## CALL FOR TENDERS

**EDQM-AO-2020-Framework contract for the provision of international consultancy services for Reorganising the Romanian Blood System**

<table>
<thead>
<tr>
<th>Object of the procurement procedure</th>
<th>Purchase of international consultancy services for the Reorganising the Romanian Blood System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project</td>
<td>REFORM/IM2020/021 - SRSP2019/273.01</td>
</tr>
<tr>
<td>Organisation and buying entity</td>
<td>Council of Europe European Directorate for the Quality of Medicines and HealthCare</td>
</tr>
<tr>
<td>Type of contract</td>
<td>Framework Contract</td>
</tr>
<tr>
<td>Duration</td>
<td>The contract shall be effective from the date of signature by both parties, for a period until the 30 November 2022. It is tacitly renewable 4 times, for periods of 03 months (maximum validity until 30 November 2023). A decision not to renew the contract may be taken by the Contracting Authority. In such case it shall be notified to the Contractor by registered letter with acknowledgement of receipt at least 1 month before renewal date. The Contractor cannot refuse the renewal of the contract.</td>
</tr>
<tr>
<td>Expected starting date</td>
<td>October 2020</td>
</tr>
<tr>
<td>Deadline for tendering</td>
<td>22 October 2020</td>
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  The TERMS OF REFERENCE describe what will be expected from the selected Providers.

- **The TENDER RULES**................................................................. 28
  The TENDER RULES explain the procedure through which the tenders will be submitted by the tenderers and assessed by the Council of Europe.

- **The ACT OF ENGAGEMENT (See Document attached)** is the document formalising the consent of the Parties to be bound by the LEGAL CONDITIONS, which are the legal provisions which will be applicable between the Council of Europe and the selected Providers. It also contains the TABLE OF FEES, which indicates the applicable fees, throughout the duration of the contract.

### HOW DOES A FRAMEWORK CONTRACT WORK?

**Stage 1:**
SELECTION of qualified Providers through a call for tenders and signature of a framework contract with all the pre-selected Providers.

**Stage 2:**
ORDER(s) are addressed, on an as needed basis, throughout the duration of the contract, to the designated Provider(s).

**Execution** as from the date of signature of each Order, unless the Order concerned provides otherwise.

### HOW TO SUBMIT A TENDER?

**Step 1:** Read the TENDER FILE

**Step 2:** Complete the ACT OF ENGAGEMENT and collect the required SUPPORTING DOCUMENTS, as listed in section F of the terms of reference (below).

**Step 3:** Send your TENDER, in accordance with the Tender Rules
### PROJECT SUMMARY

**Project Title:** Reorganisation of the Romanian Blood System  
**Beneficiary country:** Romania  
**Maximum budget of the global project:** 700 000 Euros  
**Funding:** European Union under the Structural Reform Support Programme (SRSP) coordinated by its Directorate General for Structural Reform and Support (DG-REFORM)  
**Implementing organisation:** Council of Europe/European Directorate for the Quality of Medicines and HealthCare  
**Starting date:** October 2020

### CONSULTANCY SERVICE SUMMARY

**Consultancy service:** Intellectual consultancy service  
**Estimated total budget for this call for tender (consultancy services):** 252 400 Euros ex. VAT  
(For information, this excludes travelling costs, which will be borne directly by the EDQM/CoE.  
**Estimated Maximum number of expert days:** 631 days  
**Number of lots:** 3
A. BACKGROUND AND DESCRIPTION OF THE PROJECT

Brief description of the Project

The European Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM/CoE) will implement from 1 October 2020 up to 30 November 2022 a Project “Reorganisation of the Romanian Blood System (RBS)” funded by the European Union (EU) under the Structural Reform Support Programme (SRSP) which is coordinated by its Directorate General for Structural Reform and Support (DG-REFORM).

The project aims to support Romania to restructure their blood transfusion system including the blood transfusion service and its regulatory oversight, the objective of which is to build a fit for purpose and efficient system aligned with European Union and Council of Europe standards, in order to cover the blood components needs of the population in Romania.

In that context, the EDQM /CoE is looking for International Consultants for the provision of expertise and consultancy services to be requested by the Council on an as needed basis.

>>> More information about the EDQM – See annex 1 on page 27

Detailed description of the Project

The Romanian Ministry of Health (MoH) requested support for the reorganisation of the Romanian Blood System (RBS) from the EU under the Structural Reform Support Programme (SRSP). The support provided by the SRSP for reorganising the RBS (including both the blood transfusion service and its regulatory oversight) will be implemented by the EDQM/CoE over a maximum 26 months period as of 1 October 2020 within the frame of a Delegation Agreement signed between the Council of Europe and the DG REFORM.

The following outcomes of the project are expected:

- **Outcome 1**: The Romanian MoH agrees on and adopts the proposals for reforming the Romanian Blood System;
- **Outcome 2**: The Romanian MoH agrees on and adopts the implementation action plan on how to reform the Romanian Blood System;
- **Outcome 3**: The Romanian MoH agrees on and adopts the implementation action plan for developing training programmes;

The overall objective and expected impact of the project is that the Romanian MoH take the necessary steps to build a fit for purpose and efficient blood transfusion system.

In order to reach these outcomes, a number of activities are planned with the aim of delivering a number of outputs (immediate results), which are summarised in the below table.

---

1 **Romanian Blood System (RBS)**: The Romanian Blood transfusion service (Blood Establishments (BEs), Hospital Blood Banks (HBBS) and Testing Laboratories) and its regulatory oversight by the appropriate bodies (e.g. designation, authorisation inspection and haemovigilance);
Please note that the project will be carried out with the support of an EDQM project coordinator and an assistant. The EDQM project coordinator will also provide scientific and technical support to the project.
<table>
<thead>
<tr>
<th>OUTPUTS</th>
<th>Key activities per output for which expertise and consultancy service is required</th>
<th>Transversal activities throughout the project</th>
</tr>
</thead>
<tbody>
<tr>
<td>OUTPUTS 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Output 1.1. Inception report</strong>&lt;br&gt;The inception report will aim to complement and fine-tune the understanding of the project’s scope and working methods.</td>
<td>- Development of Terms of Reference for involved parties&lt;br&gt;- Fine-tuning of the project planning, working methodology and governance&lt;br&gt;- Research activities to fine-tune the project plan and to propose an evidence-based proposal for restructuring the RBS</td>
<td></td>
</tr>
<tr>
<td><strong>Output 1.2. Report of Proposals for restructuring the RBS</strong>&lt;br&gt;The report of proposals for restructuring the RBS will describe the steps to reform the RBS at a national level sustained with a gap analysis and comparison of potential scenarios for restructure.</td>
<td>- Building a gap analysis around the restructuring components of the project&lt;br&gt;- Organising validation meeting(s) with key stakeholders to review the restructuring proposals</td>
<td>- <strong>Transversal activities:</strong>&lt;br&gt;Meetings (physical and/or virtual meetings) will be organised on a regular basis and as needed with other selected providers for all outputs and the EDQM’s project coordinator&lt;br&gt;- On-site visits in Romania&lt;br&gt;- Joint drafting of documents, reports and deliverables</td>
</tr>
<tr>
<td>OUTPUTS</td>
<td>Key activities per output for which expertise and consultancy service is required</td>
<td>Transversal activities throughout the project</td>
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<td>--------------------------------------------------------------------------------</td>
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<tr>
<td><strong>OUTPUTS 2</strong></td>
<td></td>
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</tbody>
</table>
| **Output 2.1. Report on IT system** - The IT system report will provide key elements for the development or redesign of a national IT system covering the entire vein-to-vein process of the Romanian blood transfusion service i.e. covering activities performed at BE, HBB and testing laboratories. The report will also contain guidance for Romania to prepare a tender application. | - Presentation of the methodology  
- In-depth analysis of the current national ICT systems used by blood transfusion services (AS-IS analysis)  
- Gathering the business requirements (BR)  
- Defining and validating BR with case scenarios  
- Defining the TO-BE model of the national IT system for blood transfusion services  
- Training for preparing a tendering application | |
| **Output 2.2. Report on investment plan to carry-out the reform** - The reform of the RBS will require significant investments, including on infrastructure, equipment, material and transport/logistics and human resources. The report will include a 5 years investment plan, with clear investment priorities and possible sources of funding from national and international sources (e.g. EU structural funds, European Investment Bank funds). It will also provide different investment scenarios with estimates for investment needs, which will be produced based on costs provided by Romania. | - Presentation of the methodology  
- Strategic orientation: Defining the objectives, key principles for the investment plan  
- Assessment of the investment needs  
- Study visit to validate the preliminary investment list  
- Preliminary feasibility analysis for the investment plan  
- Training on cost and economic analysis | |
| **Output 2.3. Report on Plans of Action for the Blood services and Regulatory oversight** - The operational action plans for the Romanian Blood Service and regulatory oversight will provide concrete steps to establish the new Romanian Blood System. Each action plan will include several scenarios and corresponding change management strategies for the reconfiguration of the regulatory oversight and 2 strategic BEs. | - Presentation of the methodology  
- Action Plan for restructuring the regulatory oversight system:  
  - Modelling of the regulatory oversight entities, functions and activities to be carried out to implement the reform  
  - Validation of scenarios with the MoH and other stakeholders  
  - Elaboration of a change control strategy  
  - Validation of the change control strategy  
- Action Plan for restructuring of the Romanian Blood service:  
  - Modelling of the functions and activities to be carried out at 2 selected BEs  
  - Validation of scenarios with the MoH and other stakeholders  
  - Elaboration of a change control strategy  
  - Validation of the change control strategy | |

**Transversal activities:**  
- Meetings (physical and/or virtual meetings) with the other selected providers for all outputs and EDQM project coordinator on a regular basis and as needed  
- On-site visits in Romania  
- Joint drafting of documents, reports and deliverables
### OUTPUTS

<table>
<thead>
<tr>
<th>OUTPUTS 3</th>
<th>Key activities per output for which expertise and consultancy service is required</th>
<th>Transversal activities throughout the project</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Output 3 - Education and training report</strong>&lt;br&gt;The report will provide Romania with a mapping of staff, their responsibilities and required education and training per sector and actions on setting up the necessary trainings</td>
<td>- Presentation of the methodology &lt;br&gt;- Mapping of staff responsibilities and existing qualification and training &lt;br&gt;- Gap analysis of current qualification and training performed against needs &lt;br&gt;- Elaboration of a training action plan &lt;br&gt;- Validation of the training action plan &lt;br&gt;- Organisation of twining visits</td>
<td><strong>Transversal activities:</strong>&lt;br&gt;- Meetings (physical and/or virtual meetings) with the other selected providers for all outputs and EDQM project coordinator on a regular basis and as needed &lt;br&gt;- On-site visits in Romania &lt;br&gt;- Joint drafting of documents, reports and deliverables</td>
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</table>

### CONFERENCE

<table>
<thead>
<tr>
<th></th>
<th>Preparing and presenting presentations</th>
<th>Transversal activities:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A conference will be organised during which the results of the project will be presented.</strong></td>
<td>- <strong>Preparing and presenting presentations</strong></td>
<td><strong>Transversal activities:</strong>&lt;br&gt;- Meetings (physical and/or virtual meetings) with the other selected providers for all outputs and EDQM project coordinator on a regular basis and as needed &lt;br&gt;- On-site visits in Romania &lt;br&gt;- Joint drafting of documents, reports and deliverables</td>
</tr>
</tbody>
</table>

>>> An indicative allocation of activities, estimated number of days per activity and timeline is provided in Annex 2 to this tender. This information might be subject to change during the execution of the contract.
B. SCOPE OF THE FRAMEWORK CONTRACT
This call for tenders will give rise to a multi-operator framework contract to provide expertise and consultancy services to support the reorganisation of the Romanian Blood System at an overall, all-inclusive price, with:

- a maximum of 6 providers (“pre-selected providers”) for lot n°1,
- a maximum of 4 providers (“pre-selected providers”) for lot n°2,
- a maximum of 4 providers (“pre-selected providers”) for lot n°3,

provided that there are sufficient candidates satisfying the exclusion and eligibility criteria.

There are no lower limits on the annual value of this framework contract.

This Contract is currently estimated to cover up to about 39 activities, to be performed at the latest by 30 November 2022. This estimate is for information purposes only and shall not constitute any sort of contractual commitment on the part of the EDQM/CoE. The Contract may potentially represent a higher or lower number of activities, depending on the evolving needs of the Organisation.

For information purposes only, the maximum total budget of the project amounts to 700 000 Euros and the total amount of the expertise and consultancy services object of present tender is estimated at 252 400 Euros tax excluded for the whole duration of the Framework Contracts. This information does not constitute any sort of contractual commitment or obligation on the part of the EDQM/Council of Europe.

The present tendering procedure aims to select Providers to support the implementation of the Project and is divided into the following lots:

**Lot 1:** Provision of expertise and consultancy service to develop restructuring proposals for the Romanian Blood System, action plans, including several scenario) to implement the restructuring proposals for the restructuration of the regulatory oversight and 2 strategic BEs and/or developing action plan for developing training and education programmes, including contribution to finetuning of the overall project scope, governance, working methodology for the outputs.

**Lot 2:** Provision of expertise and consultancy service to develop business requirements (including AS-IS, TO BE models and Business requirements) for the design or redesign of the vein to vein IT system used by Romanian BEs and HBBs and providing guidance on preparing a tender application, including contribution to finetuning of the overall project scope, governance, working methodology for the outputs.

**Lot 3:** Provision of expertise and consultancy service to develop a 5 years investment plan (including infrastructure, equipment, material and transport/logistics for the RBS) and providing providing guidance on how to perform a cost and economic analysis, including contribution to finetuning of the overall project scope, governance, working methodology for the outputs.
It is possible to bid for more than one lot. Providers wishing to bid for two or more lots should submit a single bid covering the relevant lots together with one Act of Engagement per lot.

Throughout the duration of the Framework Contract, pre-selected Providers may be asked to:
<table>
<thead>
<tr>
<th>Lot 1</th>
<th>Deliverables to be drafted/contribution to deliverables</th>
<th>Maximum number of providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Contribute to finetuning of the overall project scope, governance, working methodology to reach the outputs and outcomes of the project, - Cooperate and participate in meetings with other providers working on the project as part of a team, - Participate in and contribute to preparation of meetings, study visits and the final conference organised in Romania, - Perform research activities including desk-based research, surveys, interviews, focus group meetings and collecting of cases/issues/observations, - Perform contextual/gap analysis, - Deliver presentations in meetings, trainings, conference, - Provide specific expertise and written contribution on regulatory oversight, legislation, blood transfusion, quality management in view of developing specific document on a given topic, - Conduct research and needs assessment on national blood legislation, - Advice on and propose amendments of the national legislation and institutional governance, - Advice and propose evidence-based proposals on how to reorganise/restructure the RBS, - Convert the proposals for restructuring of the regulatory oversight into operational actions plan i.e activities to be carried out to reach the restructuration, - Model the regulatory oversight entities, functions and activities, interaction between entities, quality documents to be in place, - Propose scenarios to restructure the regulatory oversight entities and validate them,</td>
<td>- Contribute to the drafting and review of meetings and study visit(s) reports, - Contribute to the drafting and review of terms of reference for involved parties, - Draft, contribute to the drafting and review of surveys, interviews questions, - Compile various type of data e.g. observations, cases and translate them into meaningful information, - Draft, contribute to the drafting of analytical reports e.g. assessment, contextual/gap analysis report, SWOT analysis, - Contribute to the drafting and review inception report, - Draft, contribute to the drafting and review of a comprehensive report on restructuring the RBS, including the reform framewerk to be followed, SWOT analysis, scenarios for the restructuration, retained proposals covering roles and responsibilities of bodies being part of the RBS (regulatory oversight bodies, BEs, HBBs, proposals for the centralisation, as needed, of collection, processing, storage, transport and testing processes, human resources, recommendations on changes to be made in the national legislation, - Draft, contribute to the drafting of key quality documents describing activities to be carry out by the regulatory oversight authority, - Draft, contribute to the drafting of the Quality Manual of the BEs, a list of minimum quality documents, list of training to facilitate the implementation, - Draft, contribute to the annual work plan of activities, - Draft, contribute to the drafting of the change control strategies - Draft, contribute to the drafting and review of comprehensive reports on the development of action plan to restructure the regulatory oversight authority and the blood transfusion service, including the methodology, the proposed scenario, the retained scenario, the action plan/change control strategies and guidance on cascading the operational action plan to other occupations/regions. - Draft an education and training report providing Romania with a mapping of staff, their responsibilities and required education and training per sector and actions on setting up the necessary training,</td>
<td>6</td>
</tr>
</tbody>
</table>
| Lot 2 | - Propose a change control strategy (e.g. step to be executed in each department) for the retained scenario and validate it,
- Convert the proposals for restructuring of the RBS into operational actions plan i.e. activities to be carried out by 2 strategically selected BEs to reach the restructuring,
- Propose scenarios to restructure 2 strategically selected BEs and validate them,
- Propose a change control strategy (e.g. step to be executed in each BE) for the retained scenario and validate it,
- Assess needs for education and training i.e. mapping, gap analysis,
- Propose an action plan for setting-up of education and training programmes,
- Deliver presentations in meetings, trainings, conference. |

|   | - Contribute to finetuning of the overall project scope, governance, working methodology to reach the outputs and outcomes of the project,
- Cooperate and participate in meetings with other providers working on the project as part of a team,
- Participate in and contribute to preparation of meetings, study visits and the final conference organised in Romania,
- Perform research activities including desk-based research, surveys, interviews, focus group meetings and collecting of cases/issues/observations,
- Perform research and contextual/gap analysis,
- Deliver presentations in meetings, trainings, conference, |

|   | - Contribute to the drafting and review of meetings and study visit(s) reports,
- Contribute to the drafting and review of terms of reference for involved parties,
- Compile various type of data e.g. observations, cases into meaningful information,
- Draft, contribute to the drafting and review of surveys, interviews questions,
- Draft/contribute to the drafting of analytical reports e.g. assessment, contextual/gap analysis report, SWOT analysis.
- Draft the AS-IS model,
- Draft the Business Requirements Document,
- Draft the TO-BE model, including the technical architecture and action plan,
- Prepare a training and its manual for drafting tender specifications of the IT system;
- Draft a comprehensive report containing the methodology used provide key elements for the development or redesign of a national IT system | 4 |
- Provide specific expertise and written contribution on development of IT systems and related project management approach e.g. AGILE,
- Finetune the methodology to be followed to provide key elements (AS-IS analysis, Business Requirements (BR), TO BE model) for the development or redesign of a national IT system covering the entire vein-to-vein process of the Romanian blood transfusion service (covering activities performed at BE, HBB and testing laboratories),
- Perform an in-depth analysis of the current national ICT systems used by blood transfusion service (AS-IS analysis),
- Gather the BR,
- Define and validate BR with case scenarios,
- Define the TO BE model,
- Contribute to the development and organisation of study visits, including workshops with Romanian stakeholders to gather the BR and validate them,
- Develop and provide a training for drafting tender specifications of the IT system;

Lot 3

- Contribute to finetuning of the overall project scope, governance, working methodology to reach the outputs and outcomes of the project,
- Cooperate and participate in meetings with other providers working on the project as part of a team,
- Participate in and contribute to preparation of meetings, study visits and the final conference organised in Romania,
- Perform research activities including desk-based research, surveys, interviews, focus group meetings and collecting of cases/issues/observations,
- Perform research and contextual/gap analysis,
- Deliver presentations in meetings, trainings, conference;

- Contribute to the drafting and review of meetings and study visit(s) reports,
- Contribute to the drafting and review of terms of reference for involved parties,
- Compile various type of data e.g. observations, cases into meaningful information,
- Draft, contribute to the drafting and review of surveys, interviews questions,
- Draft/contribute to the drafting of analytical reports e.g. assessment, contextual/gap analysis report, SWOT analysis,
- Draft, contribute to the drafting and review of a comprehensive investment plan report which will include a five-year investment plan, with clear investment priorities and possible sources of funding from national and international sources (e.g. EU structural funds, European Investment Bank,
- Provide specific expertise and written contribution on development of investment plans systems and related project management approach,
- Finetune the methodology to be followed to establish a five years investment plan,
- Define the strategic orientation of the investment plan,
- Assess the investment needs for infrastructure, equipment, material and transport/logistics and validate them,
- Perform a feasibility analysis of the investment plan
- Develop and provide a training on cost and economic analysis for an investment plan,

funds) and which will provide different investment scenarios with estimates for investment needs, produced based on costs provided by Romania.

- For all the above:
  o Facilitate the development of desired deliverables, as requested by the EDQM/Council of Europe and in compliance with EDQM/Council of Europe standard.

The above list is not considered exhaustive. The Council reserves the right to request deliverables not explicitly mentioned in the above list of expected services, during the framework contract, but related to the field of expertise object of the present Framework Contract.
C. OBLIGATIONS OF THE PROVIDER
The Provider undertakes to take account of the Council’s needs by seeking, throughout its performance of the contract and whenever necessary, all information and/or documents useful for a perfect understanding of those needs.

The Provider undertakes to inform and advise the Council at all stages of the Project and to warn the Council, in good time, of any difficulties. The Provider undertakes to advise the EDQM about any precaution to be taken and warn if the mission can impact the project.

The Provider undertakes in particular to notify the Council without delay, in writing, of the necessity for the Provider to provide missing information.

In terms of quality requirements, the pre-selected Service Providers must ensure, inter alia, that:

- The services are provided to the highest professional/academic standard;
- Any specific instructions given by the Council – whenever this is the case – are followed.

In addition to the orders requested on an as needed basis, the Provider shall keep regular communication with the Council to ensure continuing exchange of information relevant to the project implementation. This involves, among others, to inform the Council as soon as it becomes aware, during the execution of the Contract, of any initiatives and/or adopted laws and regulations, policies, strategies or action plans or any other development related to the object of the Contract (see more on general obligations of the Provider in Article 3.1.2 of the Legal Conditions in the Act of Engagement).

Unless otherwise agreed with the Council, written documents produced by the Provider shall be in English (see more on requirements for written documents in Articles 3.2.2 and 3.2.3 of the Legal Conditions in the Act of Engagement).

D. FEES
Bidders are invited to indicate their unit fees, by completing the table of fees, as attached in Section A of the Act of Engagement. These fees are firm and not subject to review.

For reminder, the maximum fees authorised is 400€ (excluding VAT) per day for the provision of the services described in this document.

Bidders proposing fees above the exclusion level indicated in the Table of fees (400€ per day) will be entirely and automatically excluded from the tender procedure.

The UNITS OF WORK ARE TIME-BASED (e.g. DAILY FEES):

The Council/EDQM will indicate on each letter of intent to order the global fee corresponding to each deliverable or tasks to be performed, calculated on the basis of the daily fees, as agreed by this Contract.
D.1 Travelling expenses

In the event of the Provider being required to travel for the purposes of the contract, and provided the Terms of reference for a specific deliverable to be indicated in each Order Form do not stipulate that the global fees already include travel and subsistence expenses, the Council undertakes, subject to its prior agreement, to reimburse travel and subsistence allowances in compliance with the Council’s applicable Rules.

See more about the terms and conditions of the reimbursement of Other expenses in the provision 4.4. of the Section C. Legal conditions of the Act of Engagement.

D.2 Other expenses

Expenses incurred by experts in connection with their attendance at meetings and onsite visits, such as visa fees and vaccination costs, which are strictly unavoidable, shall be reimbursed. Such claims shall be accompanied by evidence of the expenditure actually incurred.

Expenses related to insurance, printing, translation, communication by telephone or fax, the use of the Internet, and rental of meeting rooms are not reimbursable.

Local travel costs incurred during meeting days are provided for within the daily allowances paid for attendance at meetings and shall not therefore be directly reimbursed.

All other expenses will not be borne by the Council.
E. HOW WILL THIS FRAMEWORK CONTRACT WORK? (Ordering PROCEDURE)

This call for tenders will give rise to a multi-operator framework contract to provide expertise and consultancy services to support the reorganisation of the Romanian Blood System at an overall, all-inclusive price, with:

- a maximum of 6 providers (“pre-selected providers”) for lot n°1,
- a maximum of 4 providers (“pre-selected providers”) for lot n°2, a maximum of 4 providers (“pre-selected providers”) for lot n°3,

provided that there are sufficient candidates satisfying the exclusion and eligibility criteria.

In order to identify the most economically attractive bids, the complete and acceptable bids will be analysed taking into account the clarity and pertinence of the information provided, on the basis of the award criteria below (see F.4 article).

Once this consultation and the subsequent selection are completed, you will be informed accordingly. Deliverables will then be carried out on the basis of Order Forms submitted by the Council to the selected Service Provider(s), by post or electronically, on an as needed basis (there is therefore no obligation to order on the part of the Council).

Signature of the framework contract does not commit the contracting authority to placing orders and does not give the contractor any exclusive rights to the services covered by the framework contract. In any case, the contracting authority reserves the right, at any time during the framework contract, to cease placing orders without the contractor thereby having the right to any compensation.

No guarantee can be provided as to the total number of purchase orders under this multiple framework contract, or as to the total amount contracted with an individual contractor.

For each specific order, the contracting authority will establish a ranking of the framework contractors (of the respective lot) in descending order by applying the following criterion:

<table>
<thead>
<tr>
<th>N°</th>
<th>Criterion</th>
<th>Weighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Technical expertise criteria (relevance of the technical capacity in regard of the specific order)</td>
<td>70-100%</td>
</tr>
<tr>
<td>2</td>
<td>Price</td>
<td>0-30%</td>
</tr>
</tbody>
</table>

1) The technical expertise score for a specific order is determined for each Provider based on the information provided on their bid and its relevance to the specific order;
2) The Price criteria will be assessed on the basis of the information given by the candidate in the act of engagement.
The ranges given for the award of specific order criteria determine the maximum variations in weighting of the award criteria. The Contracting Authority undertakes to respect them.

- An order form, with deliverables and the desired timeline for the execution of the services, is then submitted to the Provider(s) with the highest score for the specific order;

- Within 3 working days the Provider(s) must confirm its willingness to accept the order and the ability to perform the services within the desired timeline, independent from any other ongoing orders;

- Willingness to accept the order shall be communicated to the Contracting Authority by e-mail (The Contracting Authority email will be provided to the selected providers);

- If the supplier(s) does not confirm its interest within 3 working days or is not able to respect the desired timeline for the execution of work, the supplier(s) having obtained the next highest score will be contacted (the "cascade system").

**Signature of orders**

An letter of intent to order is considered to be legally binding when the Order, is signed by the Provider, and is approved by the Council, by displaying a Council’s Purchase Order number on the Order, as well as by signing and stamping the Order concerned. Copy of each approved Order Form shall be sent to the Provider, to the extent possible on the day of its signature.

By signing the order the provider commits to executing the services within the stated timelines and to produce the requested deliverables according to the fees stated in the order. There shall be no payment for additional time required to produce the agreed deliverables (an order is an engagement based on «Deliverables», not «Hours»).

**Invoicing, payment request**

The invoices or payment requests shall be addressed to:

**Council of Europe - EDQM**
Administration and Finance Division (DAF)
7 allée Kastner
CS30026,
67081 Strasbourg

Invoicing shall refer to the stipulations of the present contract.

The Contractor undertakes to abide by all statutory provisions in force and to comply with its tax obligations.

The Council of Europe enjoys exemption from excise duties and taxes for its purchases of goods and services pursuant to Article 1 of the Supplementary Agreement to the General Agreement on Privileges and Immunities of the Council of Europe.
For service providers subject to VAT in the 28-member European Union, the procedures for dealing with VAT are those used for a beneficiary not subject to VAT. Consequently the supply of services in principle is taxed where the service provider is established.

Payment shall be made by bank transfer within an overall time-limit for payment that may not exceed 60 days dating from the receipt of invoices, unless an error, omission, point of dispute or failure to perform the services concerned is observed.

The economic operator undertakes to observe all applicable rules and to fulfil with his/her tax obligations.

Pursuant to Article 1 of the Supplementary Agreement to the General Agreement on Privileges and Immunities of the Council of Europe, the Council of Europe enjoys exemption from excise duties and taxes for its purchases of goods and services.

Service providers subject to VAT in the 28-member European Union shall follow the procedures for a beneficiary Non-subject to VAT.

**Services taxable in France:**

- **Providers established in France**
  - Non-subject to VAT: the amount will be established as a net lump sum (without reference to VAT).
  - Subject to VAT: the amount will be established including all taxes.

- **Providers established in the European Union (outside France)**
  - Non-subject to VAT: the amount will be established as a net lump sum (without reference to VAT).
  - Subject to VAT, depending on the service provided, 2 cases are possible:

  1) Services materially performed in France. The amount shall be established including all taxes. The amount shall be established including all taxes (French VAT). Service providers are required to register in France for VAT purposes by lodging an application form with the competent tax authority, the Foreign enterprises Tax Service: sie.entreprises-etrangeres@dgfip.finances.gouv.fr

Service des impôts des entreprises étrangères (SIEE) - DRESG
10, rue du Centre
93465 Noisy-le-Grand Cedex

+ 33 (0)1 57 33 85 00
Open Monday to Friday, 9 am to 12 noon and 1 pm to 4 pm

2) Services materially performed in the country of the provider but taxable in France. The amount shall be established including all taxes (French VAT). Service providers are required to register for VAT purposes at the VAT Mini One Stop Shop (VAT MOSS) of their choice.
The commercial invoices should show the VAT rate (%), followed by the words "French VAT", the amount of VAT and the phrase: **French VAT collected and paid to the VAT Mini One Stop Shop, address...**

- **Providers established in a third country (outside France and outside the European Union)**
  
  Depending on the nature of the services provided, 2 cases are possible:

  1) Services materially performed in France. The amount shall be established including all taxes (French VAT). Providers shall have to appoint a tax representative in France.

  1) Services materially performed in the country of the Provider but taxable in France. The amount shall be established including all taxes (French VAT). Service providers are required to register for VAT purposes at the VAT Mini One Stop Shop (VAT MOSS) of their choice.

  The commercial invoices should show the VAT rate (%), followed by the words "French VAT", the amount of VAT and the phrase: **French VAT collected and paid to the VAT Mini One Stop Shop, address...**

**Services taxable in the country of the service provider established in the European Union (excluding France):**

- **Subject to VAT:** the amount shall be established excluding taxes, the following shall appear on the pro-forma invoice and on the final invoice:

  

  Before each order the service provider must submit a pro-forma invoice to the Council of Europe, this pro-forma invoice will be used to obtain a VAT exemption certificate from the French tax authorities.

  The Council of Europe shall provide a VAT exemption certificate to the service provider with each order. The exemption certificate shall be kept by the accounting services of the Provider and should be presented to the competent tax authorities to justify VAT free invoicing.

- **Non-subject to VAT:** the amount will be established as a net lump sum (without reference to VAT).

**Services taxable in the country of the service provider established in a third country (e.g., Norway, Switzerland, etc.):**

The amount shall be established according to the local VAT provisions of the country of the Provider.
F. ASSESSMENT

F.1 Exclusion criteria – annex 3 to be completed and signed (by signing annex 3 and the Act of Engagement, you declare on your honour not being in any of the below situations)²

Tenderers shall be excluded from participating in the tender procedure if they:

- have been sentenced by final judgment on one or more of the following charges: participation in a criminal organisation, corruption, fraud, money laundering;
- are in a situation of bankruptcy, liquidation, termination of activity, insolvency or arrangement with creditors or any like situation arising from a procedure of the same kind, or are subject to a procedure of the same kind;
- have received a judgment with res judicata force, finding an offence that affects their professional integrity or serious professional misconduct;
- do not comply with their obligations as regards payment of social security contributions, taxes and dues, according to the statutory provisions of their country of incorporation, establishment or residence;
- are or are likely to be in a situation of conflict of interests;
- are or if their owner(s) or executive officer(s), in the case of legal persons, are included in the lists of persons or entities subject to restrictive measures applied by the European Union (available at www.sanctionsmap.eu).
- are likely to be directly or indirectly a beneficiary of the project e.g being employed by the one of the beneficiaries of the project e.g. Romanian Ministry of Health, organizations being part of the Romanian Blood System.

The individual candidate shall provide the sworn statement certifying that they are not in any of the above-mentioned situations (Annex 3 to be completed/signed and provided).

The individual candidate commits to notify the Contracting Authority immediately, should they be in any of the situations listed above during the validity period of the contract.

F.2 Absence of conflict of interest

Tenderers must complete and provide the declaration of interests and confidentiality undertaking form (Annex 4 to be completed/signed and provided). In addition, any potential interest shall be declared before each meeting and recorded in the meeting minutes. A new declaration of interest and confidentiality undertaking form must be provided by the selected providers whenever a potential conflict of interest arises.

² The Council of Europe reserves the right to ask tenderers, at a later stage, to supply the following supporting documents:
   - An extract from the record of convictions or failing that an equivalent document issued by the competent judicial or administrative authority of the country of incorporation, indicating that the first three requirements listed above under “exclusion criteria” are met;
   - A certificate issued by the competent authority of the country of incorporation indicating that the fourth requirement is met;
   - For legal persons, an extract from the companies register or other official document proving ownership and control of the Tenderer;
   - For natural persons (including owners and executive officers of legal persons), a scanned copy of a valid photographic proof of identity (e.g. passport).
F.3 Eligibility criteria for each lot

Candidates shall demonstrate that they fulfil the following criteria (to be assessed on the basis of all supporting documents as listed):

<table>
<thead>
<tr>
<th>Mandatory</th>
<th>Minimum supporting documents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lot 1</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Technical knowledge, expertise and work experience</strong> in one or more of the following areas:</td>
<td>- A detailed CV using the Europass format (4 pages maximum);</td>
</tr>
<tr>
<td>- Blood transfusion or similar domain, including donation, collection, testing, processing, distribution and transfusion of blood and blood components, risk management and change management,</td>
<td>- A motivation letter (2 pages maximum) including reasons for applying and why the tenderer could make added value to the project,</td>
</tr>
<tr>
<td>- Regulatory oversight of blood and blood components or health related domains (e.g tissues and cells, pharmaceutical industry), including the inspection and/or authorisation / accreditation of operators,</td>
<td>- A description how the tenderer will meet the requirements described in table 1 included in section A.</td>
</tr>
<tr>
<td>- Health legal expertise, in health law making, transposition and implementation,</td>
<td>- At least 2 examples of previous relevant work (e.g reports, publications), which shall confirm the relevance of experience for the work the tenderer is applying for;</td>
</tr>
<tr>
<td>- Restructuration of national blood and/or health system, through EU or international funding instruments such as the Structural Reform Support Programme (SRSP) and/or European/International Cooperation Projects in the field of blood transfusion or related health domains,</td>
<td>- Minimum 2 reference letters demonstrating implementation of relevant work in the previous years, containing contact details of reference persons</td>
</tr>
<tr>
<td>- Knowledge of relevant EU legislation or regulatory framework in one or more of the relevant fields covered by the project (e.g EU blood legislation, ICT Interoperability framework) and the Council of Europe / EDQM Guide to the preparation, Use and Quality Assurance of Blood Components,</td>
<td></td>
</tr>
<tr>
<td>- Minimum 5 years of experience.</td>
<td></td>
</tr>
</tbody>
</table>

**Soft Skills**
- Excellent drafting including report writing, communication and presentation skills;
- Excellent background research and analytical skills;
- Excellent project management skills;
- A proven track record of working effectively within a team;

**Languages**
- Fluency in written and spoken English (at least level C1 of the CEFR4);

**Others**
- Availability to travel, required as part of the project, for on-site study visits / meetings;
<table>
<thead>
<tr>
<th><strong>Mandatory</strong></th>
<th><strong>Minimum supporting documents</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lot 2</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sound technical knowledge, expertise and work experience in:</strong></td>
<td>- A detailed CV using the Europass format (4 pages maximum);</td>
</tr>
<tr>
<td>- Business requirements gathering, developing, and/or qualifying/validating purchasing, procurement of IT/computerised system,</td>
<td>- A motivation letter (2 pages maximum) including reasons for applying and why the tenderer could make added value to the project,</td>
</tr>
<tr>
<td>- Tenders drafting and application,</td>
<td>- A description how the tenderer will meet the requirements described in table 1 included in section A.</td>
</tr>
<tr>
<td>- IT project management methodology, in a health related domain, ideally the blood transfusion domain</td>
<td>- At least 2 examples of previous relevant work (e.g. reports, publications), which shall confirm the relevance of experience for the work the tenderer is applying for;</td>
</tr>
<tr>
<td>- Minimum 5 years experience.</td>
<td>- Minimum 2 reference letters demonstrating implementation of relevant work in the previous years, containing contact details of reference persons</td>
</tr>
<tr>
<td><strong>Soft Skills</strong></td>
<td></td>
</tr>
<tr>
<td>- Excellent drafting including report writing, communication and presentation skills;</td>
<td></td>
</tr>
<tr>
<td>- Excellent background research and analytical skills;</td>
<td></td>
</tr>
<tr>
<td>- Excellent project management skills;</td>
<td></td>
</tr>
<tr>
<td>- A proven track record of working effectively within a team;</td>
<td></td>
</tr>
<tr>
<td><strong>Languages</strong></td>
<td></td>
</tr>
<tr>
<td>- Fluency in written and spoken English (at least level C1 of the CEFFR4);</td>
<td></td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td></td>
</tr>
<tr>
<td>- Availability to travel, required as part of the project, for on-site study visits / meetings;</td>
<td></td>
</tr>
<tr>
<td><strong>Mandatory</strong></td>
<td><strong>Minimum supporting documents</strong></td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td><strong>Lot 3</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Technical knowledge, expertise and work experience in</strong></td>
<td>- A detailed CV using the Europass format (4 pages maximum);</td>
</tr>
<tr>
<td>- Developing investment plans including infrastructure, equipment, material and transport/logistics,</td>
<td>- A motivation letter (2 pages maximum) including reasons for applying and why the tenderer could make added value to the project,</td>
</tr>
<tr>
<td>- Performing feasibility study of investment plans,</td>
<td>- A description how the tenderer will meet the requirements described in table 1 included in section A.</td>
</tr>
<tr>
<td>- Cost and economic analysis in investment planning,</td>
<td>- At least 2 examples of previous relevant work (e.g reports, publications), which shall confirm the relevance of experience for the work the tenderer is applying for;</td>
</tr>
<tr>
<td>- Tenders drafting and application, in a health related domain, ideally the blood transfusion domain</td>
<td>- Minimum 2 reference letters demonstrating implementation of relevant work in the previous years, containing contact details of reference persons</td>
</tr>
<tr>
<td>- Minimum 5 years experience.</td>
<td></td>
</tr>
<tr>
<td><strong>Soft Skills</strong></td>
<td></td>
</tr>
<tr>
<td>- Excellent drafting including report writing, communication and presentation skills;</td>
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<tr>
<td>- Excellent background research and analytical skills;</td>
<td></td>
</tr>
<tr>
<td>- Excellent project management skills;</td>
<td></td>
</tr>
<tr>
<td>- A proven track record of working effectively within a team;</td>
<td></td>
</tr>
<tr>
<td><strong>Languages</strong></td>
<td></td>
</tr>
<tr>
<td>- Fluency in written and spoken English (at least level C1 of the CEFR4);</td>
<td></td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td></td>
</tr>
<tr>
<td>- Availability to travel, required as part of the project, for on-site study visits / meetings;</td>
<td></td>
</tr>
</tbody>
</table>
**F.4 Award criteria for each lot**

In order to identify the most economically attractive bids, the complete and acceptable bids will be analysed taking into account the clarity and pertinence of the information provided, on the basis of the criteria below.

<table>
<thead>
<tr>
<th>No.</th>
<th>Criterion</th>
<th>Weighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Quality of the offer – minimum of 7.5/10</td>
<td>70%</td>
</tr>
<tr>
<td></td>
<td>- Proven relevant knowledge, expertise and work experience (50);</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Proven relevant soft skills (drafting including report writing, communication and presentation; research and analytical/project management skills) - (12.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Knowledge and/or experience of the national context or similar context - (7.5);</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Price</td>
<td>30%</td>
</tr>
</tbody>
</table>

1) The "Quality value" criterion will be assessed on the basis of the candidate's technical offer.

The following skills shall be taken into account when assessing the quality of the offer:

<table>
<thead>
<tr>
<th>Lot n°1</th>
<th>Technical knowledge, expertise and work experience</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Experience working as a consultant, or in an advisory capacity, with national, regional, or European/International institutions;</td>
</tr>
<tr>
<td></td>
<td><strong>Languages</strong></td>
</tr>
<tr>
<td></td>
<td>- Knowledge of Romance languages and/or previous experience in South-Eastern Europe (SEE) countries.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lot n°2</th>
<th>Technical knowledge, expertise and work experience in:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Experience in the blood transfusion field,</td>
</tr>
<tr>
<td></td>
<td>- Experience in restructuring of national blood and/or health system, through EU or international funding instruments such as the Structural Reform Support Programme (SRSP) and/or European/International Cooperation Projects in the field of blood transfusion or related health domains,</td>
</tr>
<tr>
<td></td>
<td>- Experience working as a consultant, or in an advisory capacity, with national, regional, or European/International institutions;</td>
</tr>
<tr>
<td></td>
<td>- Knowledge of relevant EU legislation or regulatory framework in one or more of the relevant fields covered by the project (e.g EU blood legislation, ICT Interoperability framework) and the Council of Europe / EDQM Guide to the preparation, Use and Quality Assurance of Blood Components;</td>
</tr>
<tr>
<td></td>
<td><strong>Languages</strong></td>
</tr>
<tr>
<td></td>
<td>- Knowledge of Romance languages and/or previous experience in South-Eastern Europe (SEE) countries.</td>
</tr>
</tbody>
</table>
**Lot n°3**

**Technical knowledge, expertise and work experience in:**

- Experience in the blood transfusion field,
- Experience in restructuration of national blood and/or health system, through EU or international funding instruments such as the Structural Reform Support Programme (SRSP) and/or European/International Cooperation Projects in the field of blood transfusion or related health domains,
- Experience working as a consultant, or in an advisory capacity, with national, regional, or European/International institutions;
- Knowledge of Romance languages and/or previous experience in South-Eastern Europe (SEE) countries.
- Knowledge of relevant EU legislation or regulatory framework in one or more of the relevant fields covered by the project (e.g. EU blood legislation, ICT Interoperability framework) and the Council of Europe / EDQM Guide to the preparation, Use and Quality Assurance of Blood Components;

**Languages**

- Knowledge of Romance languages and/or previous experience in South-Eastern Europe (SEE) countries.

Score/10 = sum of subcriteria = the result being multiplied by the weighting of the criterion.

**Important:** Candidates with a Quality value of less than 7.5/10 may not be considered.

2) The "Price" criterion will be analysed taking into account the total sum given in the Act of Engagement.

Score/10 = (lowest price/price of the bid examined) x 10, the result being multiplied by the weighting of the criterion.

**Important:** Tenderers proposing fees above the exclusion level indicated in the Table of fees (400€ per day) will be entirely and automatically excluded from the tender procedure.

It is possible to bid for more than one lot. Providers wishing to bid for two or more lots should submit a single bid covering the relevant lots together with one Act of Engagement per lot.

Candidates may be asked to provide additional information when their bid is not sufficiently clear and requires further explanation, if their bid is unusually low or when there is a discrepancy between the single overall, all-inclusive price, the schedule of prices and the bid itself.

The EDQM / Council of Europe reserves the right to hold interviews with eligible tenderers.

**G. DOCUMENTS TO BE PROVIDED**

- **Two** completed and signed copies of the Act of Engagement (for each lot, if bid for more than one lot),
- A list of all owners and executive officers, for legal persons only;
- Tenderers must provide information their VAT status);
- Sworn statement filled and signed (as provided in Annex 3).
- Declaration of interests and confidentiality undertaking form filled and signed, (as provided in Annex 4).

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3 The Act of Engagement must be completed, signed and scanned in its entirety (i.e. including all the pages). The scanned Act of Engagement may be sent page by page (attached to a single email) or as a compiled document, although a compiled document would be preferred. For all scanned documents, .pdf files are preferred.
Minimum for each lot (see above)

- A detailed CV using the Europass format (4 pages maximum);
- A motivation letter (2 pages maximum) including reasons for applying and why the tenderer could make added value to the project,
- A description how the tenderer will meet the requirements described in table 1 included in section A.
- At least 2 examples of previous relevant work (e.g reports, publications), which shall confirm the relevance of experience for the work the tenderer is applying for;
- Minimum 2 reference letters demonstrating implementation of relevant work in the previous years, containing contact details of reference persons

All documents shall be submitted in English failure to do so will result in the exclusion of the tender. If any of the documents listed above are missing or failure to sign documents when signature is expressly called for, the Council of Europe reserves the right to reject the tender.

Candidates should be aware that incomplete bids (missing documents or failure to sign documents when signature is expressly called for) are liable to be rejected.

The Council reserves the right to reject a tender if the scanned documents are of such a quality that the documents cannot be read once printed.

The provided documents will be treated strictly confidentially

* * *
PART II – TENDER RULES
CALL FOR TENDERS
FOR THE PROVISION OF INTERNATIONAL CONSULTANCY SERVICES FOR REORGANISING THE ROMANIAN BLOOD SYSTEM

ARTICLE 1 – IDENTIFICATION OF THE CONTRACTING AUTHORITY
1.1 Name and address
Council of Europe, European Directorate for the Quality of Medicines & HealthCare (EDQM)
Address: Council of Europe - EDQM, 7 allée Kastner, CS 30026, F67081 Strasbourg

1.2 Background
The activities of the Organisation are governed by its Statute. These activities concern the promotion of human rights, democracy and the rule of law. The Organisation has its seat in Strasbourg and has set up external offices in about 20 member and non-member states (in Ankara, Baku, Belgrade, Brussels, Bucharest, Chisinau, Erevan, Geneva, Kyiv, Lisbon, Moscow, Paris, Podgorica, Pristina, Rabat, Sarajevo, Skopje, Tbilisi, Tirana, Tunis, Warsaw, Venice and Vienna).

Council of Europe procurements are governed by the Financial Regulations of the Organisation and by Rule 1395 of 20 June 2019 on the procurement procedures of the Council of Europe.

The Organisation enjoys privileges and immunities provided for in the General Agreement on Privileges and Immunities of the Council of Europe, and its Protocols, and the Special Agreement relating to the Seat of the Council of Europe.4

Further details on the project are provided in the Terms of Reference.

ARTICLE 2 – VALIDITY OF THE TENDERS
Tenders are valid for 180 calendar days as from the closing date for their submission.

ARTICLE 3 – DURATION OF THE CONTRACT
The duration of the framework contract is set out in Article 2 of the Legal Conditions in the Act of Engagement.

ARTICLE 4 – CHANGE, ALTERATION AND MODIFICATION OF THE TENDER FILE
Any change in the format, or any alteration or modification or reserve of the original tender will cause the immediate rejection of the tender concerned.

ARTICLE 5 – CONTENT OF THE TENDER FILE
The tender file is composed of:
- Technical specifications/Terms of reference;
- Tender rules and Annex 1, 2, 3 and 4;
- An Act of Engagement, including the Legal Conditions of the contract.

ARTICLE 6 – LEGAL FORM OF TENDERERS
The tenderer must be either a natural person, or a duly registered company under sole proprietorship of a natural person, or equivalent, provided that the signatory of the Act of Engagement is individually liable for all obligations undertaken by the entity, and is the owner of the moral rights in any creations of the entity. If contracted by the Council of Europe, the signatory of the Act of Engagement shall provide the deliverables personally, in accordance with the terms as provided in the current Tender File, Act of Engagement and future Order Forms

ARTICLE 7 – SUPPLEMENTARY INFORMATION

4 Available on the website of the Council of Europe Treaty Office: www.conventions.coe.int

General information can be found on the website of the Council of Europe: http://www.coe.int

Other questions regarding this specific tendering procedure shall be sent at the latest by ten days before the deadline for submissions of tenders, in [English or French], and shall be exclusively sent to the following address: purchasing@edqm.eu. This address is to be used for questions only; for modalities of tendering, please refer to the below Article.

ARTICLE 8 – MODALITIES OF THE TENDERING

Tenders must be sent to the Council of Europe both electronically OR in paper hardcopy.

Electronic copies shall be sent only to cdm@coe.int. Tenders submitted to another e-mail account will be excluded from the procedure;

Paper hardcopies shall be sent in A4 format (21x29.7 cm) by post, as specified below:
- Tenders shall be submitted in a sealed envelope. The first sealed envelope shall be placed inside a second envelope addressed to the Tenders Board, showing the file reference number and object, as follows:

<table>
<thead>
<tr>
<th>COUNCIL OF EUROPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>For the attention of the Tenders Board</td>
</tr>
<tr>
<td>CALL FOR PROVISION OF CONSULTANCY SERVICES</td>
</tr>
<tr>
<td>(ROMANIAN BLOOD SYSTEM - EDQM-AO-2020)</td>
</tr>
<tr>
<td>B.P. 7</td>
</tr>
<tr>
<td>F – 67075 STRASBOURG Cedex</td>
</tr>
<tr>
<td>FRANCE</td>
</tr>
</tbody>
</table>

- Tenders are requested to indicate their names and address on the outside envelope for identification purposes.
- Tenders submitted to another postal address will be excluded from the procedure.

ARTICLE 9 – DEADLINE FOR SUBMISSION OF TENDERS
The deadline for the submission of tenders is 22 October 2020 as evidenced by the postmark, or by the receipt of delivery provided by the dispatching company (For hardcopies).

ARTICLE 10 – ASSESSMENT OF TENDERS
Tenders shall be assessed in accordance with Rule 1395 of 20 June 2019 on the procurement procedures of the Council of Europe. Assessment shall be based upon the criteria as detailed in the Terms of Reference.

ARTICLE 11 – NEGOTIATIONS
The Council reserves the right to hold negotiations with the bidders in accordance with Article 20 of Rule 1395.

Article 12 – Cancellation
The Contracting Authority may, at any time during the procedure, decide to cancel this call for tenders, without the candidates or tenderers being entitled to claim any compensation.
FINAL CHECK LIST

1) BEFORE SENDING YOUR TENDER, CHECK THAT IT INCLUDES:

- Two completed and signed copies of the Act of Engagement (by lot);
- Tenderers must provide information their VAT status;
- Sworn statement filled and signed (as provided in Annex 3);
- Declaration of interests and confidentiality undertaking form filled and signed, (as provided in Annex 4).

And for each lot
- A detailed CV using the Europass format (4 pages maximum);
- A motivation letter (2 pages maximum) including reasons for applying and why the tenderer could make added value to the project,
- A description how the tenderer will meet the requirements described in table 1 included in section A.
- At least 2 examples of previous relevant work (e.g reports, publications), which shall confirm the relevance of experience for the work the tenderer is applying for;
- Minimum 2 reference letters demonstrating implementation of relevant work in the previous years, containing contact details of reference persons

2) HOW TO SEND TENDERS?

Tenders must be sent to the Council of Europe both electronically or in paper hardcopy.

Electronic copies shall be sent only to cdm@coe.int. Tenders submitted to another e-mail account will be excluded from the procedure;

Paper hardcopies shall be sent in A4 format (21x29.7 cm) by post, as specified below:
- Tenders shall be submitted in a sealed envelope. The first sealed envelope shall be placed inside a second envelope addressed to the Tenders Board, showing the file reference number and object, as follows:

  COUNCIL OF EUROPE  
  For the attention of the Tenders Board  
  CALL FOR PROVISION OF CONSULTANCY SERVICES  
  (ROMANIAN BLOOD SYSTEM - EDQM-AO-2020)  
  B.P. 7  
  F – 67075 STRASBOURG Cedex  
  FRANCE

- Tenderers are requested to indicate their names and address on the outside envelope for identification purposes.
- Do not send a copy of your tender to the buyer entity. Tenders submitted to any other postal address than the one indicated above will be excluded from the procedure.

The deadline for the submission of tenders is 22 October 2020 as evidenced by the postmark, or by the receipt of delivery provided by the dispatching company (For hardcopies).