Contacts between the Agency and applicants are prohibited throughout the procedure save in exceptional circumstances and under the following conditions only:

   Before the final date for submission of applications:

   At the request of the applicant, the Agency may provide additional information solely for the purpose of clarifying the nature of the concession agreement. Should an applicant have a question, this should be submitted in writing (by letter or by e-mail) to:

   Dagmar Vogl
   Pharmacovigilance Department
   European Medicines Agency
   30 Churchill Place
   London E14 5EU
   Email: training_concession@ema.europa.eu

   Requests for additional information received less than five calendar days before the closing date for submission of applications will not be processed for practical reasons.

   The Agency may also, on its own initiative, inform applicants of any error, inaccuracy, omission or other clerical error in the text of the concession notice, invitation letter or technical specifications and their annexes.

   Any additional information including that referred to above will be made available in an identical manner simultaneously to all applicants.

   After the opening of applications:

   If clarification is required or if obvious clerical errors in the application need to be corrected, the Agency may contact the applicant provided the terms of the application are not modified as a result.

9. This invitation does not constitute any contractual obligation on the part of the Agency. The Agency's obligation commences only upon signature of a concession agreement with the successful applicant.

   The Agency may, until the concession agreement is signed, withdraw from the agreement or cancel the procedure without any compensation to applicants. In such a situation a decision to cancel would be notified to all applicants.

10. Processing your reply to this invitation may involve the recording and processing of personal data (such as names, addresses and Curricula Vitae). 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 application 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

11. 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 Regulation[1] 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

12. Applications will be opened at the Agency's premises at 14:00 GMT on 23 April 2015. One representative per applicant is permitted to be present at the opening of the applications. The name of any such representative is to be notified in advance in writing to the Agency no later than 14:00 GMT on Wednesday, 22/04/2015 to the address given in point 2 of this letter.

All applicants will be informed of the outcome of their application.

I inform you that the Agency has published a Guidebook for Tenderers which may be downloaded from its external website at http://ema.europa.eu/. It is recommended that you read this Guidebook before preparing your submission.

Yours faithfully,

Andreas Pott
Deputy Executive Director

Encs:

1. Labels for submission of application
2. Acknowledgement form
3. Technical Specifications and draft concession agreement

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

## Label for the outer envelope

Dagmar Vogl

Pharmacovigilance Department

European Medicines Agency

Procurement Procedure – Reference: EMA/2014/35/RE

30 Churchill Place

Canary Wharf

London E14 5EU

**NOT TO BE OPENED BY THE INTERNAL MAIL SERVICE**

## Label for the inner envelope

Concession procedure

Reference: EMA/2014/35/RE

Attn Pharmacovigilance Department

**NOT TO BE OPENED BY THE INTERNAL MAIL SERVICE**

# Acknowledgement form

| To: | From: |
|---|---|
| Dagmar Vogl<br>Pharmacovigilance Department<br>European Medicines Agency<br>30 Churchill Place<br>Canary Wharf<br>LONDON E14 5EU<br>UK | |

Date: [complete]

Dear [complete]

**Subject: Service concession in the area of pharmacovigilance training, ref. EMA/2014/35/RE - OJEU reference S 37]**

* We intend to submit an application in accordance with your instructions[2].

* We are unable/do not wish to submit an application. Our reasons are set out below.[3]

| Please submit your reasons here (or in a separate letter) for declining the opportunity to submit a application. |
|---|
| |

Yours sincerely

For and on behalf of:

Note to applicants: completion and return of this form is requested but is not mandatory. Responses received are treated in confidence for internal evaluation purposes only and will have no consequences for the applicants.

[2] Delete as applicable.
[3] Delete as applicable.