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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 216-330791

Contract award notice

Section I: Contracting authority

I.1) Name, addresses and contact point(s):

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

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_H05_2010.html

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.1.4) 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.1.5) **Common procurement vocabulary (CPV):**

73110000.

II.1.6) **Contract covered by the Government Procurement Agreement (GPA):**

Yes.

II.2) **Total final value of contract(s)**

II.2.1) **Total final value of contract(s):**

Value 247 118 EUR, excluding VAT.

Section IV: Procedure

IV.1) **Type of procedure**

IV.1.1) **Type of procedure:**

Open.

IV.2) **Award criteria**

IV.2.1) **Award criteria:**

The most economically advantageous tender in terms of:

1. Quality of the proposed standards for collecting information on the common assessment report for CAVOD and HTA practices in Member States. Weighting: 50.
2. Quality of the proposed approach for formulating a final recommendation on the common assessment report for CAVOD and HTA practices. Weighting: 20.
3. Quality of the proposed interaction with stakeholders, Member State authorities, EMA and their committees and the Commission. Weighting: 15.
4. Quality of the overall organisation and approach to execution of the contract, including understanding of potential risks to the study. Weighting: 15.

IV.2.2) **An electronic auction was 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:**

Yes.

Contract notice:

Notice number in the OJEU: [2010/S 63-092819](#) of 31.3.2010.

Section V: Award of contract

Title: 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

- V.1) **Date of contract award:**
22.10.2010.
- V.2) **Number of offers received:**
6.
- V.3) **Name and address of economic operator to whom the contract has been awarded:**
Ernst and Young Advisory, Faubourg de l'Arche, 11 allée de l'Arche, 92400 Courbevoie, FRANCE. Tel. +33 146937723. Fax +33 146934433. E-mail: philippe.grand@fr.ey.com Internet: <http://www.ey.com/fr>
- V.4) **Information on value of contract:**
Initial estimated total value of the contract:
Value: 250 000 EUR.
Total final value of the contract:
Value: 247 118 EUR, excluding VAT.
- V.5) **The contract is likely to be subcontracted:**
No.

Section VI: Complementary information

- VI.1) **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) **Procedures for appeal**
- VI.3.1) **Body responsible for appeal procedures:**
General Court of the European Union, rue du Fort Niedergrünwald, 2925 Luxembourg, LUXEMBOURG. Tel. +352 4303-1. Fax +352 4303-2100. E-mail: cfi.registry@curia.europa.eu Internet: <http://curia.europa.eu/en/index.htm>
- VI.3.2) **Lodging of appeals:**
Precise information on deadline(s) for lodging appeals:
Within 2 months of the petitioner's 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.3.3) **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. Tel. +352 4303-1. Fax +352 4303-2100. E-mail: cfi.registry@curia.europa.eu Internet: <http://curia.europa.eu/en/index.htm>
- VI.4) **Date of dispatch of this notice:**
27.10.2010.