



Information webinar

CHAFEA/LUX/2020/OP/0013

Service Contract for the Provision of Joint Health Technology Assessment (HTA) Work Supporting the Continuation of EU Cooperation on HTA

CHAFEA- Health Team

25 March 2021

Welcome

Rules of the webinar

- All participants are muted.
- Please type your questions in the chatbox. They will be addressed during the Q&A session.
- The webinar is recorded, but will only be used for internal reporting.
- All Q&A will be published on the e-tendering page after the webinar.

Speakers

- Unit B6 Medical devices, Health Technological Assessments, DG SANTE,
 - Ms Anna-Eva AMPELAS, Head of Unit
 - Ms Flora GIORGIO, Team leader
 - Ms Ioana-Raluca SISKI, Policy Officer
- Health and Food Unit, CHAFEA
 - Mr Georgios Margetidis, Programme Coordinator
 - Ms Chiara TRIPEPI, Project Officer

Agenda

- 15:00 Welcome
- 15:15: Presentation of the open call
- 15:45 Q&A session
- 16:15 Wrap-up
- 16:30 End of the webinar

Preparing your offer

Background, call objectives, tasks & deliverables and timeline

Outline

- Background - EU cooperation on HTA
- Call for tender
 - Objective
 - Activities covered
 - Timeframe & Deliverables
 - Applicants' profile

Background - EU cooperation on HTA - PRESENT

- Directive 2011/24 on the application of patients' rights in cross-border healthcare, Article 15

[HTA Network \(Strategic\)](#) + [EUnetHTA Joint Actions \(Scientific and technical\)](#)



Joint Action 3 (2016-2021)



+ HTA methodology

As of October 2020

Background - EU cooperation on HTA- FUTURE

- **Commission Proposal for a Regulation strengthening EU cooperation on HTA (2018/0018(COD))**
 - provides for a sustainable legal framework for EU cooperation on HTA;
 - focuses on clinical aspects of HTA activities, supports joint work (joint assessments, joint scientific consultations, horizon scanning) on innovative medicines and some high risk medical devices;
 - facilitates additional voluntary joint work;
 - under co-decision procedure, significant progress during DE and PT presidencies;
 - EU4Health funding earmarked for step-wise preparation and implementation of the new HTA legal framework.

Call for tender - Objectives

- Address **key methodological issues** which have been identified as instrumental to foster the value of EU cooperation on HTA and provide input to a potential new legal framework on HTA
- Provide some continuity for key **joint HTA activities**
 - Joint clinical assessments (joint REA)
 - Joint scientific consultations (early dialogues)
- **Coordination** of joint activities



Call for tender
Health Programme
(2020 WP)



New framework for
EU cooperation on HTA



Call for tender – Activities covered

Task 1. Further development of HTA methodology

“as a minimum”:

1. For JCA:

1.1. Templates for JCA (e.g. Template for the submission dossier by health technology developer; Template for the JCA reports and summary) reports

1.2. Methodological guidelines for JCA (e.g. scoping process, comparators and comparisons; endpoints used for JCA, applicability of evidence for the context of a JCA, assessment of high risk medical devices)

1.3. Procedural guidelines for the appointment of assessors and co-assessors for JCA.

**EUnetHTA guidance
+ other relevant
cooperation initiatives
+ international
methodological guidelines**

Call for tender – Activities covered

Task 1. Further development of HTA methodology

2. For JSC for medicinal products (including parallel JSC):

2.1. Templates for JSC (e.g. template for the briefing book to be submitted by health technology developer requesting a JSC; template for the JSC report)

2.2. Updated procedural guidelines for JSC, taking into account the existing guidance documents developed by EUnetHTA JA3 and the European Medicine Agency and taking into account the feedback from health technology developers, and experts from stakeholders' representatives, including patients' and health professionals organisations involved in the joint work.

Call for tender – Activities covered

Task 1. Further development of HTA methodology

3. Templates, guidelines and recommendations to ensure transparency, confidentiality and un-biased decision-making when carrying out joint HTA work, such as:

- Guidance for the interaction between HTA experts (ie assessors and/or co-assessors of joint work) and health technology developers during JCA and JSC;
- Guidance for consulting patients, clinical experts, and other experts during JCA and JSC;
- Template(s) for input to be provided by patients, clinical experts, and other experts when consulted during JCA;
- Recommendations for guidance for identifying and handling conflict of interest, declaration of interest form(s), confidentiality agreement form(s).

Call for tender – Activities covered

Task 2. Joint HTA work

2.1. **8 JSC** or at least, not less than 6 JSC

- based on voluntary requests / expressions of interest from HTDs
- Selection of requests - based on clearly defined criteria + ensuring transparency, impartiality and avoiding conflict of interest

**EMA-EUnetHTA
collaboration**

2.2. **2 JCA** for medicinal products or at least, not less than 1 JCA

AND

4 JCA/CA for medical devices, or at least, not less than 2 JCA/CA.

**EUnetHTA guidance
+ other relevant cooperation initiatives
+ international methodological guidelines**

Call for tender – Activities covered

Task 3. Coordination of the joint work

- Secretariat activities supporting the development of HTA methodology
- Secretariat activities supporting the production of JCA/CA and JSC
- Internal communication between partners and external communication, including setting up an appropriate robust IT system with a high level of security for exchanging confidential information.
- Organisation of consultations on the newly developed methodologies with HTA experts across EU + HTA international community,
- Interaction with stakeholders
- Organisation of any other actions which could support advancing EU cooperation on HTA for the benefit of the entire HTA community
- Regular reporting

Call for tender – Timeframe & Deliverables

<i>Month</i>	<i>Activity/Deliverables/Meetings</i>
M1	Inception/kick-off meeting, minutes from meeting
M2	Coordination activities plan
M3	Secure IT portal (for internal and external communication, also hosting the repository of documents and tools developed by EUnetHTA JAs)
M3-23	Further developing methodology for joint HTA work (JSC, JCA)
M3-23	Carrying out JSCs (launch call for expression of interest, selection process, carry out parallel JSCs, report on lessons learned)
M3-23	Carrying out JCAs for medicinal products (launch call for expression of interest, selection process, carry out JCA, JCA report) and CAs for medical devices
M11	Mid-term meeting with Chafea and DG SANTE (to evaluate the progress of work, identify the potential challenges for achieving the planned objectives). Minutes from the meeting
M21	Meeting with European HTA experts – dissemination of results, call for feedback/input on advanced HTA methodology
M24	Advanced HTA methodology for joint work – report, including newly developed templates and guidance documents
M24	Final report on JSCs carried out
M24	Final report on JCA(s) and CA(s) carried out
M24	Final report on coordination activities

Call for tender – Applicants' profile

- ✓ Solid experience in carrying out HTA at national/regional level;
- ✓ Knowledge and experience in developing HTA methodology and/or performing joint HTA activities (e.g. joint REA/CA, ED);
- ✓ Experience in the management and coordination of EU and/or international cooperation projects in the field of health (preferably in the field of HTA), including organising multi-stakeholder activities;
- ✓ Balance geographical coverage within EU.

CHAFEA/LUX/2020/OP/0013

Service Contract for the Provision of Joint Health Technology Assessment (HTA) Work Supporting the Continuation of EU Cooperation on HTA

- **New deadline: 06 May 2021, 17:00 CET**
- Opening of offers: 11 May 2021, 11:00 CET
- Estimated total value: EUR 3 000 000,00
- Duration of the contract: 24 months
- Submission of the offers: through e-tendering

Submitting an offer

Key legal and procedural requirements

General information on tendering

- Economic operators can submit a tender either as a **sole tenderer** or **as a group of tenderers**.
- **A joint tender** is a situation where a tender is submitted by a group (with or without legal form) of economic operators regardless of the link they have between them. The group as a whole is considered a tenderer.
 - **All members of the group assume joint and several liability towards the Contracting authority** for the performance of the contract as a whole
 - **Group members must appoint a Group leader** and a single point of contact authorised to act on their behalf in connection with the submission of the tender and all relevant questions, clarification requests, notifications, etc., that may be received during the evaluation, award and until the contract signature
 - **The joint tender must clearly indicate the role and tasks of each member and of the Group leader who will act as the Contracting authority's contact point for the contract's administrative or financial aspects and operational management.** The Group leader will have full authority to bind the group and each of its members during contract execution. If the joint tender is successful, the Contracting authority shall sign the contract with the Group leader, authorised by the other members to sign the contract on their behalf via power of attorney

General information on tendering

- **Subcontracting** is the situation where the **contractor enters into legal commitments with other economic operators which will perform part of the contract on its behalf**. The contractor retains full liability towards the Contracting authority.
- All contractual tasks may be subcontracted unless the Technical specifications expressly reserve the execution of certain critical tasks to the sole tenderer itself, or in case of a joint tender, to a member of the group.
- Tenderers are required to give an **indication of the proportion of the contract that they intend to subcontract**, as well as to **identify and describe briefly the envisaged contractual roles/tasks of subcontractors** meeting any of these conditions for performance of the contract as a whole.
- Any such subcontractor must provide the tenderer with **a commitment letter**.
- **Changes concerning subcontractors identified in the tender** (withdrawal/replacement of a subcontractor, additional subcontracting) **during the procurement procedure** (after the submission deadline and before contract signature) **require the prior written approval of the Contracting authority** subject to verifications.

Evaluation of tenders

- The evaluation of the tenders that comply with the submission conditions will consist of the following elements:
 - Check if the tenderer has access to procurement (see Section 2.2);
 - Verification of administrative compliance (e.g. signed by duly authorised representative(-s) of the tenderer);
 - Verification of non-exclusion of tenderers on the basis of the exclusion criteria;
 - Selection of tenderers on the basis of selection criteria;
 - Verification of compliance with the minimum requirements defined in the Tender specifications;
 - Evaluation of tenders on the basis of the award criteria.
- The Contracting authority will evaluate the abovementioned elements in the order that it considers to be the most appropriate. If the evaluation of one or more elements demonstrates that there are grounds for rejection, the tender will be rejected and will not be subjected to further full evaluation

Exclusion criteria

- The objective of the exclusion criteria is to assess whether the tenderer is in any of the exclusion situations listed in Article 136(1) of the Financial Regulation.
- As evidence of non-exclusion each tenderer needs to submit with its tender a Declaration on Honour (Annex 2)

Selection criteria

- The objective of the selection criteria is to assess whether the tenderer has:
 - Legal and regulatory capacity,
 - Economic and financial capacity,
 - Technical and professional capacity,

Legal and regulatory capacity

For this specific open call for tenders, tenderers **do not need to prove specific legal and regulatory capacity to perform the contract.**

Economic and financial capacity

Criterion F1	
Minimum level of capacity	Average yearly turnover of the last two financial years above EUR 750.000.
Basis for assessment	This criterion applies to the tenderer as a whole, i.e. a consolidated assessment of the combined capacities of all <i>involved entities</i> will be carried out.
Evidence	Copy of the profit and loss accounts and balance sheet for the last two years for which accounts have been closed from each concerned <i>involved entity</i> , or, failing that, appropriate statements from banks. The most recent year must have been closed within the last 18 months.

The evidence of economic and financial capacity does need not be provided with the tender but may be requested by the Contracting authority or the EU Validation Services at any time during the procedure. Please note that a request for evidence in no way implies that the tenderer has been successful.

Technical and professional capacity

Due to the nature of the tasks requested by this call for tender, it is expected that the tenderer will respond to the following profile:

- Solid experience in carrying out HTA at national/regional level;
- Knowledge and experience in developing HTA methodology and/or performing joint HTA activities (e.g. joint REA/CA, ED);
- Experience in the management and coordination of EU and/or international cooperation projects in the field of health (preferably in the field of HTA), including organising multi-stakeholder activities;
- Balance geographical coverage within EU.

See table on page 24-25 of the tender specifications for details
(minimum requirements + supporting documents)

Award criteria

- The objective of the award criteria is to **evaluate the tenders with a view to choosing the most economically advantageous tender**. In order to determine the most economically advantageous tender for the award of the contract, **a quality/price ratio of 60/40 will be applied to each tender** in the following way:
 - The **points awarded for technical quality multiplied by 0,6** (indicate weighting attributed to the quality).
 - The **points awarded for the price multiplied by 0,4** (indicate weighting attributed to the price).
- The points for technical quality and those for price will then be added together, the tenderers will be ranked according to their total number of points and the contract will be awarded to the tenderer achieving the highest score.

Criterion 1 - Quality of the proposed methodology

60 points – minimum score 60%

This criterion will assess with reference to the **quality and relevance of the proposed methods, how they reflect the objectives of the call for tender and the justification for the proposed methodology**, to fulfil the three tasks as laid down in the tender specifications. The tender must give indications on the methodology to be used in the provision of the service and on its appropriateness for the purpose. It will assess the solutions proposed to consult/involve the HTA community and stakeholders in order to fulfil the tasks covered by this tender.

- Sub-criterion 1.1: Quality and relevance of the proposed methodology for the implementation of Task 1 – HTA methodology (20 points – minimum score 60%)
- Sub-criterion 1.2: Quality and relevance of the proposed methodology for the implementation of Task 2 – Joint HTA work (20 points – minimum score 60%)
- Sub-criterion 1.3: Quality and relevance of the proposed methodology for the implementation of Task 3 – Coordination of HTA activities (20 points – minimum score 60%)

Criterion 2 – Organisation of the work and resources

25 points – minimum score 60%

This criterion will assess the **roles and responsibilities of the proposed team** assigned in relation to the allocated task(s).

It also assesses the **global allocation of time and resources** to the service and to each task or deliverable, and whether this allocation is adequate for the work. This assessment will be based on the details provided by the tenderer in the technical offer on the allocation of time (timetable) and human resources (clear division of the tasks among the staff of the joint tenderers and possible subcontractors) and the rationale behind the choice of this allocation.

It also assesses **the quality and appropriateness of the IT platform to be set-up** and used for the execution of the tasks and the overall management of the service.

Criterion 3 - Quality control measures

15 points – minimum score 60%

This criterion will assess the **quality control system** applied to the service foreseen in this tender specification concerning the quality of the deliverables, the language quality check, risks management and continuity of the service in case of absence of the member of the team dedicated to a particular task.

It will also assess the **adequate organisational and technical measures to ensure the full compliance with the Data protection legal framework** when processing personal data. The data protection plan must be detailed in the tender and specifically refer to the data flows; actors involved, specific actions proposed to comply with data protection principles and obligations. A generic data protection plan will result in a low score under this criterion.

The quality of the proposed **contingency plan** will be assessed under this criterion as well.

Award- Ranking of tenders

The contract will be awarded based on **the most economically advantageous offer, according to the 'best price-quality ratio' award method**. The maximum total quality score is 100 points. Tenders shall be ranked according to the “best price-quality ratio” in accordance with the following formula:

score for tender X	=	$\frac{\text{cheapest price}}{\text{price of tender X}}$	*	100	*	price weighting (in 40%)	+	total quality score (out of 100) for all award criteria of tender X	+	quality criteria weighting (in 60%)
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The tenderers will be ranked according to their total number of points and the contract will be awarded to the tenderer achieving the highest score.

Tenders must score minimum 60% for each criterion and sub-criterion, and minimum 70 % in total. Tenders that do not reach the minimum quality levels will be rejected and will not be ranked.

Submitting the tender

Tenders are to be submitted via the e-Submission application according to the instructions laid down in the Invitation to tender letter and the e-Submission Quick Guide.

Make sure you prepare and submit your electronic tender in e-Submission early enough to ensure it is received within the deadline specified under Heading IV.2.2 of the contract notice.

!! Deadline: 06 MAY 2021 17:00 CET

A tender received after this deadline will be rejected.

Submitting an offer

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English (en) ▾

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Call for tenders' details

Title:	Service Contract for the Provision of Joint Health Technology Assessment (HTA) W...		
Contracting authority:	Consumer, Health, Agriculture and Food Executive Agency (Chafea)		
TED publication date:	28/01/2021	Status:	Open
Time limit for receipt of tenders:	30/04/2021		

Data Document Library Questions & answers

Submit a tender

Information

Tender reference number	CHAFAE/LUX/2020/OP/0013
Title	Service Contract for the Provision of Joint Health Technology Assessment (HTA) Work Supporting the Continuation of EU Cooperation on HTA
Description	The subject of this call for tenders is to address methodological issues to foster joint HTA work supporting EU cooperation in this area. The service is expected to cover the following key: (1) Advance development of HTA methodology to be applied when carrying out joint work (i.e. Joint Clinical Assessments (henceforth 'JCA') and Joint Scientific Consultations (henceforth 'JSC')). (1). Joint HTA work including: (a) 8 JSC for medicinal products or at least, not less than 6; and (b) 2 JCA for medicinal products and 4 JCA/collaborative assessments (CA) for medical devices, not less than 1 JCA for medicinal products and 2 JCA/CA for medical devices respectively.

Actions
Submit a tender
Help
Help on this page

Accessing e-Submission

Microsoft Internet Explorer is no longer a supported browser. Please check the system requirements for more information

Tendering data

Title: Service Contract for the Provision of Joint Health Technology Assessment (HTA) Work Supporting the Continuation of EU Cooperation on HTA

Description: The subject of this call for tenders is to address methodological issues to foster joint HTA work supporting EU cooperation in this area. The service is expected to cover the following key:(1) Advance development of HTA methodology to be applied when carrying out joint work (i.e. Joint Clinical Assessments (henceforth 'JCA') and Joint Scientific Consultations (henceforth 'JSC')). (1). Joint HTA work including:(a) 8 JSC for medicinal products or at least, not less than 6; and(b) 2 JCA for medicinal products and 4 JCA/collaborative assessments (CA) for medical devices, not less than 1 JCA for medicinal products and 2 JCA/CA for medical devices respectively.

Procedure

Procedure reference number: CHAFEA/LUX/2020/OP/0013

Procurement type: Services

Publication date: 28/01/2021

Deadline: 30/04/2021 17:00:59 UTC+02:00

Procedure type: Open procedure

Awarding method: Best price-quality ratio

Opening Date: 04/05/2021 11:00:00 UTC+02:00

36 days left until closure

Consult the procedure documents [here](#) to find out which information and documents the contracting authority requires to be provided or sent in the submission.

Show more



e-Submission service

The e-Submission service of the European Commission allows participants to prepare and submit their responses to procedures electronically in a structured and secure way.

Make sure that you read the **System Requirements** before you start, and that you submit on time.

To use e-Submission, participants (all members of a consortium) must be registered in the Commission online register of organisations participating in the EU grants or procurement procedures. After registration, each organisation obtains a Participant Identification Code (PIC). Registration is free of charge and takes about 5-10 minutes to complete. To check if an organisation is already registered in the Commission organisation register or to register a new organisation, [click here](#).

Yes, I have read and I accept the **Terms and Conditions** and I acknowledge that I have read and understood the **Data Protection Notice**



New submission

e-Submission

Procedure

Procedure reference number

CHAFEA/LUX/2020/OP/0013

Deadline

30/04/2021 17:00:59 UTC+02:00

36 days left until closure

Submission ID: 300014569
Last saved: 25/03/2021 12:10:00 UTC+02:00

Submission documents

1 Ways to submit

2 Parties

3 Tender data

4 Submission report

5 Submit

Different ways to submit.

Please select the appropriate options below and then click 'next' to continue.

Organization type

Sole submission Group submission

Involving subcontractors

Choose the language for your submission

English (en)

Documents for submission

The documents to be submitted with the tender in e-Submission are listed in Annex 1 of the tender specifications.

- **Technical offer.** The technical offer must provide all the information needed to assess the compliance with Section 1.4 of these specifications and the award criteria. Tenders deviating from the minimum requirements or not covering all the requirements may be rejected on the basis of non-compliance and not evaluated further.
- **Financial offer.** A complete financial offer, including the breakdown of the price needs to be uploaded. For this purpose, the Financial Model in Annex 6 shall be completed, duly signed and uploaded in e-Submission.

Q&A session

Thank you



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