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L-Luxembourg: 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

2010/S 63-092819

CONTRACT NOTICE

Services

SECTION I: CONTRACTING AUTHORITY

I.1) NAME, ADDRESSES AND CONTACT POINT(S)

Executive Agency for Health and Consumers, EAHC, Health Unit
Jean Monnet Building, rue Alcide de Gasperi
Attn: Ingrid Keller
2920 Luxembourg
LUXEMBOURG
Tel. +352 4301-35330
E-mail: EAHC-HP-TENDER@ec.europa.eu
Fax +352 4301-30359

Internet address(es)

General address of the contracting authority <http://ec.europa.eu/eahc/>

Address of the buyer profile <http://ec.europa.eu/eahc/health/tenders.html>

Further information can be obtained at: As in above-mentioned contact point(s)

Specifications and additional documents (including documents for competitive dialogue and a dynamic purchasing system) can be obtained at: As in above-mentioned contact point(s)

Tenders or requests to participate must be sent to: As in above-mentioned contact point(s)

I.2) TYPE OF THE CONTRACTING AUTHORITY AND MAIN ACTIVITY OR ACTIVITIES

European institution/agency or international organisation

Other Public health

The contracting authority is purchasing on behalf of other contracting authorities No

SECTION II: OBJECT OF THE CONTRACT

II.1) DESCRIPTION

II.1.1) Title attributed to the contract by the contracting authority

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.

II.1.2) Type of contract and location of works, place of delivery or of performance

Services

Service category: No 8

II.1.3) The notice involves

A public contract

II.1.4) Information on framework agreement

II.1.5) Short description of the contract or purchase(s)

The purpose of the present contract is a proposal for 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 drugs. The aim of these common assessment reports for the clinical added value for orphan drugs should be to provide a well-informed opinion on the place of the product with the authorised therapeutic indication in the therapeutic strategy of the rare condition, to the best of current knowledge. For this purpose detailed discussions with the Member States and interested parties on the best way to establish such a mechanism are necessary. The main objectives of this study are:

1. to describe the regulatory process followed by an orphan drug, from orphan designation at the European level to reimbursement in the Member States and to examine to what extent the information produced by the authorities responsible for orphan designation and marketing authorisation is directly useful for the drug reimbursement decision process;
2. to describe the health technology assessment expertise used at national level for this purpose and level of involvement of existing international health technology assessment networks;
3. to propose a format for the common assessment report for scientific assessment of the clinical added value for orphan drugs structured in a usable way for national decision makers. The proposal should also refer to the modalities of revision of this report. Data included in this format should also permit identifying strategy and timelines to develop an agreed minimum sufficient set of data for demonstrating the clinical relevance and effective place of the product in the therapeutic strategy and, therefore, the continuance of its availability to patients; and
4. to define, in strong agreement with the European Commission's competent units, with the European Union Committee of Experts on Rare Diseases, the European Medicines Agency and with the Committee for Orphan Medicinal Products and other European Medicines Agency committees which is the most appropriate consultative structure for performing this task in a coordinated way at EU level.

II.1.6) **Common procurement vocabulary (CPV)**

73110000

II.1.7) **Contract covered by the Government Procurement Agreement (GPA)**

Yes

II.1.8) **Division into lots**

No

II.1.9) **Variants will be accepted**

No

II.2) **QUANTITY OR SCOPE OF THE CONTRACT**

II.2.1) **Total quantity or scope**

Excluding VAT 250 000 EUR

II.2.2) **Options**

No

II.3) **DURATION OF THE CONTRACT OR TIME-LIMIT FOR COMPLETION**

Duration in months: 11 (from the award of the contract)

SECTION III: LEGAL, ECONOMIC, FINANCIAL AND TECHNICAL INFORMATION

III.1) **CONDITIONS RELATING TO THE CONTRACT**

III.1.1) **Deposits and guarantees required**

See tender specifications.

- III.1.2) **Main financing conditions and payment arrangements and/or reference to the relevant provisions regulating them**
See tender specifications.
- III.1.3) **Legal form to be taken by the group of economic operators to whom the contract is to be awarded**
See tender specifications.
- III.1.4) **Other particular conditions to which the performance of the contract is subject**
No
- III.2) **CONDITIONS FOR PARTICIPATION**
- III.2.1) **Personal situation of economic operators, including requirements relating to enrolment on professional or trade registers**
Information and formalities necessary for evaluating if requirements are met: See tender specifications.
- III.2.2) **Economic and financial capacity**
Information and formalities necessary for evaluating if requirements are met: See tender specifications.
Minimum level(s) of standards possibly required See tender specifications.
- III.2.3) **Technical capacity**
Information and formalities necessary for evaluating if requirements are met:
See tender specifications.
Minimum level(s) of standards possibly required
See tender specifications.
- III.2.4) **Reserved contracts**
No
- III.3) **CONDITIONS SPECIFIC TO SERVICES CONTRACTS**
- III.3.1) **Execution of the service is reserved to a particular profession**
No
- III.3.2) **Legal entities should indicate the names and professional qualifications of the staff responsible for the execution of the service**
Yes

SECTION IV: PROCEDURE

- IV.1) **TYPE OF PROCEDURE**
- IV.1.1) **Type of procedure**
Open
- IV.1.2) **Limitations on the number of operators who will be invited to tender or to participate**
- IV.1.3) **Reduction of the number of operators during the negotiation or dialogue**
- IV.2) **AWARD CRITERIA**
- IV.2.1) **Award criteria**
The most economically advantageous tender in terms of the criteria stated in the specifications, in the invitation to tender or to negotiate or in the descriptive document
- IV.2.2) **An electronic auction will be used**
No
- IV.3) **ADMINISTRATIVE INFORMATION**
- IV.3.1) **File reference number attributed by the contracting authority**
'EAHC/2010/HEALTH/05'.

- IV.3.2) **Previous publication(s) concerning the same contract**
No
- IV.3.3) **Conditions for obtaining specifications and additional documents**
Time limit for receipt of requests for documents or for accessing documents 11.5.2010 - 16:00
Payable documents No
- IV.3.4) **Time-limit for receipt of tenders or requests to participate**
20.5.2010 - 16:00
- IV.3.5) **Date of dispatch of invitations to tender or to participate to selected candidates**
- IV.3.6) **Language(s) in which tenders or requests to participate may be drawn up**
Spanish. Danish. German. Greek. English. French. Italian. Dutch. Portuguese. Finnish. Swedish. Czech. Estonian. Hungarian. Lithuanian. Latvian. Maltese. Polish. Slovak. Slovenian. Irish. Bulgarian. Romanian.
- IV.3.7) **Minimum time frame during which the tenderer must maintain the tender**
Duration in month(s): 8 (from the date stated for receipt of tender)
- IV.3.8) **Conditions for opening tenders**
Date: 4.6.2010 - 10:00
Place 12, rue Guillaume Kroll (Drosbach building), room A/043, 1882 Luxembourg, LUXEMBOURG.
Persons authorised to be present at the opening of tenders Yes
1 representative per tenderer. The interested tenderers are kindly requested to register not later than 1.6.2010 by e-mail or by fax. 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.

SECTION VI: COMPLEMENTARY INFORMATION

- VI.1) **THIS IS A RECURRENT PROCUREMENT**
No
- VI.2) **CONTRACT RELATED TO A PROJECT AND/OR PROGRAMME FINANCED BY EU FUNDS**
Yes
reference to project(s) and/or programme(s): Decision No 1350/2007/EC of the European Parliament and of the Council of 23.10.2007 establishing a second programme of Community action in the field of health (2008–2013).
- VI.3) **ADDITIONAL INFORMATION**
- VI.4) **PROCEDURES FOR APPEAL**
- VI.4.1) **Body responsible for appeal procedures**
General Court of the European Union
rue du Fort Niedergrünwald
2925 Luxembourg
LUXEMBOURG
E-mail: CFI.Registry@curia.europa.eu
Tel. +352 4303-1
Internet: <http://curia.europa.eu/en/index.htm>
Fax +352 4303-2100
- VI.4.2) **Lodging of appeals**
Precise information on deadline(s) for lodging appeals: Within 2 months of the petitioner being notified or, failing this, of the date on which he became aware thereof. Lodging a claim with the European Ombudsman does not mean that this deadline will be suspended or a new one set.
- VI.4.3) **Service from which information about the lodging of appeals may be obtained**

General Court of the European Union
rue du Fort Niedergrünwald
2925 Luxembourg
LUXEMBOURG
E-mail: CFI.Registry@curia.europa.eu
Tel. +352 4303-1
Internet: <http://curia.europa.eu/en/index.htm>
Fax +352 4303-2100

VI.5) **DATE OF DISPATCH OF THIS NOTICE:**
19.3.2010