



EXECUTIVE AGENCY FOR HEALTH AND CONSUMERS 2010

Health Unit

EAHC
Executive Agency
for Health and Consumers

LUXEMBOURG

Luxembourg,
EAHC LB/SS/su D (2010)/100720

Subject: Call for tender n° EAHC/2010/Health/05 concerning the creation of a mechanism for the exchange of knowledge between Member States and European authorities on the scientific assessment of the clinical added value for orphan medicines

Contract notice 2010/S 63-092819 of 31/03/2010

Dear Sir/Madam,

1. I enclose the call for tenders relating to the above-mentioned contract.

The call for tender is not divided into lots.
Tenderers shall be able to provide all services requested.

2. If you are interested in this contract, you should submit a tender in quadruplicate (one original and 3 copies) in one of the official languages of the European Union.

Please note that the working language of the Executive Agency is English.

3. Tenderers may choose to submit tenders:
 - 3.1. a) either by registered mail or by a courier service not later than **20/05/2010**, to the following address:

**Executive Agency for Health and Consumers
Health Unit**

For the attention of **Mrs Ingrid Keller**
Jean Monnet Building
Rue Alcide de Gasperi
L-2920 Luxembourg

In case of delivery by registered mail or by courier, the evidence of the date of dispatch shall be constituted by the postmark/the date of the deposit slip or by the receipt of dispatch issued by the courier service.

The tenderer shall obtain the receipt of delivery issued by the postal or courier service clearly indicating the date and time of dispatch. By the deadline indicated in this point, the tenderers are kindly requested to send a copy of this receipt to the Executive Agency by e-mail (**EAHC-HP-TENDER@ec.europa.eu**) or by fax (+352 4301-30359), specifying the title and reference number of this procurement procedure, together with the name, email address, the telephone number of the tenderer and the language of the submitted offer.

b) or delivered by hand to the following address:

**Executive Agency for Health and Consumers
Health Unit**

For the attention of **Mrs Ingrid Keller**
Jean Monnet Building
Rue Alcide de Gasperi
L-2920 Luxembourg

not later than 16.00 on **20/05/2010**. In this case, an acknowledgement of receipt must be obtained by the tenderer as proof of submission, signed and dated by the staff member who took delivery. The Executive Agency is open from 09.00 to 17.00 Monday to Thursday, and from 09.00 to 16.00 on Fridays. It is closed on Saturdays, Sundays and Commission holidays.

- 3.2. An Opening Board will be set up to open the tender and to check whether the procedures for the submission of tenders have been complied with. The Opening Board will open the tenders on 04/06/2010 at 10.00 in L-1882 Luxembourg, 12, rue Guillaume Kroll (Drosbach Building), room A03/43.

A representative of each tenderer may attend the opening of the tenders. In this case, the interested tenderers are kindly requested to register not later than 01/06/2010 by e-mail or by fax (as indicated in point 3.1). At the opening, the representative of the tenderer may be asked to present its credentials/power of attorney to be checked by the Executive Agency.

4. Tenders must be submitted using the double envelope system – i.e. one outer envelope and three inner envelopes – in order to guarantee the confidentiality and the integrity of data.

4.1. The **three inner envelopes** shall be composed of and shall be indicated as:

- **Envelope A ‘Evidence on the eligibility and capacity of the tenderer’** shall contain one original (clearly marked as ‘Original’) and 3 copies (each clearly marked as ‘Copy’) of the supporting information and documentation related the tenderer’s eligibility and capacity.
- **Envelope B ‘Technical proposal’** shall contain one original (clearly marked as ‘Original’) and 3 copies (each clearly marked as ‘Copy’) of the technical proposal.

- **Envelope C ‘Financial proposal’** shall contain one original (clearly marked as ‘Original’) and 3 copies (each clearly marked as ‘Copy’) of the financial proposal.

Except in Envelope C, the tender must not contain any reference to the amounts included in the ‘Financial proposal’ that could hint the price offered by the tenderer.”

Tenderers are kindly asked to number the documents placed in each envelope and provide in English the lists of numbered documents concerning each envelope.

Tenderers are asked to provide the scanned versions (in pdf format) of the signed original documents placed in each envelope on three separate CDs/DVDs (clearly marked as ‘Evidence on the eligibility and capacity of the tenderer’/’Technical proposal’/’Financial Proposal’). Each CD/DVD shall be put in the relevant envelope.

In case of discrepancies between the original tender and the copies, or between the paper and the scanned version, the original tender in a paper format is binding.

- 4.2. Moreover, the **outer envelope**, addressed to the unit indicated in the invitation to tender, should be marked as follows:

<p>TENDER</p> <p>– NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT</p> <p>Tender Ref. no. EAHC/2010/Health/05</p> <p>Title of the call for tender: Creation of a mechanism for the exchange of knowledge between Member States and European authorities on the scientific assessment of the clinical added value for orphan medicines</p> <p>Name of the tenderer:</p> <p>Address of the tenderer:</p> <p>Language of the tender:</p>
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If self-adhesive envelopes are used, they must be sealed with adhesive tape and the sender must sign across this tape.

5. The tender specifications describe the subject, the details of the call for tender and list all the documents that must be produced in order to tender, including supporting evidence of the exclusion, selection (economic and financial, technical and professional capacity) and award criteria.

The tender should be organised and presented in a way that allows for clear identification of each set of criteria, and clearly matching of these criteria with the respective supporting documents requested by the tender specifications.

The tender specifications and the draft contract can be downloaded from the following website: <http://ec.europa.eu/eahc/health/tenders.html>

6. The tenderer or his duly representative is requested to sign:
 - Annex Ia ('Tender submission' form). Please note that Annex I should be provided in English;
 - Annex Ib ('Letter of mandate'), only in case of consortia;
 - Annex IIa, IIb, IIc ('Legal entity form');
 - Annex III ('Financial identification form');
 - Annex IV ('Declaration on honour' form);
 - Annex V ('Financial offer' – all pages);
 - Annex VII ('Economic and Financial capacity' form).

Tenders must be perfectly legible so that there can be no doubt as to words and figures.

7. The period of validity of the tender, during which tenderers may not modify the terms of their tenders in any respect is 8 months from the deadline for submitting tenders.
8. Submission of a tender implies acceptance of all the terms and conditions set out in this invitation to tender, in the specification and in the draft contract and, where appropriate, waiver of the tenderer's own general or specific terms and conditions. It is binding on the tenderer to whom the contract is awarded for the duration of the contract.
9. Contacts between the contracting authority and tenderers are prohibited throughout the procedure save in exceptional circumstances and under the following conditions only:

- 9.1. Before the final date for submission of tenders:

- * At the request of the tenderer, the Contracting Authority may provide additional information solely for the purpose of clarifying the nature of the contract.

Any requests for additional information must be made in writing only to the Executive Agency:

Executive Agency for Health and Consumers
Health Unit
For the attention of Mrs Ingrid Keller
Drosbach Building A03/018
L-2920 Luxembourg

E-mail: EAHC-HP-TENDER@ec.europa.eu
Fax: +352 4301-30359

Requests for additional information received less than 5 working days before the closing date for submission of tenders will not be processed.

- * The Executive Agency may, on its own initiative, inform interested parties of any error, inaccuracy, omission or any other clerical error in the text of the call for tenders.
- * Any additional information including that referred to above will be published not later than 5 working days before the deadline for dispatching tenders on the website indicated in point 5. It is the tenderer's responsibility to check for additional information and updates during the tendering period.
- * Requests for translation of the call for tender documents into any of the official languages of the European Union can be made at latest 15 working days before the closing date for submission of tenders. Any translation request after this deadline will not be processed.

Please note that the translations can be made available only for the information of the tenderers; in case of differences between the different language versions only the English version is binding.

9.2. After the opening of tenders:

- * If clarification is required or if obvious clerical errors in the tender need to be corrected, the contracting authority may contact the tenderer provided the terms of the tender are not modified as a result.

10. This invitation to tender is in no way binding on the Executive Agency. The Agency's contractual obligation commences only upon signature of the contract with the successful tenderer.

Up to the point of signature, the Contracting Authority may either abandon the procurement or cancel the award procedure, without the candidates or tenderers being entitled to claim any compensation. This decision must be substantiated and the candidates or tenderers notified.

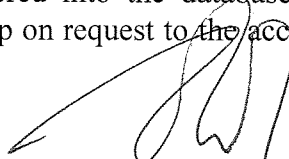
11. You will be informed whether or not your tender has been accepted.
12. If your offer includes subcontracting, it is recommended that contractual arrangements with subcontractors include mediation as a method of dispute resolution.
13. Processing your reply to the invitation to tender will involve the recording and processing of personal data (such as your name, address and CV). 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 Community 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 tender in accordance with the specifications of the invitation to tender and will be processed solely for that purpose by the Unit which launched the call for tender.

You are entitled to obtain access to your personal data on request and to rectify any such data that is inaccurate or incomplete. If you have any queries concerning the processing of your personal data, you may send them to the address indicated above. You have the right of recourse at any time to the European Data Protection Supervisor for matters relating to the processing of your personal data¹.

- 14 Please be informed that for the purposes of safeguarding the financial interest of the Communities, your personal data may be transferred to internal audit services, to the European 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 93, 94, 96 (1)(b) and 96 (2)(a) of the Financial Regulation² may be included in a central database and communicated to the designated persons of the Commission, other institutions, agencies, authorities and bodies mentioned in Article 95 (1) and (2) of the 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, up on request to the accounting officer of the Commission.³



Luc BRIOL
Director of EAHC

¹ Clause to be used where the processing of personal data falls within the scope of Regulation (EC) No 45/2001. It applies to the processing of personal data wholly or partly by automatic means, and to the processing other than by automatic means of personal data which form part of a filing system or are intended to form part of a filing system, viz. any structured set of personal data which is accessible according to specific criteria. Any questions should be referred to the Executive Agency's data protection coordinator or the Commission's data protection officer (<http://www.cc.cec/dataprotectionofficer/>). You should add to this clause a reference to any other recipients. If the data controller decides that additional information is needed, information regarding the legal basis of the processing operation and time limits for storing data can be included."

² Council Regulation (EC, Euratom) N° 1605/2002 of 25 June 2002 (OJEU L 248 of 16.09.2002), as amended by Council Regulation (EC, Euratom) N° 1995/2006 of 13.12.2006 (OJEU L 390 of 30.12.2006).

³ See Commission Regulation (EC, Euratom) No 1302/2008 of 17 December 2008 on the central exclusion database.