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SPECIFICATIONS ATTACHED TO THE INVITATION TO TENDER

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

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1. Title of contract

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

2. Purpose and context of contract

Rare diseases, including those of genetic origin, are life-threatening or chronically debilitating diseases which are of such low prevalence that special combined efforts are needed to address them so as to prevent significant morbidity or perinatal or early mortality or a considerable reduction in an individual's quality of life or socio-economic potential. As a guide, low prevalence is taken as prevalence of not more than 5 per 10 000 in the European Union.

The European Commission (hereafter referred to as the 'Commission') adopted the 11 November 2008 *the Commission Communication COMM(2008) 679 final to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Rare Diseases: Europe's challenges* and on 8th June 2009 the Council adopted a *Council Recommendation on a action in the field of rare diseases*. Both documents setting out an overall EU strategy to support Member States in diagnosing, treating and caring for the 36 million EU citizens with rare diseases. The limited number of patients affected and the fragmentation of knowledge about them across the European Union makes rare diseases a prime example of where working at European level is necessary and beneficial. The Communication sets out an EU strategy for action in three main areas: (i) improving recognition and visibility of rare diseases; (ii) supporting national plans for rare diseases in the Member States; and, (iii) strengthening cooperation and coordination for rare diseases at European level.

The *Orphan Regulation (Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products* was proposed by the Commission in July 1998 and is in force since 2000. It sets up the criteria for orphan designation in the EU and describes the incentives (e.g. 10-year market exclusivity, protocol assistance) to encourage the research, development and bringing to the market medicines to treat, prevent or diagnose rare diseases, to ensure that patients with rare diseases will also get the same quality treatment as other patients. The Regulation does not concentrate on access or research. The rationale behind this legislation is to compensate industry for the risks and lower potential return on investment as a consequence of the inherently low number of patients. This scheme is considered as a success with an increasing number of Orphan Designation requests filed at the European Medicines Agency (EMA). Orphan Designation refers to granting the orphan status to a medicinal product, which might still be at early stages of development while Marketing Authorisation refers to the approval to bring the product to the market. Since the development of the regulation to promote research and development on orphan medicines in the EU in 2000, over 600 medicines obtained Orphan Designation and more than 50 received Marketing Authorisation. While Orphan Designation and Marketing Authorisation for these orphan medicines are decisions taken at the EU level, the medicine reimbursement decision is a Member State (MS) responsibility. National medicine reimbursement committees are facing the trend of the increasing number of new orphan

medicines entering the market and expect a relative increase in the budget spent on orphan medicines as compared to medicines for more common diseases mainly because of the high prices charged for these orphan medicines.

However difficulties to access Orphan Medicines from patients in several Member States are stated as one of the main problems for equal rights and equal treatment at EU level. Point 5.3 is one of the key elements of the Communication COMM(2008) 679 final and specifically refers to this:

5.3. Access to Orphan Drugs

There are specific bottlenecks in access to orphan drugs through the decision making process for pricing and reimbursement linked to rarity. The way forward is to increase collaboration at the European level for the scientific assessment of the (added) therapeutic value of Orphan Medicinal Products. The Commission will set up a working party to exchange knowledge between Member States and European authorities on the scientific assessment of the clinical added value of orphan medicines. These collaborations could lead to non-binding common clinical added value assessment reports with improved information that facilitate the national pricing and reimbursement decisions, without pre-empting respective roles of the authorities. Furthermore, the involvement of the EMEA and existing international Health Technology Assessment networks as the Health Technology Assessment International (HTAi), the European Network for Health Technology Assessment (EUnetHTA) or the Medicines Evaluation Committee (MEDEV) should be considered.

In a similar way the Council Recommendation on an action in the field of rare diseases refers to the same topic in the recital (19):

(19) It is of utmost importance to ensure an active contribution of the Member States to the elaboration of some of the common instruments foreseen in the Commission communication on rare diseases: Europe's challenges of 11 November 2008, especially on diagnostics and medical care and European guidelines on population screening. This could be also the case for the assessment reports on the therapeutic added value of orphan medicinal products, which could contribute to accelerating the price negotiation at national level, thereby reducing delays for access to orphan drugs for rare diseases patients.

and in paragraph 5 (17) (e):

17. Gather national expertise on rare diseases and support the pooling of that expertise with European counterparts in order to support:

(e) the sharing Member States' assessment reports on the therapeutic or clinical added value of orphan drugs at Community level where the relevant knowledge and expertise is gathered, in order to minimise delays in access to orphan drugs for rare disease patients.

Same approach was endorsed by the in the EU High Level Pharmaceutical Forum¹ conclusions and recommendations – “Improving Access to Orphan Medicines for all affected EU citizens” – adopted by Member States on 2 October 2008 acknowledged “*the overall objective [of this document] is to promote the sustainable development of valuable orphan medicines and to improve sustainable access to these medicines for all affected in the EU*”(p1).

This policy document calls for “*exchange of knowledge amongst Member States and European authorities on the scientific assessment of the clinical added value of orphan medicines*” (p4). “*Such exchange could improve the flow of knowledge from EU-level authorities (e.g. EMEA Committees) to the Member States’ pricing and reimbursement authorities, in particular with knowledge gathered during the marketing authorisation procedures (quality, safety, efficacy), revision of the orphan designation criteria at the time of the marketing authorisation (significant benefit) and potentially the evaluation of paediatric use (paediatric investigation plans)*” (p4). “*Bundling the fragmented know-how to assess the clinical value of orphan medicines would allow the timely production of well-informed opinions, based on more data, shared information, experiences and in-depth discussion*” (p4). “*These collaboration could lead to non-binding common clinical added value assessment reports with improved information that facilitate the national pricing and reimbursement decisions, without pre-empting respective roles of the authorities*” (p4). This policy document also calls to “*establish early dialogue between companies and pricing and reimbursement authorities, including clinical value assessment authorities regarding orphan medicines in the pipeline and the future needs for these medicines*” (p3). “*It would offer an early occasion to discuss what clinical data would be required for later clinical added value assessments and pricing and reimbursement decisions*” (p3). “*Such dialogue might require an upfront coordination between Member States and the European authorities, in full respects of different competences, in order to jointly pass common messages to the individual companies*”(p3).

Patients organisations represented by EURORDIS (European Organisation for Rare Diseases) adopted on September 2009 the “Proposal for the Practical Implementation of Policy Principles to Improve Access to Orphan Drugs in the EU“ in which it is stated that: “*The gathering of expertise at European level can also support the coordination of the national requirements for additional studies after Marketing Authorisation. However, the primary objective of the Working Party should be to gather and make available the results of the existing scientific review of all data available at the time of Marketing Authorisation. This would be already a huge step forward in sharing scientific evaluation outcomes with Member States, enabling them to make the best-informed decisions possible on Pricing & Reimbursement in a timely manner, to the benefit of patients*”.

Finally, same approach is also endorsed by the “Industry Recommendations and Suggestions for the Practical Implementation of Policy Principles to Improve Access to Orphan Medicinal Products in the EU“ issued by EUROPA BIO (The European Association for Bioindustries) and EBE (European Biopharmaceutical Enterprises) and adopted by their members last 25 November 2009: “*The success of the proposed new working party in “facilitat[ing] the national pricing and reimbursement decisions” and “minimis[ing] delays for access to orphan drugs” will depend on a carefully and realistically defined role, mandate,*

¹ <http://ec.europa.eu/pharmaforum/>

composition and functioning as well as an explicitly stated link between it and the Member States. If the creation of a new working party and the creation of a new element in the orphan process are not carried out carefully, the outcome could result in even greater delays in patient access”.

In some Member States it should be not ignored that they have decided to have two separate bodies to carry out the functions of marketing authorisation and of relative effectiveness.

In the case of France, three institutions play a role with regard to orphan medicines on the French market: the French Agency for the Sanitary Security of Health Products (*Afssaps - Agence Française de Sécurité Sanitaire des Produits de Santé*), the High Health Authority (*HAS – Haute Autorité de Santé*), and the Ministry of Health. The HAS is a public independent authority having as objectives to improve the quality and security of the health services, to maintain a high-performance health system and to inform patients on their diseases and treatment. The demand for inclusion on the reimbursement list is examined by the Transparency Committee of the HAS. The Transparency Committee renders an advice on the clinical added value (*SMR: Service Médical Rendu*) and the improvement in the clinical added value (*ASMR: Amélioration du Service Médical Rendu*) as compared with existing therapies. The Committee then proposes a positive or negative advice to the Health and Social Security Ministers relating to the reimbursement of the medicine.

In the case of the United Kingdom, a distinction is made between the regulatory processes, pricing, HTA processes and the commissioning policies: Regulatory processes (the medicine obtains a licence at EMEA level), Pricing which is regulated by the Pharmaceutical Price Regulation Scheme (PPRS) 86, and the HTA processes [three HTA regional bodies provide guidance to the National Health Service on the use of health technologies based on appraisal of clinical and cost effectiveness evidence: National Institute for Health and Clinical Excellence (NICE) for England. NICE produces guidance on public health, health technologies selected by the health ministers and clinical practice, Scottish Medicines Consortium (SMC) for Scotland which reviews all new medicines. SMC has developed a specific policy for orphan medicines and All Wales Medicines Strategy Group (AWMSG) for Wales issues.

This large consensus between the European Union strategy in the field of rare diseases in order to facilitate timely and equal accessibility to orphan medicines, and the interest of stakeholders as expressed in the statements mentioned above (pharmaceutical companies and patients organisations) cannot ignore the difficulties in such approach derived from the present EU regulatory scheme.

The purpose of the present contract is to propose a methodology for a relative effectiveness assessment in order to facilitate timely and effective access to orphan medicines by those affected by a rare condition by the way of increasing collaboration at the European level achieving, if possible, a common methodology for health technology assessments of new medicines. For this detailed discussions with the Member States and interested parties on the best way to make progress are necessary.

For the purposes of this call for tender, the working definitions adopted by the EU High Level Pharmaceutical Forum will be used:

- *Efficacy*: is the extent to which an intervention does more good than harm under ideal circumstances.
- *Relative efficacy*: can be defined as the extent to which an intervention does more good than harm, under ideal circumstances, compared to one or more alternative interventions.
- *Effectiveness* is the extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice.
- *Relative effectiveness* can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice.

The problem of delays in access to medicines because of Member States' health technology assessments is not limited to orphan medicines but is a horizontal issue. Priority should be given, if possible, to the development of a common methodology for the assessments.

The scientific expertise of the EMA (European Medicines Agency) and from the COMP (Committee for Orphan Medicinal Products) and the expertise provided by existing international Health Technology Assessment networks as the Health Technology Assessment International (HTAi), the European Network for Health Technology Assessment (EUnetHTA) or the Medicines Evaluation Committee (MEDEV) should be considered.

The contracting authority of the service contract under this public procurement procedure will be the Executive Agency for Health and Consumers (hereafter referred to as the 'Executive Agency' or 'EAHC').

3. Subject of contract

3.1. Terms of the contract

The purpose of the present contract is to identify and assess the possible options for the creation of a mechanism for the exchange of knowledge between Member States and European authorities on the scientific assessment of the relative effectiveness of orphan medicines to be implemented, if possible, from 2011. The aim of these common assessment reports for the scientific assessment of the relative effectiveness of orphan medicines 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, particularly the EMA and the COMP, on the best way to establish such mechanism are necessary. This mechanism – covering medicines developed for rare diseases – will have to be considered in the broader context of Health Technology Assessment for all medicinal products and take into account that an orphan medicine should be not only assessed for their risk/benefit ratio, but also for their clinical added-value expressed as relative effectiveness.

The main objectives of this study are:

1. To describe the regulatory process followed by an orphan medicine, from orphan designation at the European level to reimbursement in the Member State and examine to what extent the information produced by the authorities responsible for orphan designation and Marketing Authorisation is directly useful for the medicine reimbursement decision process;
2. To describe the Health Technology Assessment expertise (focusing on relative efficacy and relative effectiveness) used at national level for this purpose and level of involvement of existing international Health Technology Assessment networks.
3. To describe what expertise is used when the medicine is prescribed to all the targeted population of patients affected by a certain rare disease. How the heterogeneity of a disease expression is appraised (e.g. differences of weight, age, clinical manifestations, history of treatments taken by each patient, differences of social situation, patient ability to comply with the constraints imposed by the treatment, etc.). The main question being the level of evidence needed to collect data which could be considered as acceptable to establish the relative effectiveness and, based on this data, how is generated an assessment of real clinical added value.
4. To propose a format for the Common Assessment Report for clinical added value for orphan medicines structured in a usable way for national decision makers, written in a clear and easy to understand language, avoiding potential ambiguities in translation in all the EU official languages and enhancing the usefulness for doctors and patients. The proposal should also refer to the modalities of revision of this report. Data included in this format should also permit to identify 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.
5. To define, in consultation with the European Commission competent Units, with the European Union Committee of Experts on Rare Diseases (EUCERD), with the EMA (European Medicines Agency) and with the COMP (Committee for Orphan Medicinal Products) and other EMA Committees (CHMP, CAT and PDCO): which is the most appropriate structure for performing this task in a coordinated EU level? This should also identify:
 - (a) Which could be the most appropriate mechanism of coordination with the COMP and other EMA committees, in terms of governance and in order to obtain the highest scientific added value?
 - (b) Which could be the most appropriate composition of this mechanism of coordination?
 - (c) What are the financial implications for setting up a new structure or using an existing structure?
6. To formulate recommendations for main tasks of this mechanism of coordination taking into account that their opinions should be in the form of non-binding Common Assessment Reports on the scientific assessment of the relative effectiveness of orphan Medicines approved at the EU level and how the dialogue with Member States to facilitate coordination of possible additional national requirements (e.g. registries, real life studies) should be structured.

7. To propose how to articulate these Common Assessment Reports on the Clinical Added Value of Orphan Medicines with the CHMP (Committee for Human Medicinal Products) post-marketing obligations to avoid duplication and make the most of available resources.

8. The options chosen for assessment should be limited to what can be implemented within the current legislative framework on pharmaceutical products, including the role of EMA.

9. The options chosen for assessment and the identified mechanisms of cooperation should take into account the broader context of HTAs and the suitability of the mechanisms to all types of medicines, not just orphan medicines.

It should be clear that the mission of this new mechanism of coordination is not to do new reviews of scientific studies or to request new submission of data. This point is important in order to respect the remits of the COMP, CHMP, CAT and PDCO.

Following interviews, information sharing and visits with all the relevant stakeholders mentioned in point 4 as well as a representative sample of national authorities, the patient's organisations (EURORDIS) and the industry representatives (EBE and EuropaBio), a summary in English and a written report should serve to document the recommendations.

3.2. Working method

The contractor is encouraged to develop the methodology for undertaking the tasks in a structured and systematic way, which should include an operational and organisational approach for Common Assessment Report for the scientific assessment of the relative effectiveness of orphan medicines.

The contractor should indicate in its proposal the potential risks to the project, including ways in which it intends to mitigate these.

3.3. Activities to be carried out, the deliverables

The tasks to be executed by the contractor:

Task 1: Research (result: Deliverable 1)

The contextual situation of the policy with regard to rare diseases and orphan medicines should be considered as background for collection and review of relevant documents and scholarly publications relating to the particularities of regulatory process followed in every Member State (such as market access, pricing, patient care, health technology assessments...).

Task 2: Comparative analysis of the Member States practices with the processes at EMA level (result: Deliverable 2)

The aim was to compare the Orphan Designation and Marketing Authorisation processes of the EMA and at Member States level. Information should be collected through research and direct interviews with concerned officials. It should be provided a comparative analysis of criteria used for reimbursement of orphan medicines and of the differences of the decision process compared to other medicinal products. This work should be based on qualitative research and interviews. Information for this activity should be collected through Activity 1

and a survey based on a qualitative questionnaire. This questionnaire has to be developed by the tenderer.

Task 3: Budget impact analysis and critical assessment (result: Deliverable 3)

For all reimbursed orphan medicines in the EU the budget impact is estimated based on the budget impact analysis presented by the companies to national authorities in reimbursement request files and publicly available information (analysis of actual and expected budget impact over the years). Forecasts and simulations of expected future budget impact of orphan medicines should be made, using as a basis the average number of medicines getting marketing authorisation each year, the percentage of orphan medicines obtaining reimbursement in EU and the average cost per patient per year of orphan medicines. Ongoing work of the Network of competent authorities on pricing and reimbursement should be taken into account. The critical assessment consist of a 'quick scan' for all reimbursed orphan drugs and a more in depth critical appraisal of some selected cases (some reimbursed and, at least, one no reimbursed). The quick scan should look at the clinical and economic evidence provided in the context of the registration and reimbursement request files submitted to the regulators, whereas the in depth critical appraisal take into account the methodological standards of registration and reimbursement request files.

Task 4: Discussion of issues (result: Deliverable 4)

To analyse critically the existing positions on the scientific assessment of the relative effectiveness of orphan Medicines issued from the European Commission, the EMA, Pharmaceutical Forum, EURORDIS and the industry looking for common points and discrepancies. To discuss, organising for this the appropriate workshops or bilateral meetings, these issues with EU partners: the European Commission competent Units, the European Union Committee of Experts on Rare Diseases (EUCERD), the EMA (European Medicines Agency), the COMP (Committee for Orphan Medicinal Products), the CHMP (Committee for Human Medicinal Products), CAT (Committee of Advanced Therapies) and the PDCO (Paediatric Drugs Committee). All the cost for the organization of these workshops/bilateral meetings should be included in the offer.

Task 5: Final Recommendation (result: Deliverable 5)

On the basis of these discussions and assessment reports, the tenderer shall propose a Final Recommendation including a format for the Common Assessment Report for the scientific assessment of the relative effectiveness of orphan Medicines structured in a usable way for national decision makers. It must be written in a clear and easy to understand language, avoiding potential ambiguities in translation in all the EU official languages and enhancing the usefulness for doctors and patients. The offer should also refer to the modalities of revision of this report. Data included in this format should also permit to identify 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 about which is the most appropriate consultative structure for performing this task in a coordinated EU level.

This work should be done in close cooperation with the European Union Committee of Experts on Rare Diseases (EUCERD).

Other

The tenderer must submit a **working plan and a detailed, step-by-step list and description of activities, preferably in the form of work packages**, including a full list of data-sources, and a time table for the completion of activities with associated milestones and a deployment schedule of various resources (personnel, etc). If the execution of the contract requires any acquisition of material (especially hardware or software) the relevant material will be the property of the European Union (and should be delivered to the Commission at the end of the contract) unless otherwise agreed.

Overview table of tasks and corresponding deliverables

Task 1	Deliverable 1	Report on the regulatory process followed by an orphan drug, from orphan designation at the European level to reimbursement in the Member State including Health Technology Assessment expertise used at national level
Task 2	Deliverable 2	Questionnaire to compare the Orphan Designation and Marketing Authorisation processes of the EMA and at Member States level
Task 3	Deliverable 3	Forecasts and simulations of expected future budget impact of orphan drugs including clinical and economic evidence provided in the context of the registration and reimbursement procedures
Task 4	Deliverable 4	Expert opinion critically analysing and summarising positions on Common Assessment Report for CAVOD at EU institutional level and EU stakeholders
Task 5	Deliverable 5	Final Recommendation (including a format for the implementation of Common Assessment Report for CAVOD at EU level)

3.4 Geographical coverage

The contractor shall ensure that the 27 Member States are covered by the report.

Timeframe for providing the services

The overall indicative timeframe is the following:

MONTH	ACTIVITY
M1	Inception/kick-off meeting An inception report should be provided to EAHC/SANCO 2 weeks before this meeting
M2	First meeting of the Network of Experts
M3	2 nd meeting with contractor 2 nd meeting of the Network of Experts. Interim report as a first presentation of the main outcomes and areas to

	be covered in the remainder of the contract.
M5	3 rd meeting of the Network of Experts - Final European Experts Consensus Workshop on Common Assessment Report for the scientific assessment of the relative effectiveness of orphan medicines
M7	Draft final report "Common Assessment Report for the scientific assessment of the relative effectiveness of orphan Medicines in the EU Member States" to be submitted to EAHC
M8	Comments from EAHC and the Commission on the draft final reports
M9	Final report "Common Assessment Report for the scientific assessment of the relative effectiveness of orphan Medicines in the EU Member States" to be submitted to EAHC

A detailed timetable should be provided in the offer.

4. Participation in the tendering procedure

Participation in tendering procedures is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with the European Union in the field of public procurement on the conditions laid down in that agreement.

4.1. Consortia

Groups of economic operators (consortia) are authorised to submit tenders (joint offers). In this case, each member of the consortium shall fulfil the requirements and accept the terms and conditions set out in the tender specifications, the contract as well as in all the relevant Annexes.

The offer must identify the consortium members by filling in the relevant points of Annex Ia. The tenderer shall clearly specify the role and tasks of each member of the consortium. The members of the consortium shall designate one member as consortium leader with full authority to bind the consortium and each of its members. Each consortium partner shall fill in, date and co-sign with the consortium leader a mandate letter (Annex Ib). The consortium leader shall act as a single point of contact with the contracting authority in connection with the present public procurement procedure.

In case the awarded tender is submitted by a consortium, all members of the consortium will be jointly and severally liable towards the contracting authority for the performance of the contract.

The contracting authority may not demand that consortia must have a given legal form in order to be allowed to submit a tender. However, the consortium awarded to sign a contract may be required to adopt a given legal form after it has been awarded the contract and before the contract is signed, if this change is necessary to the proper performance of the contract.

The tenderer shall note that:

- The **exclusion criteria** as indicated in point 16.1 of the tender specifications will be applicable to each member of the consortium, therefore the ‘Declaration of honour’ (Annex IV) must be supplied in the offer by each member.

During the evaluation or before the signature of the contract, the contracting authority may request valid documentary evidence demonstrating that the exclusion criteria are met by the consortium partners in accordance with Annex IV.

The leader and the members of the *awarded consortium* will be obliged to submit the exclusion criteria evidence before the signature of the contract, except if they are public bodies.

- The consortium leader shall provide **evidence of access to contracts (proof of eligibility)** as stated in point 17.1 by filling in
 - Annex Ia (Tender submission form),
 - Annex Ib (Mandate letter filled in and dated by the consortium partner and co-signed by the consortium leader),
 - Annex IIa / IIb / IIc (Legal entity form) and
 - Annex III (Financial identification form).
- During the evaluation, the **selection criteria for economic and financial capacity** of the consortium members will be – partly individually and partly in a consolidated way – assessed therefore the offers must include evidence on this regarding each consortium member. Each consortium member shall fill in and sign Annex VII.
- During the evaluation, the **selection criteria for technical and professional capacity** will be assessed in relation to the combined capacities of all members of the consortium, as a whole; therefore the offers must include evidence on this.

4.2. Subcontracting

Subcontracting is allowed. However, the contracting authority may demand information from the tenderer on any part of the contract that the tenderer may intend to subcontract to third parties and on the identity of any subcontractor. The contracting authority reserves the right to validate the proposed subcontractor(s).

The offer must clearly identify the subcontractor(s) by filling in the relevant points of Annexes Ia of these tender specifications and prove their willingness to accept tasks proposed to them by the tenderer (e. g. by way of enclosing a written commitment of the subcontractors(s)). Moreover, by filling in Annex Ia, the tenderer shall provide information as to what proportion of the contract the tenderer intends to subcontract in total and also by each subcontractor, in case there are more subcontractors identified. In addition to this, the offer shall describe which main task(s) will be subcontracted.

Once the contract has entered into force, the contractor shall retain full liability towards the contracting authority for the performance of the contract as a whole. The Executive Agency will not have any direct legal commitment with the subcontractor(s).

The tenderer shall note that:

- As a general rule, the **exclusion criteria** as stated in point 16.1 of the tender specifications will be applicable to the tenderer and each its subcontractor, therefore the ‘Declaration of honour’ (Annex IV) must be supplied in the offer by them.

During the evaluation or before the signature of the contract, the contracting authority may request valid documentary evidence demonstrating that the exclusion criteria are met by the subcontractor(s) in accordance with Annex IV.

Before the signature of the contract, the *awarded tenderer including the subcontractor(s)* will be asked to submit the exclusion criteria evidence. As an exception,

- that/those subcontractor(s) of the awarded tenderer who will be subcontracted for a value less than € 60 000 of the total amount of the contract,
- and the tenderer and/or the subcontractor(s) being a public body will not be obliged to submit such evidence.

- Only the tenderer shall provide **evidence of access to contracts (proof of eligibility)** as stated in point 17.1. by filling in
 - Annex Ia (Tender submission form),
 - Annex IIa / IIb / IIc (Legal entity form) and
 - Annex III (Financial identification form).
- When a subcontractor will be subcontracted for a value of more than € 60 000, the tenderer shall submit information and evidence on the **selection criteria for the economic and financial capacity** of the identified subcontractor by filling in Annex VII and enclosing the evidence as indicated in point 17.2.
- The **selection criteria for technical and professional capacity** will be applied to the combined capacities of the tenderer and the subcontractors identified whether in the tender or during the implementation of the contract –, to the latter in respect of the part of the work that they will perform, therefore the offers must include evidence on this.

Instructions on how to fill in the Annexes of these tender specifications in case of joint offers and/or subcontracting are available in Annex VIII (Checklist).

5. Documentation for tenderers

The following set of documents is provided to the tenderers:

- Invitation to tenderers
- Tender specifications
 - Annex Ia: Tender submission form
 - Annex Ib: Letter of mandate
 - Annex IIa: Legal entity form for public entities
 - Annex IIb: Legal entity form for private entities
 - Annex IIc: Legal entity form for individuals

- Annex III: Financial identification form
- Annex IV: Declaration of honour
- Annex V: Financial offer form
- Annex VI: Draft contract and annexes
- Annex VII: Economic and financial capacity overview form
- Annex VIII: Checklist

6. Visits to premises or briefing

Three meetings with the Commission services should be proposed by the Contractor. The meetings will take place in the offices of Unit C2 (Health Information Unit), Directorate-General for Health and Consumers (Luxembourg, 11 Rue Eugene Ruppert) or at the Health Unit, Executive Agency for Health and Consumers (Luxembourg, Rue Guillaume Kroll 12.).

This shall include a meeting at the start of the project (kick-off meeting) where a detailed work programme for the execution of the contract should be presented (inception report). The Contractor shall present proposals for when the other meetings as indicated in the timeframe under point 3 should take place, based on the need for the EAHC/DG SANCO to be updated on the state of progress at regular intervals (e.g. at the end of each stage).

7. Variants

Variants are not accepted.

8. Volume of contract

The maximum contract price is **EUR 250 000**.

The duration of the contract will be 11 months; the tasks covered by the contract shall be completed within 9 months of the signature by the last contracting party.

9. Price

- Prices must be quoted in Euro using, if necessary, the conversion rates published in the C series of the Official Journal of the European Union on the day when the contract notice was published (if no notice was published, on the day when the invitation to tender was sent out).
- Prices must be fixed amounts in Euro.
- Estimated travel and subsistence expenses must be indicated separately.

This estimate should be based on Article I.3.3 of the contract annexed to these specifications and include any travel required to meet representatives of the Executive Agency. In any event, it should represent the maximum amount of travel and subsistence expenses payable for all the services provided.

- Prices should be quoted free of all duties, taxes and other charges, including VAT, as the Communities are exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Communities; the amount of VAT should be shown separately.
- Prices are firm and not subject to revision.

10. Terms of payment

- Pre-financing:

Following the signature of the contract by the last contracting party, within 30 days of the latest of the following dates:

- the receipt by the Executive Agency of a request for pre-financing with a relevant invoice;
- the receipt and approval of the inception report;
- the receipt by the Executive Agency of a duly constituted financial guarantee (if foreseen by the contract)

a pre-financing payment equal to 30% of the total amount referred to in Article I.3.1 the contract (see Annex VI of the tender specifications) shall be made.

- Interim payment:

The request for interim payment of the contractor shall be admissible if accompanied by:

- an interim technical report;
- the relevant invoice;
- a statement of reimbursable expenses (travel and subsistence allowances) for the reported period in accordance with Article II.7 of the contract.

The Executive Agency will have 45 days from receipt to approve or reject the interim technical report, and the contractor shall have 20 days in which to submit additional information or a new report.

Within 30 days of the date of approval of the interim technical report, an interim payment corresponding to the relevant invoice, equal to 30% of the total amount referred to in Article I.3.1 of the contract shall be made, increased by the amount of approved reimbursable expenses.

- Payment of the balance:

The request for payment of the balance of the contractor shall be admissible if accompanied by:

- the final technical report in accordance with the instructions laid down in the tender specifications;
- the relevant invoice;
- a statement of reimbursable expenses (travel and subsistence allowances) for the reported period in accordance with Article II.7 of the contract.

The Executive Agency will have 45 days from receipt to approve or reject the final technical report, and the contractor shall have 20 days in which to submit additional information or a new report.

Within 30 days of the date of approval of the final technical report, payment of the balance corresponding to the relevant invoice, equal to 40% of the total amount referred to in Article I.3.1 of the contract shall be made, increased by the amount of approved reimbursable expenses.

- Payment for travel and subsistence expenses:

Reimbursement will be made on presentation of statements of reimbursable expenses according to Article II.7 of the contract, and after their approval.

11. Reports and documents to be submitted

The work carried out by the contractor under the contract will be the subject of the following reports, which must be sent to the Executive Agency by the contractor both in hard copy and electronic format.

All reports should have numbered paragraphs and pages.

- **Interim report or documents:** in 3. hard copies and in electronic format, in English

The report or documents will describe the work carried out and the results obtained during each period or phase, the duration of which is specified below, and state in particular:

- the effects, if any, of the results obtained on the overall work covered by the contract;
- the work programme planned for the following period.

Interim report or documents must be sent to the Executive Agency no later than 3 months after signature of the contract.

- **Final report:** in 9 hard copies and in electronic format, in English

The final report will describe all the work carried out and the results obtained under the contract. It will also contain a summary of the main results obtained.

The draft final report must be submitted to the Executive Agency no later than 7 months after signature of the contract. The Executive Agency will then either inform the contractor that it approves the draft or will send him its comments.

Within 30 days of receiving any such comments, the contractor will send the Executive Agency his final report, which will either take account of the comments or put forward alternative points of view.

In the absence of any comments from the Executive Agency within 30 days of its receiving the draft report, the contractor may request written acceptance of it.

The final report will be deemed to have been approved by the Executive Agency if it does not expressly inform the contractor of any comments within 30 days of its request.

12. Contractual terms and guarantees

In drawing up his bid, the tenderer should bear in mind the provisions of the standard contract attached to this invitation to tender (Annex VI).

Submission of a tender implies acceptance of all the terms specified in the present specifications and in particular in the attached standard contract including the general conditions applicable to contracts (Annex VI).

All documents presented by the tenderer become the property of the European Union and are deemed confidential.

The Executive Agency will not reimburse expenses incurred in preparing and submitting offers.

13. No obligation to award the contract

Completing the adjudication or the procedure of the call for tenders in no way imposes on the Executive Agency an obligation to award the contract.

The Executive Agency shall not be liable for any compensation with respect to tenderers whose tenders have not been accepted, nor shall it be liable when deciding not to award the contract.

14. Administrative and financial penalties

1. Without prejudice to the application of penalties laid down in the contract, candidates or tenderers and contractors who have been guilty of making false declarations or have been found to have seriously failed to meet their contractual obligations in an earlier procurement procedure shall be excluded from all contracts and grants financed by the Union budget for a maximum of two years from the time when the infringement is established, as confirmed after an adversarial procedure with the contractor.

That period may be extended to three years in the event of a repeat offence within five years of the first infringement.

Tenderers or candidates who have been guilty of making false declarations shall also receive financial penalties representing 2 % to 10 % of the total value of the contract being awarded.

Contractors who have been found to have seriously failed to meet their contractual obligations shall receive financial penalties representing 2 % to 10 % of the total value of the contract in question.

That rate may be increased to 4 % to 20 % in the event of a repeat offence within five years of the first infringement.

2. In the cases referred to in paragraph 16.1 points (a), (c) and (d) of these specifications, the candidates or tenderers shall be excluded from all contracts and grants for a maximum of two years from the time when the infringement is established, as confirmed after an adversarial procedure with the contractor.

In the cases referred to in paragraph 16.1 points (b) and (e) of these specifications, the candidates or tenderers shall be excluded from all contracts and grants for a minimum of one year and a maximum of four years from the date of notification of the judgment.

Those periods may be extended to five years in the event of a repeat offence within five years of the first infringement or the first judgment.

3. The cases referred to in paragraph 16.1 point (e) of these specifications shall be the following:

(a) cases of fraud as referred to in Article 1 of the Convention on the protection of the European Communities' financial interests drawn up by the Council Act of 26 July 1995²;

(b) cases of corruption as referred to in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997³;

(c) cases of participation in a criminal organisation, as defined in Article 2(1) of Joint Action 98/733/JHA of the Council⁴;

(d) cases of money laundering as defined in Article 1 of Council Directive 91/308/EEC⁵.

15. Requirement as to the tender

The tender must include:

- (a) an administrative part including all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the exclusion and selection criteria set out under paragraphs 16 and 17 respectively of these Tender Specifications;

² Official Journal of the European Communities, C 316, 27.11.1995, p. 48.

³ Official Journal of the European Communities, C 195, 25.06.1997, p. 1.

⁴ Official Journal of the European Communities, L 351, 29.12.1998, p. 1.

⁵ Official Journal of the European Communities, L 166, 28.06.1991, p. 77.

- (b) a technical part including all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the award criteria set out under paragraph 18 of these Tender Specifications;
- (c) a financial part setting out prices in accordance with paragraph 19 of these Tender Specifications.

ADMINISTRATIVE PART

The evaluation will be made in three stages: exclusion, selection and award. Only the offers which fulfil the criteria detailed below will be selected for the award stage.

16. Exclusion criteria

16.1. Candidates or tenderers shall be excluded from participation in a procurement procedure if:

- (a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- (b) they have been convicted of an offence concerning their professional conduct by a judgment which has the force of res judicata;
- (c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;
- (d) they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed;
- (e) they have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;
- (f) they are currently subject to an administrative penalty referred to in Article 96 (1) of the Financial Regulation (The contracting authority may impose administrative or financial penalties on the following: (a) candidates or tenderers in the cases referred to in point (b) of Article 94, (b) contractors who have been declared to be in serious breach of their obligations under contracts covered by the budget. In all cases, however, the contracting authority must first give the person concerned an opportunity to present his observations.)

Points (a) to (d) of the first subparagraph shall not apply in the case of purchase of supplies on particularly advantageous terms from either a supplier which is definitively winding up its business activities, or from the receivers or liquidators of a bankruptcy, through an arrangement with creditors, or through a similar procedure under national law.

Candidates or tenderers must certify that they are not in one of the situations listed above by completing and signing the 'Declaration of honour' (Annex IV).

As a general rule, the successful tenderer will be requested, after the award and before the signature of the contract, to also provide evidence that it is not in any of the situations described in points (a), (b), (d) and (e) above within the time limit stipulated by the contracting authority. In case the successful tender was submitted by a consortium and/or subcontractors are identified, the exclusion criteria evidence shall be submitted in accordance with point 4 of the tender specifications.

This evidence must be in one of the forms described in paragraph 16.2 below.

16.2. Evidence

- (a) The contracting authority shall accept as satisfactory evidence that the candidate or tenderer to whom the contract is to be awarded is not in one of the situations described in point (a), (b) or (e) of paragraph 16.1, a recent extract from the judicial record or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied.
- (b) The contracting authority shall accept, as satisfactory evidence that the candidate or tenderer is not in the situation described in point (d) of paragraph 16.1, a recent certificate issued by the competent authority of the State concerned. Where the document or certificate referred to in paragraph 16.1 is not issued in the country concerned and for the other cases of exclusion referred to in paragraph 16.1, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.
- (c) Depending on the national legislation of the country in which the candidate or tenderer is established, the documents referred to in paragraph 16.2 shall relate to legal persons and/or natural persons including, where considered necessary by the contracting authority, company directors or any person with powers of representation, decision-making or control in relation to the candidate or tenderer.

16.3. Contracts may not be awarded to candidates or tenderers who, during the procurement procedure:

- (a) are subject to a conflict of interest;
- (b) are guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the contract procedure or fail to supply this information;
- (c) find themselves in one of the situations of exclusion, referred to in paragraph 16.1, for this procurement procedure.

Candidates or tenderers must certify that they are not in the situation in point (a) by completing and signing the form in Annex IV, 'Declaration of honour'.

17. Selection criteria

Tenderers must demonstrate that they have the capacity to provide the services required. Only those tenders fulfilling all the selection criteria will be examined in the light of the award criteria.

17.1. Proof of eligibility

The tenderer (in case of a consortium, the consortium leader) shall provide evidence of access to contracts (eligibility) according to the followings:

- a) the tenderer indicates in which State it has its headquarters or domicile (Annex Ia) and presents the supporting evidence normally acceptable under its own law.
- b) it indicates its VAT number (Annex IIa/IIb);
- c) it indicates the name and position of the person authorised to sign the contract (Annex Ia);
- d) it indicates its bank account number and bank address (R.I.B. or standard form in Annex III);
- e) if the tenderer is a natural person, it shall complete the standard form in Annex IIc.
- f) In case of a consortium, the consortium leader shall submit the Mandate letters (Annex Ib) signed and dated by the consortium members and co-signed by the consortium leader; in case of subcontracting the tenderer shall submit the written commitment proving the willingness of the subcontractor(s) to accept the task proposed to it / them by tenderer.

17.2. Economic and financial capacity

17.2.1. Purpose

Tenderers are required to provide sufficient information of their financial standing and more particularly proof that they have the necessary resources and financial means to carry out the work that is the subject of the tender.

The Executive Agency shall have sole discretion in judging the adequacy of tenderers' economic and financial capacity with regard to the provision of the services and, where it considers this insufficient, the right to reject any offer, to accept an offer subject to any advance or stage payments being deferred until the work has been completed or to ask the tenderers to provide a guarantee or performance guarantee.

17.2.2. Economic and financial capacity check

For any tenderer participating in the call, verification of the organisation's economic and financial capacity is mandatory.

In order to be economically and financially viable, a tenderer must demonstrate:

- **Liquidity:** capable of covering its short-term commitments;
- **Solvency:** capable of covering its medium and long-term commitments;
- **Profitability:** generating profits, or at least with a self-financing capacity.

As a consequence, the liquidity, the solvency and the profitability of the tenderer shall be assessed by the Executive Agency.

Proof of its economic and financial capacity shall be furnished by the tenderer by the presentation of balance sheets or extracts from balance sheets and profit and loss accounts for at least the last two years for which accounts have been closed, where publication of the balance sheet is required under the company law of the country in which the economic operator is established.

Tenderers (and in case of a consortium, the consortium leader and the consortium members) are also requested to fill in the form 'Economic and Financial Capacity Overview' in Annex VII.

If, for some exceptional reason that the Executive Agency considers justified, the tenderer is unable to provide the references requested by the Executive Agency, he may prove his economic and financial capacity by any other means that the Executive Agency considers appropriate. In case of public bodies, other documents, in particular the body's budget for the current year could be considered as appropriate.

17.2.2.1 Used ratios and noteworthy value

The tenderer's economic and financial capacity check is based on three financial ratios defined as follows:

Purpose	Indicators	Ratios
Liquidity	Current Ratio ⁶	$\frac{\text{Current Assets (3)}^7}{\text{Trade and Other Debts (6)}}$
Profitability	Profitability Ratio ⁸	$\frac{\text{Gross Operating Profit (14)}}{\text{Turnover (7)}}$

⁶ For the last year for which accounts have been closed

⁷ The figures mentioned between brackets refer to the respective accounts listed in Annex VII

⁸ For the best of the last two years for which accounts have been closed

Solvency	Financial Autonomy Ratio ⁹	$\frac{\text{Capital and Reserves (4)}}{\text{Total Liabilities (4 + 5 + 6)}}$
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In addition, noteworthy values are used as complementary data (Flag).

Purpose	Indicators	Ratios
Financial Capacity	Turnover Flag	The average Turnover (7) of the last 2 accounting years minus $\frac{\text{Estimated Maximum Amount of the Services}}{\text{Duration of the provided service in years}}$
	Equity Flag	Capital and Reserves (4) minus Paid-up Capital (4.1)

17.2.2.2. Thresholds

According to the results obtained for each of the abovementioned ratios, the following quotes are given:

Purpose	Indicators	Weak	Acceptable	Good
		0	1	2
Liquidity	Current Ratio	$i < 1$	$1,00 \leq i \leq 1,25$	$i > 1,25$
Profitability	Profitability Ratio	$i < 0,05$	$0,05 \leq i \leq 0,15$	$i > 0,15$
Solvency	Financial Autonomy Ratio	$i < 0,20$	$0,20 \leq i \leq 0,33$	$i > 0,33$

Flags are assessed according the following criteria:

Purpose	Indicators	Weak	Good
Financial Viability and Capacity	Turnover Flag	$i < 0$	$i \geq 0$
	Equity Flag	$i < 0$	$i \geq 0$

17.2.3 Conclusion of the economic and financial capacity checks

The financial assessment on the basis of the above mentioned ratios results in scores of "Good", "Acceptable" or "Weak" for the liquidity, profitability and solvency aspects of the tenderer.

⁹ For the last year for which accounts have been closed

A tenderer subject to a verification of its economic and financial capacity who obtains an overall score of less than 3 points as a result of the above ratios will be considered to have a "Weak" economic and financial capacity.

Moreover, despite an overall score of 3 points or more under the abovementioned ratio analysis, the economic and financial capacity of a tenderer will be considered as "Weak", if both the noteworthy values, knowing the Turnover Flag and the Equity Flag, are considered "Weak".

17.3. Technical and professional capacity

Technical and professional capacity of the tenderer shall be evaluated and verified in accordance with point 17.3.1 and 17.3.2 as follows:

17.3.1. Requirements

The tenderer must meet the following criteria

- i. at least 10 years of relevant professional experience in the field of health technological assessment or clinical assessment of medicines.,
- ii. the capacity to put together a team with members of at least 5 years experience of relevant professional activities. The team shall have a leader with at least 10 years of relevant professional experience.

Technical and professional capacity of tenderers shall be evaluated and verified in accordance with paragraph 2.

17.3.2. Evidence

Evidence of the technical and professional capacity of tenderers shall be furnished on the basis of the following documents:

- (a) the educational and professional qualifications of the service provider or contractor and/or those of the firm's managerial staff and, in particular, those of the person or persons responsible for providing the services or carrying out the works.

The tenderer shall enclose the curricula vitae as well as a summary table of main expertise of the persons responsible for providing the services. A list of the publications in scientific journals of the team members shall also be enclosed.

- (b) a reference list of the principal services provided and projects participated in the past three years, with the sums, dates and recipients, public or private.

TECHNICAL PART

The technical part shall describe in detail how the services described in point 3 will be provided by the tenderer. Since tenderers will be judged on the content of their written offers, these must make it clear that how could they meet the requirements of the tender specifications.

Tenders must be clear and concise, with continuous page numbering, and assembled in a coherent fashion (e.g. bound or stapled, etc.).

18. Award criteria

The contract will be awarded to the tenderer who submits the most economically advantageous bid, as assessed on the basis of the following factors:

(a) Technical evaluation criteria in their order of importance as weighted by percentage:

N°	Qualitative Award criteria	Weighting (max. points)
1.	Quality of the proposed standards for collecting information on Common Assessment Report for CAVOD and HTA practices in Member States	50
2.	Quality of the proposed approach for formulating a Final recommendation on Common Assessment Report for CAVOD and HTA practices	20
3.	Quality of the proposed interaction with stakeholders, Member State authorities, EMA and their committees and the Commission	15
4.	Quality of the overall organisation and approach to execution of the contract, including understanding of potential risks to the study	15
Total points		100

The criteria are detailed as follows:

1. Quality of the proposed standards for collecting information on Common Assessment Report for CAVOD and HTA practices in Member States:

The tenderer should clearly describe the data sources and the methodology of collection of required data that will be used, highlighting the detail and accuracy of the data expected.

2. Quality of the proposed approach for formulating a Final recommendation on Common Assessment Report for CAVOD and HTA practices:

The tenderer should provide supporting information on their proposed methodology for establishing the network of experts; namely, identification of the experts, and proposed composition and size of the network. Furthermore, the tenderer should establish and outline a minimum requirements that the expert opinion to serve for the preparation of a Final

recommendation on Common Assessment Report for CAVOD and HTA practices should meet.

3. Quality of the proposed interaction with stakeholders, Member State authorities, EMA and their committees and the Commission:

The tenderer should clearly state any proposed meetings, workshops, conferences, etc. to ensure broad involvement of stakeholders, Member States, the EMA and their committees and the Commission/EAHC. The purpose and expected outcome of these events should also be outlined.

4. Quality of the overall organisation and approach to execution of the contract, including understanding of potential risks to the study:

Offers will be assessed with regards to the organisation of the team, of the work and the availability of resources for the completion of the contractual tasks, which should be clearly outlined in the tender. A short assessment of the potential risks must also be included in the application.

For each of the above criteria, a 60% threshold is required. Tenderers falling below this threshold will be eliminated. Moreover, tenders that have not obtained a total at least 60 out of the 100 points will be excluded.

(b) Price.

The tenders will be ranked by applying the following formula:

The tenders will be ranked by applying the following formula:

Technical quality will be weighed against price on a 70/30 basis.

The points of the price are calculated by the following formula: (price of the lowest passing bid/price of the bid in question) x 100.

Then, the price and quality scores will be calculated by multiplying:

- The points awarded for the technical quality by 0.70
- the points awarded for the financial bid by 0.30.

The price and quality scores are then added together and the contract will be awarded to the tender achieving the highest score.

FINANCIAL PART

19. Financial part

Prices must be presented in the standard format of Annex V.