



SPECIFICATIONS ATTACHED TO THE INVITATION TO TENDER

Call for tender n° EAHC/2010/Health/02 concerning the identification and development of tools aiming at facilitating recognition of prescriptions from another Member State

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1. Title of contract

Identification and development of tools aiming at facilitating recognition of prescriptions from another Member State

2. Purpose and context of contract

Purpose

The general objective of the contracted services is to facilitate effective mutual recognition of prescriptions among EU Member States (MS) in respect of patient safety. To this purpose the below operational objectives are instrumental:

- The identification and development of a non-exhaustive list of elements to be included in prescriptions,
- The identification and development of tools for the establishment of a register/registers of prescribers fit to practice in their MS. The said register(s) shall be readily accessible to dispensers in other MS',
- A problem measurement meant to identify the current-day size of potential improvements in effectiveness and patient safety resulting from enhanced mutual recognition of prescriptions.

The above objectives are interlinked with other initiatives from the European Commission:

- the EURO-MED-STAT database (see <http://www.euromedstat.cnr.it>)
- Telemedicine (see http://ec.europa.eu/information_society/activities/health/policy/telemedicine/index_en.htm)
- IMI (Internal Market Information System) to the extent IMI aims to enhance administrative cooperation between MS public administration e.g. in the area of the mutual recognition of professional qualifications. (see http://ec.europa.eu/internal_market/imi-net/index_en.html.)

Context

Research (Mäkinen 2007, "Delivery of European cross-border healthcare and the relevance and effects of EU regulations and judicial processes") indicates that the mutual recognition of medical prescriptions issued in another Member State is hampered by (among other reasons) the fact that:

- recognition in some countries is limited to prescriptions issued only in certain MS countries (e.g. the Nordic countries),
- verification of the validity of the prescriber is required prior to dispensing.

Further, this research illustrated (therapeutic) substitution is commonly applied to overcome problems with local non-availability of prescribed products. Restrictions on dispensing of foreign prescription in practice were summarized as pertaining to:

- the type of prescribed product,
- the authenticity of the prescription,
- the medium of the prescription ("paper, fax, etc.").

The above findings clearly corroborate the case for policy action addressing enhanced co-operation in this field, enabling:

- a product verification that is:
 - correct,
 - comprehensive to the extent it should allow for product substitution/exclusion, etc.
- verification of the prescribing authority.

3. Subject of contract

Services to be delivered

The contractor will have to prepare a study which will be divided in 4 main work packages (WP), each corresponding to a deliverable to be made. These WP are detailed below.

WP1: Core set of prescription form items

Prescriptions will apply to medicinal products and medical devices dispensed in an outpatient setting (as applicable in a given MS, most likely pharmacies).

A non-exhaustive list of elements to be included in prescriptions shall be identified ("core set"). This core set shall enable an identification of prescribed products for outpatient delivery that is both correct and comprehensive to the extent it will allow for product substitution/exclusion. Current prescription form practices in MS' shall be described. Finally, current MS practices shall be compared to the proposed core set as regards the technical feasibility of MS adopting the core set.

As regards the overview of current MS practices the applied methodology is likely to build on existing evidence and further **desk research**. A **survey** among MS government officials (at least 1 per MS) will validate existing evidence and fill possible data gaps. No face-to-face meetings are requested.

Existing evidence on prescription form items shall be identified to design two **structured questionnaires** (one for medicinal products and one for medical devices). Next, **expert panel** expertise shall be sought to establish a consensus core set of prescription form items. As regards medicinal products, a **two-round Delphi survey** (first round starting with the above mentioned structured questionnaire) shall be performed in an expert group comprising 25 prescribers (as qualified in their MS of practice, likely to be physicians, though not including pharmacologists), 25 providers (as qualified in their MS of practice; likely to be pharmacists) and 10 pharmacologists. Per MS at least 1 expert should be present in this group. As regards medical devices, a two-round Delphi survey (first round starting with the above mentioned structured questionnaire) shall be performed in an expert group comprising 25 prescribers (as qualified in their MS of practice; likely to be GPs or orthopaedic physicians), 25 providers (as qualified in their MS of practice; likely to be pharmacists and/or medical equipment shop keepers and/or orthotists). Per MS at least 1 expert shall be present in this group. Experts are not allowed to be in both groups. Both expert groups can be consulted by mail, web-based applications, etc. No face-to-face meetings are requested. Based on the outcome of expert panel expertise and the overview of current MS practices (see above) it shall be decided how core sets for medicinal products and devices can be combined in a single core set.

Finally, the proposed core set shall be assessed vis-à-vis current MS practices in a technical report. This report will identify organisational issues per MS related to either adopting a common prescription format for all prescriptions or adopting a specific prescription format for cross-border care only.

The expected deliverable (Deliverable 1) for WP1 consists of one report with three sections:

- Firstly describing the methods applied and the resulting outcomes of the establishment of the "**overview of current MS practices**".
- Secondly describing the methods applied and the resulting outcomes of the establishment of the "**core set**".
- Thirdly a technical section should **identify organisational issues** per MS related to either adopting a common prescription format for all prescriptions or adopting a specific prescription format for cross-border care only.

The draft deliverable shall be transmitted to EAHC/DG SANCO by the start of month 7 (see timeframe below).

WP2: Prescriber register(s)

Prescribers are defined as health professionals qualified in their MS of practice to prescribe medicinal product and/or medical devices for outpatient delivery.

The ability for dispensers to verify the authority of prescribers practicing in other MS' is critical for effective dispensing practices. Two options shall be identified and analysed:

- a) an EU-centralized prescriber register accessible to dispensers in another MS,
- b) national prescriber registers accessible to dispensers in another MS.

These options shall be compared to current practices to analyse the technical feasibility of MS' adopting a prescriber register/ prescriber registers accessible to dispensers in another MS.

Desk research and a **survey** among MS government officials (at least 1 per MS) will enable a comparison of current prescriber register practices in MS'.

For both options (a) and b) above) an assessment is needed of issues related to interoperability, data transfers, accessibility (rights), update frequency and quality mechanisms. This evaluation will mainly require **expertise** from the contractor on **organisational, IT and legal issues**.

Finally, the proposed options will be analysed vis-à-vis current MS practices in a **feasibility analysis** (report as output) assessing organisational, IT and legal differences.

The expected deliverable (Deliverable 2) for WP2 consists of one report with three sections:

- Firstly describing the methods applied and the resulting outcomes of the establishment of the "comparison of current prescriber register practices in MS'".
- Secondly describing the methods applied and the resulting outcomes of the assessment of both register options.
- Thirdly describing the "feasibility analysis assessing organisational, IT and legal differences".

The draft deliverable shall be transmitted to EAHC/DG SANCO by the start of month 7 (see timeframe below).

WP3: Problem measurement

The changes (improvements) in effectiveness and patient safety of dispensing practices resulting from possible future changes made by MS' in line with recommendations in this project (refer also to WP4) shall be identified. A problem measurement is therefore requested (the problem being ineffective recognition of prescriptions) and an operational scheme needed. This measurement scheme should:

- identify a set of indicators best capturing the problem size and typology,
- allow for a comparative measurement of said indicators, both under the current and hypothetically altered cross-border prescriber-dispenser setting.
- address practical issues (organisation, sampling issues, updatability etc.).

Note that the validity of the measurement scheme shall be justified in general terms (e.g. "likely to cover x% of cross-border prescriptions at present time") and that indicators as well shall be defined in general terms (cf infra).

The contractor shall carry out a **desk research** which will identify:

- the most relevant pathologies in terms of prevalence (certain chronic conditions, seasonal allergies, etc.) in this subpopulation of cross-border care patients. At least 6 different pathologies should be included (note that at least 1 medical device should be covered in the eventual list of selected products).
- the most relevant "prescriber-dispenser country combinations" as related to factors such as tourism, temporary work abroad, etc. At least 4 different MS' shall be included, of which at least 3 different prescriber MS' and at least 3 different dispenser MS' and at least 4 different prescriber-dispenser MS combinations.
- problem measurement indicators (such as correct dispensing / assessment method of evidence-based nature of observed (therapeutic/generic) substitution /non-dispensing / wrong-dispensing).

Based on the above desk research a **structured questionnaire** shall be drafted. **Expert panel input** will then be sought to identify the most relevant medicinal products and medical devices for the considered patient population. A **two-round Delphi survey** (first round starting with the above mentioned structured questionnaire) shall be performed in an expert group comprising 30 prescribers (as qualified in their MS of practice to prescribe medicinal products and/or medical devices). Experts shall be practicing in one of the selected prescriber MS and balanced proportionally to MS (patient) population. Experts are allowed to also be present in one of the expert groups from WP1. At least 10 different products shall be selected, including at least 1 medical device. No face-to-face meetings are requested.

The problem measurement will present **mock prescriptions** (presenting hypothetical prescriptions for selected medicinal products / medical devices) among dispensers in selected dispenser MS'. Two measurements will be done:

- "control measurement": based on the current prescription formats from prescriber countries
- "intervention measurement": based on the "core set" identified under WP1.

A **Sampling design** analysis shall be performed to identify the needed minimum number of dispensers in both measurement groups.

The results from the comparative measurement test shall subsequently be submitted to an **expert panel** to draw patient safety conclusions in terms of expected health events (e.g. adverse events) and their quantitative impact: days in hospital/days off work/quality-of-life/healthy life years/...) for both measurements. A **three-round Delphi survey** (first round starting with identification of possible health impacts) shall be performed in an expert group comprising 30 physicians (including 10 pharmacologists). Per MS at least 1 expert should be present in this group. Experts are not allowed to have been involved in any of the other WPs. No face-to-face meetings are requested.

The expected deliverable (Deliverable 3) for WP3 consists of one report describing the methods applied and the resulting outcomes of design, execution and assessment of the problem measurement.

The draft deliverable shall be transmitted to EAHC/DG SANCO by the start of month 13 (see timeframe below).

WP4: Summary Report

The output from work packages 1-3 shall be integrated in a **summary report** containing recommendations on a core set of prescription items, prescriber register practice and health outcome measurement schemes. Organisational/legal and other bottlenecks related to said recommendations shall be identified and strategic/operational **recommendations** to address the identified issues shall be made. An executive summary of no more than 5 pages shall be included in the summary report.

The expected deliverable (Deliverable 4) for WP4 is the "summary report". The draft deliverable shall be transmitted to EAHC/DG SANCO by the start of month 13 (see timeframe below).

Timeframe for providing the services

The overall indicative timeframe is the following:

MONTH	ACTIVITY
M 1	Kick-off meeting in Brussels or Luxembourg; inception report documenting the discussion and agreements in the meeting
M 7	Draft Deliverables 1 and 2 (transmitted by the start of the month) Meeting in Brussels or Luxembourg to discuss deliverables 1 and 2
M 9	Final version of deliverables 1 and 2 (interim report)
M 13	Draft deliverable 3 and 4 (transmitted by the start of the month) Meeting in Brussels or Luxembourg to discuss deliverable 3 and 4 + debriefing.
M 14	Final versions of deliverable 3 and 4 (final report)

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

Generally, the meetings will take place in the offices of Unit C5 (Health Strategy and Health Systems), Directorate-General for Health and Consumers (Brussels, Rue Froissart 101) or at the Health Unit, Executive Agency for Health and Consumers (Luxembourg, Rue Guillaume Kroll 12.).

Three visits are requested (timing is referred to in the above time frame). Meetings concern (expected output):

- Kick-off meeting: summary of timelines, task package and further questions on project.
- Presentation of draft deliverables 1 and 2
- Presentation of draft deliverables 3 and 4

PowerPoint presentations are requested at each meeting. The presentations and any other documents should be sent to EAHC/DG SANCO at least 5 working days before the meeting. Minimum attendance includes the team leader and two team members. All costs related to these meetings will be covered by the final contract price.

7. Variants

Variants are not accepted.

8. Volume of contract

The maximum contract price is **EUR 400.000**.

The duration of the contract is 16 months; the tasks covered by the Contract shall be completed within 14 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, summarizing the discussion of and agreements made in the kick-off meeting;
- 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 (defined as deliverable 1 and 2);
- 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 (deliverables 1 and 2), 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 (final version of deliverables 3 and 4);
- 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 reports or documents:** in 5 hard copies and in electronic format, in English

The interim report is defined as the deliverables 1 and 2. These must be sent to the Executive Agency no later than 7 months after signature of the contract.

- **Final report:** in 5 hard copies and in electronic format, in English

The final report is defined as deliverable 3 and 4.

The draft final report must be submitted to the Executive Agency no later than 13 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 1995¹;

(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 1997²;

(c) cases of participation in a criminal organisation, as defined in Article 2(1) of Joint Action 98/733/JHA of the Council³;

(d) cases of money laundering as defined in Article 1 of Council Directive 91/308/EEC⁴.

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;
- (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;

¹ Official Journal of the European Communities, C 316, 27.11.1995, p. 48.

² Official Journal of the European Communities, C 195, 25.06.1997, p. 1.

³ Official Journal of the European Communities, L 351, 29.12.1998, p. 1.

⁴ Official Journal of the European Communities, L 166, 28.06.1991, p. 77.

- (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 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.

The tenderers' capacity will be assessed on the basis of the economic and financial capacity and the technical and professional capacity criteria:

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 ⁵	$\frac{\text{Current Assets (3)}^6}{\text{Trade and Other Debts (6)}}$
Profitability	Profitability Ratio ⁷	$\frac{\text{Gross Operating Profit (14)}}{\text{Turnover (7)}}$

⁵ For the last year for which accounts have been closed

⁶ The figures mentioned between brackets refer to the respective accounts listed in Annex VII

⁷ For the best of the last two years for which accounts have been closed

Solvency	Financial Autonomy Ratio ⁸	$\frac{\text{Capital and Reserves (4)}}{\text{Total Liabilities (4 + 5 + 6)}}$
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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.

⁸ 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. The project team should have at least 15 years of relevant professional experience (cumulated over team members and team leader) in the field of public health research,
- ii. The tenderer must have the capacity to put together a team with members of at least 3 years experience for each of the following relevant professional activities within the healthcare field:
 - o survey methods,
 - o expert panel consultation methods,
 - o IT (data systems interoperability, data confidentiality, etc.),
 - o statistics (sampling design issues, epidemiology, etc.),
 - o organisation of healthcare systems, and
 - o legal expertise (data confidentiality, etc.).

The team shall have a leader with at least 7 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.
- (b) 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.

(c) the reference list of the principal services/works provided by the tenderer in the past 5 years, with the sums and the dates.

TECHNICAL PART

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

In particular, the tenderer shall prove that it understood the background and the objectives of the call for tender; it shall describe how (e.g. with what kind of a methodology) the study, divided into 4 work packages will be prepared, and how the implementation (including the possible risks) of the contract will be managed.

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.	Understanding of the objectives of the contract and the work to be carried out	40
2.	Methodology	40
3.	Management of the performance of the project	20
<i>Total points</i>		100

The criteria are detailed as follows:

Award criterion 1 – Understanding of the objectives of the contract and the work to be carried out

This criterion serves to assess whether the tenderer has understood all of the issues involved, as well as the nature of the work to be undertaken and the content of the final products.

Award criterion 2 – Methodology

Offers will be assessed with reference to the suitability of the proposed methods for analysing, reviewing and evaluating documents/websites in accordance with the needs of the contracting authority as laid down in the tender specifications.

The tender should give indications on the methodology used in the work that will be undertaken and on its appropriateness for this purpose, in conformity with the guidelines included in the approach. Special attention shall be given to the proposed methodology related to WP3.

Since assessment of the tenders will be based on the quality of the proposed services, tenders should elaborate on all points addressed by these specifications in order to score as many points as possible. The mere repetition of mandatory requirements set out in these specifications, without going into details or without giving any added value, will only result in a very low score. In addition, if certain essential points of these specifications are not expressly covered by the tender, the Executive Agency may decide to give a zero mark for the relevant qualitative award criteria.

Award criterion 3 – Management of the performance of the project

Offers will be assessed as regards 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.

For criterion 2 above, a 75% threshold is required. Tenderers falling below this threshold will be eliminated. Moreover, tenders that have not obtained a total at least 60 out the 100 points will be excluded.

(b) Price.

Technical quality will be weighed against price on a 60/40 basis.

The points of the price are calculated by the following formula:

$(\text{price of the lowest passing bid} / \text{price of the bid in question}) \times 100.$

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

- The points awarded for the technical quality by 0.60
- the points awarded for the financial bid by 0.40.

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.