



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13/08/2016
EMA/303203/2016

Invitation to apply for a Service Concession in the area of Meeting and Training Organisation - ref. EMA/2016/43/RS [advertised in OJEU ref. S 156 of 13/08/2016]

Dear Madam/Sir

1. EMA ('EMA' or 'the Agency') is planning to award the above-mentioned concession which has been published in the Official Journal of the European Union. The concession documents consist of the concession notice in the Official Journal of the European Union, this invitation letter, the concession specifications and their annexes and the draft concession contract.
2. If you are interested in this concession, you should submit an application in one of the official languages of the European Union. The Agency prefers however to receive documentation in English.
3. Attached to this letter you will find a "acknowledgement form". We would be grateful if you would complete and return it by email (to: Training_Concession@ema.europa.eu) within seven days of receipt of this letter to indicate whether or not you intend to submit an application.
4. If you are interested in this concession, you should submit one application in one original paper copy with one copy of all documents on CD-ROM, DVD or USB memory stick (except for the costing sheet containing prices) following the instructions below with regard to outer and inner envelopes.

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

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

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, DVD or USB memory stick.

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.

Outer envelope(s)

The application must be placed inside one or more outer envelopes addressed to:



Dagmar Vogl
Pharmacovigilance Department
European Medicines Agency
Concession Procedure – Reference: EMA/2016/43/RS
30 Churchill Place
Canary Wharf
London E14 5EU

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

Inner envelopes

The outer envelope(s) should contain two closed inner envelopes, one containing the financial offer (costing sheet with prices) and one containing the rest of the application submission.

The separate inner envelope containing the financial offer (costing sheet with prices) must be clearly labelled and must be submitted with a separate CD-ROM, DVD or USB memory stick. Information relating to this element should be given nowhere else in the application.

The inner envelopes should be marked as follows, indicating whether the financial offer is enclosed:

<p style="text-align: center;">Application</p> <p style="text-align: center;">Concession Procedure – Reference: EMA/2016/43/RS</p> <p style="text-align: center;">Attn Pharmacovigilance Department</p> <p style="text-align: center;">NOT TO BE OPENED BY THE INTERNAL MAIL SERVICE</p> <p style="text-align: center;"><i>[indicating if FINANCIAL OFFER is enclosed or not]</i></p>

All documents in electronic copy on the CD-ROM, DVD or USB memory stick should be in either Adobe Portable Document Format (.pdf) or in standard Office 2010 format (i.e. doc and .xls).

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

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.
5. Applications must be submitted in one of the following ways:
- Either by **registered post or by courier service**, dispatched no later than **24:00 UK time on 30/09/2016**, 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 **30/09/2016**, 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 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 4 above but delivery must be made to the following address:

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

6. All tenders 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.
7. All applications submitted must be valid for a period of nine months from the closing date for receipt of tenders during which the applicant may not modify the terms of the application in any respect.
8. The submission of an application in response to this invitation automatically implies the applicant's acceptance of all the terms and conditions stipulated in the concession documents. It also implies that the applicant renounces its own terms and conditions. This is binding on the applicant to whom the concession is awarded for the duration of the concession contract. Applicants are requested to confirm acceptance of the draft concession contract and terms and conditions of this concession as part of their response.
9. All costs incurred for the preparation and submission of applications are to be borne by the applicant and will not be reimbursed.
10. 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 indicated in point 5 above:

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

Dagmar Vogl
 Regulatory Affairs & Best Evidence Department
 European Medicines Agency
 30 Churchill Place
 London E14 5EU
 Email: Training_Concession@ema.europa.eu

EMA is not bound to reply to requests for additional information received less than six days before the date of receipt of applications. The Agency may, on its own initiative, inform the interested parties of any error, inaccuracy, omission or any clerical error in the text of the concession documents.

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 obvious clerical errors in the application need to be corrected or confirmation of a specific or technical element is necessary, the Agency will contact the applicant provided this does not lead to substantial changes to the terms of the submitted application.

11. This invitation is in no way binding on the Agency. The Agency's contractual obligation commences only upon signature of a concession contract with the successful applicant.

Up to the point of signature, the Agency may cancel the award procedure without the applicants being entitled to claim any compensation. This decision must be substantiated and the applicants notified.

12. Once the Agency has opened the application, it becomes its property and it shall be treated confidentially.

13. Applicants will be informed by the outcome of this concession procedure by e-mail only. It is the applicants' responsibility to provide a valid e-mail address together with contact details in the application and to check this e-mail address regularly.

14. 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

15. Your personal data may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 106 of the Financial Regulation¹. For more information, see the Privacy Statement at:

http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm#BDCE

16. Applications will be opened at the Agency's premises on 05/10/2016 at 1400H UK time. One representative per applicant is permitted to be present at the opening. The name of any such representative is to be notified in advance in writing by email (Training_Concession@ema.europa.eu) at least one working day prior to the opening session.

¹ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298 of 26.10.2012, p. 1) as amended.

For security reasons, visitors are requested to identify themselves with a valid identity card or passport. The Agency may refuse access to persons who have not registered or do not carry a valid ID.

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 application.

Yours faithfully,

(signature on file)

Noël Wathion
Deputy Executive Director

Encs:

1. Labels for submission of a tender
2. Tender acknowledgement form
3. Procurement documents

Label for the outer envelope

Dagmar Vogl
Pharmacovigilance Department
European Medicines Agency
Concession Procedure – Reference: EMA/2016/43/RS
30 Churchill Place
Canary Wharf
London E14 5EU
NOT TO BE OPENED BY THE INTERNAL MAIL SERVICE

Label for the inner envelope

Application
Concession Procedure – Reference: EMA/2016/43/RS
Attn Pharmacovigilance Department
NOT TO BE OPENED BY THE INTERNAL MAIL SERVICE
[indicating if FINANCIAL OFFER is enclosed or not]

Acknowledgement form

To: Dagmar Vogl Pharmacovigilance Department European Medicines Agency 30 Churchill Place Canary Wharf LONDON E14 5EU UK Email: Training_Concession@ema.europa.eu	From:
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Date: [complete]

Dear [complete]

Subject: Concession Procedure no. EMA/2016/43/RS for a service concession in the area of training organisation

- * We intend to submit an application in accordance with your instructions².
- * 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 an application.

Please indicate how you heard of this concession procedure.

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.