INFO SESSION

Call for tenders to speed up the development of and access to innovative Medical Countermeasures (MCMs)

HADEA/2023/OP/0036

23 October 2023

Moderation

Agnès Mathieu-Mendes

Head of Unit A2, EU4Health and SMP Food
European Health and Digital Executive Agency

European Commission

Meeting settings

Please note that:

- Your microphone and camera have been turned off for the duration of this webinar;
- The chat and participants' list are disabled;
- In case of technical issues, you can still contact the organisers (HaDEA Webex C – tech support) via the Webex chat.

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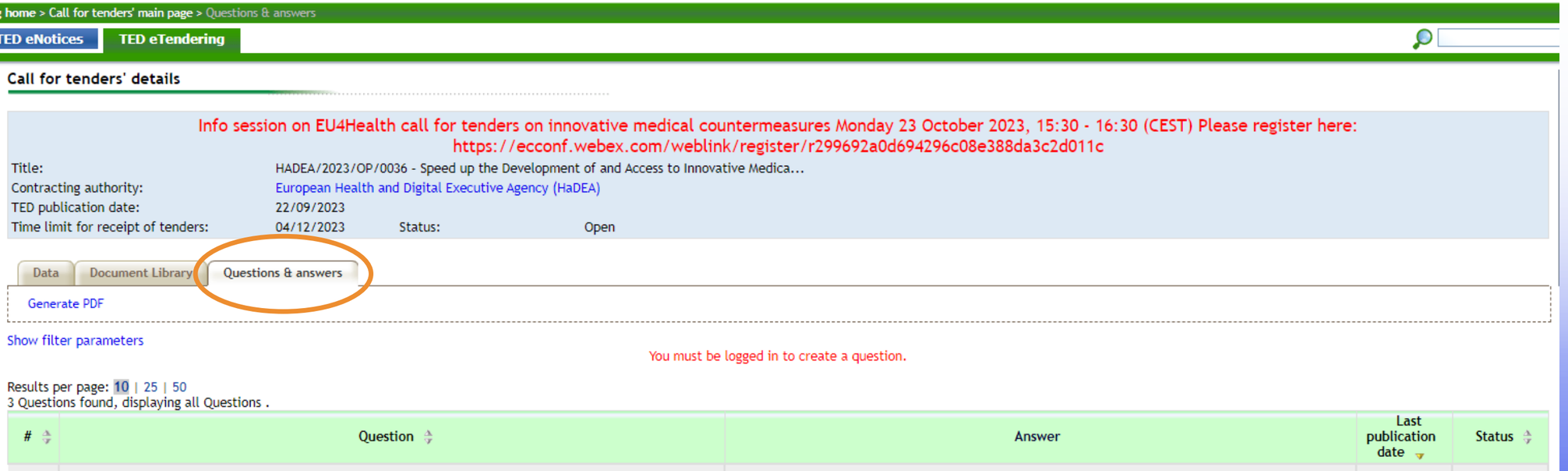
Contacts

- Any request for additional information about this call for tenders must be submitted in writing via Ted eTendering in the "Questions & answers" tab of the call
- Deadline to submit your questions: 24/11/2023, 23:59 (CEST)

eTendering
Calls for tenders from the European institutions



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Welcome

Angelo Marino

Head of Department A,
‘Health & Food’
European Health and
Digital Executive Agency

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Agenda

15:30	**Welcome** Angelo Marino, Head of Department A, Health and Food - HaDEA
15:35	**Policy context and political priorities** *Political relevance of the tender* Laurent Muschel, Deputy Head of HERA and acting Director-General - HERA
15:40	**Introducing the call for tenders and lots** *Main highlights of the call, objectives, budget available* Lot 1: Ana Duarte, Policy Officer – HERA.3 Lots 2 and 3: Bangin Brim, Policy Officer – HERA.2 Lot 4: Andreas Prenner, Policy Officer – HERA.2
16:10	**How to participate in the call for tender** *Overview of technical and administrative steps to submit a tender* Sofia Lourenço, Legal advisor – HaDEA A2.3
16:30	**Closing remarks** Agnès Mathieu-Mendes, Head of Unit A2 - HaDEA

Policy context and political priorities

Laurent Muschel
Deputy Head and Acting Director-General of the Health Emergency preparedness and Response Authority (HERA)

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Introducing the call for tenders and lots

Ana Duarte

Policy Officer,
HERA.3

Bangin Brim

Policy Officer,
HERA.2

Andreas Prenner

Policy Officer,
HERA.2

HERA.2 - Intelligence Gathering, Analysis and Innovation
HERA.3 - Medical Countermeasures

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Lot 1: Vaccines to combat antimicrobial resistance

Ana Duarte - Policy Officer HERA.03 Medical Countermeasures Unit

Lot 1- Background

- The increase of antimicrobial resistance (AMR) has become a pressing global health concern as it limits the availability of effective antimicrobials in treating life threating infections
- **AMR →** one of HERA three priority health threats to prepare against
- **EU Council recommendation on AMR →** need to increase investment in research and innovation to develop new antimicrobial agents, diagnostic tools, and alternative treatment strategies
- Lot 1 aims to speed up the **development of vaccine candidates targeting bacterial infections** as an alternative treatment strategy to address the rising incidence of AMR (22 million EUR)

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Lot 1

- **Product description:** The product shall target at least one of the twelve bacterial families classified as "priority pathogens" in the 2017 WHO Bacterial Priority Pathogens List. The product may also target *Mycobacterium tuberculosis*

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Lot 1

- **Level of development:** Lot 1 aims at supporting the advancement of **vaccine candidates that have successfully completed at least Phase I clinical studies** for further (and more precise) characterisation of immunogenicity, and safety of the vaccine candidate (within Phase II clinical trials), as well as clinical trials and concurrent non-clinical development of Phase III vaccine trials

- When relevant and duly justified (e.g., lack of commercial interest or another type of market failure that leads to crowding out investments and partnerships), **tenders may only cover the assessment of a primary efficacy endpoint of Phase III trials**, specifying the measure of the disease-related outcome of public health interest, such as mortality or disease morbidity, that supports the vaccine candidate indication for use

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Lot 1

- The offer shall contain the approval (or provide evidence to be in the process of obtaining approval) to run a clinical trial for Phase II. **Clinical trials should be ideally planned in one or several EU/EEA Member States**. Justification should be provided where the Phase II clinical trials are conducted entirely outside the EEA. The offer should detail the methodology for recruitment and possible challenges, to obtain more robust study results

- A detailed data management plan of the clinical trials (including trial master file template, case report form design, among other), as well as a robust methodology for technological measurement, and a statistical analysis plan, allied with the EU regulatory requirements

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Lot 1

- The offer shall contain an **implementation plan of the development of the vaccine candidate**, which must specify the current stage of development of the product and the foreseen steps to advance further on the support to the innovation throughout the duration of the contract
- Additionally, the offer shall outline a **preliminary roadmap for placing the product on the market** and a plan fostering regular information update between the tenderer and the contracting authority
- **The award criteria** include: the offer relevance for public health challenges and EU added value, innovation, promising biological activity and safety and the methodology for conducting the clinical and concurrent non-clinical development activities

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Lot 1

- The contracting authority **acknowledges that the clinical development might not be successful** or regulatory approval may not be obtained and subsequently an authorised vaccine or IMP may not be available
- Therefore, the offer shall also contain a **risk assessment and mitigation measures plan** to be updated should any changes occur throughout the implementation of the tasks

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Lot 1

- The **duration of the contract under Lot 1 will be 48 months** – with submission of progress reports at M6, M12, M24, M36, and of a final report at M48

The following tasks shall be carried out by the contractor of Lot 1.

Task	Description
1	Initiation and risk management
2	Clinical and concurrent non-clinical development of the product(s)
3	Phasing-out

- Regular **meetings with the contracting authority and DG HERA** will take place **every three months** to monitor the implementation of the tasks and address potential challenges (these will be in general online or face to face in specific cases)

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Lot 2 and Lot 3 (broad-spectrum antivirals)

Bangin Brim – HERA.2 (Intelligence gathering, Analysis and Innovation unit)

Broad-spectrum antivirals

- Lot 2 – broad-spectrum antivirals targeting **respiratory RNA viral families**, such as *Paramyxo-, Orthomyxo-* and *Coronaviridae*
- Lot 3 – broad-spectrum antivirals targeting **viral families known for causing viral haemorrhagic fever (VHF),** such as *Arena-, Bunya-, Flavi-, Filoviridae*

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Broad-spectrum antivirals

The antivirals subject of this call shall aim to (1) directly block viral targets and function (direct-acting antivirals), (2) have an anticipated efficacy against multiple species or genera in at least one, but preferably several viral families, (3) be preferably new chemical entities which include small molecules and small biotherapeutics like nucleic acids or peptides that are directly acting against viral targets and functions, i.e. not through the modulation of the host responses, (4) and preferably have safety profiles and suitable routes of administration (e.g. oral or intranasal) for broad use in the outpatient setting to treat early stages of infection by reducing viral burden.

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Lots 2 and 3 – task 1

The following tasks shall be carried out by the contractor and are to be considered for each of the two lots (Lot 2 and Lot 3).

Task	Description
1	Initiation and risk management
2	Clinical and concurrent non-clinical development of the product(s)
3	Phasing-out

Task 1: Initiation and risk management

This task refers to the initiation and risk management of the project highlighting activities to be delivered during the entire period of the contract. This task foresees the presentation of a planning of the services to be performed including any update of the implementation plan.

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Lots 2 and 3 – task 2

Task 2: Clinical and non-clinical development of the product(s)

This task includes all the activities necessary for the contractor to implement the proposed services and advance as much as possible the clinical and concurrent non-clinical development of the product. In the offer, the tenderer shall specify, in detail, the content of the proposed actions and why they are necessary for the successful clinical and concurrent non-clinical development. The offer shall also specify, in a more general manner, activities that will be developed concomitantly, but not covered under this contract, and how they are connected.

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Lots 2 and 3 – task 2

Activities relevant for the **clinical development** within the scope of Lot 2 and 3 should support the clinical development of the antiviral and include, but are not limited to, the following non-exhaustive list of possible activities: :

- Determination of study objectives and the design of the study
- Preparation of clinical trial protocol (determination of inclusion and exclusion criteria for recruitment of participants)
- Project and data management tasks, as well as reporting and monitoring
- Safety management and quality control tasks
- Conducting feasibility evaluation and/or pre-study site visits/screening visits
- Patients' recruitment, both within the EU/EEA, and outside the EU/EEA in duly justified cases
- Securing the R&D supply chain of the clinical trial and administering the study protocol
- Collection of samples/clinical assessment and measurement of biochemical or other indicators

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Lots 2 and 3 – task 2

- Conducting on-site trial tasks, such as study visit attendance, protocol adherence and study logs
- Development of documentation of adverse events, tracking of participant disposition, review board submissions and approvals
- Monitoring and evaluation of recruiting sites, including preparation for inspections and audits;
- Statistical analysis;
- Submission package preparation for conducting the clinical trial phase II, documents, forms, and translations into English of the key documents;
- Data handling and record keeping

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Lots 2 and 3 – task 2

Activities relevant for the **concurrent non-clinical development** within the scope of Lots 2 and 3 should support the clinical development of the candidate and should include the following non-exhaustive list of activities:

- Good Laboratory Practice (GLP) experiments for the evaluation of chronic toxicity, reproductive and developmental toxicity, carcinogenicity and genotoxicity, carried out during the clinical phase of development;
- quality documentation and required analytical procedures to produce such documentation: regarding manufacturing process (e.g., development, validation and evaluation); control of raw materials and starting materials; characterisation (e.g., integrity, impurities and homogeneity); control of the active substance; reference standards and materials; container and closure systems; and stability;

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Lots 2 and 3 – task 2

- Demonstrations related to formulation development, such as compatibility of materials used; requirements for products requiring additional preparation (e.g., reconstitution process is sufficiently robust and will not cause a negative impact on quality/safety/clinical properties); development of batch formula, control of excipients, control of the investigational medicinal products, adventitious agents' safety evaluation;

- Additional formulation optimisation, change, or quality tests, with activities relevant for Phase II of clinical development (e.g. addressing formulation change or change in manufacturing);
- Further assessment of clinical findings;
- Adaptations necessary to the formulation during clinical development, related to the preparation, dose, and schedule to be tested in Phase III clinical trials.

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Lots 2 and 3 – task 3

Task 3: Phasing-out

This task refers to the activities in the last period of the project and the submission of the draft and of the final report accompanied by all final deliverables and relevant documentation.

A draft final report shall be submitted no later than 46 months after the signature of the contract to provide sufficient time to evaluate and send back comments to be implemented in the final version.

The Final Report (one for Lot 2 and one for Lot 3) will describe all the work carried out and the results obtained. It will be accompanied by all final deliverables and relevant documentation.

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Award criteria for Lot 2 and 3

- **Criterion 1 – Relevance and Innovation**

  The criterion will assess the information submitted in the minimum requirements: how the medical countermeasure addresses the EU added value, the public health challenges, innovation and promising activity based on the evidence provided in the offer:

  - Sub-criterion 1.1 – Relevance to Public Health Challenges and EU added value
  - Sub-criterion 1.2 – Innovation: Broad-spectrum antiviral (BSA), and BSA-containing drug combinations (‘antiviral cocktails’)
  - Sub-criterion 1.3 - Safety profile and overall soundness of the scientific approach and technology used

Questions can only be submitted via TED eTendering.

Award criteria for Lot 2 and 3

- **Criterion 2 – Methodology for conducting the clinical and non-clinical activities**
  - This criterion will assess the appropriateness of the tasks described in these tender specifications, related to the clinical and concurrent non-clinical development activities of the product, the detailed data management plan of the clinical trials and regulatory activities including all related tasks requested in the process of submission of the market authorisation in the EU.
  - This encompasses the technological measurement, and a statistical analysis plan of the study/clinical trial, trial activities and all related tasks requested in the process of submission of the market authorisation in the EU and the preliminary roadmap for placing the product on the market.

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Award criteria for Lot 2 and 3

- **Criterion 3 – Appropriateness of the organisation of the work and resources**

  This criterion will assess elements related to the organisation of the work and plausible allocation of time and human resources for the implementation of the tasks.

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Award criteria for Lot 2 and 3

- **Criterion 4 – Quality of the measures implemented for a continuous high performance, including quality control and data protection**

  This criterion will assess the quality the measures proposed for data protection, project risk assessment and project mitigating measures of the risks associated to the implementation of the tasks.

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Lot 4: Point of care metagenomic sequencing for universal pathogen detection

Andreas Prenner - Policy Officer, HERA.02

Background

- SARS-CoV-2 circulated in humans up to two months before identification as novel virus;
- Routine-use **pathogen-agnostic diagnostic medical devices** could:
  - **Drastically reduce time until pathogen identification**, potentially making the difference between contained local outbreak and pandemic;
  - Accelerate public health response to outbreaks: **bridge time until PCR and antigen tests developed;**
  - Provide clinical utility for the **treatment of ongoing infectious diseases and AMR**, allowing the administration of pathogen-specific treatment options;
  - Allow **identification and tracking of viral variants** as they arise.

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Objective

- Development of a metagenomic next-generation sequencing (mNGS) based test;
- Detection of any respiratory viral pathogen, including novel and emerging, from human respiratory samples;
- mNGS workflows no significant traction at the point of care, still mostly used in specialised laboratories. Main barriers to more widespread adoption:
  - Complex workflows requiring skilled professionals for both test preparation and result interpretation;
  - High cost;
  - Slow time-to-result.

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Target Product Profile (1/2)

Table 1: Product Attributes	
Description of System	Complete sample-to-answer solution; including sample processing, enrichment of target sequences and ideally removal of interfering nucleic acids (the generation of host genomic information is not an intended output of the device), library generation, sequencing, bioinformatics analysis, and reporting of results in a clinically relevant format
Result Output	Visual output easily readable by clinicians based on the bioinformatics analysis of mNGS data that **qualitatively** and **ideally quantitatively** (e.g., viral load) reports the viral pathogen(s)
Time to Result	Ideally less than 6 hours
Cost	Both device and especially per-sample cost equivalent to or less than existing molecular test panels (e.g., multiplex PCR devices)

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Target Product Profile (2/2)

Table 1: Product Attributes	
Target Population	Patients with acute symptoms of viral infection, e.g., the common cold or influenza-like illness
Use Setting	Point of care settings (hospitals, ICUs, clinical labs)
Clinical Performance Characteristics	Positive predictive value (PPV) > 90% (ideally > 98%) and negative predictive value (NPV) > 99%, sensitivity=> 95%, specificity > 95% (ideally >99%), and limit of detection < 1000 (ideally < 10) genome equivalents/mL
Pathogen Targets	All pathogenic respiratory viruses including emerging/novel viruses at a minimum.
Sample type	Respiratory samples
Regulatory Compliance	CE Mark based on the relevant EU conformity assessment procedure in accordance with IVDR (EU) 2017/746

Questions can only be submitted via TED eTendering.

Task description

- **Task 1:** Initiation and planning
- **Task 2:** Product development activities
  - Development of a fully integrated sample preparation cartridge
  - Integration with a sequencing device usable at the point of care
  - Implementation of performance evaluation phase. Validation against attributes outlined in TPP
  - Technical documentation for the relevant EU conformity assessment procedure
  - Application for conformity assessment shall be submitted at least two months before project completion
- **Task 3:** Phasing out

Questions can only be submitted via TED eTendering.

Exclusion of tenderers: minimum requirements

- Rationale for the need of public funding
- Implementation plan, including Gantt chart outlining development activities
- Breakthrough innovation description, including when relevant
- Level of development, including key milestones and existing reviews by authorities
- Description of exercise of priority rights (price per unit, plans for manufacturing/stockpiling, supply and distribution of the products to the EU/EEA)
- Composition of the project team

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Exclusion of tenderers: minimum requirements

- Explanation of the device development and detailed information on the attributes mentioned in table 1
- Product description and indication/intended use: clear regulatory strategy, outlining regulatory path to market and a performance evaluation plan
- Project risk management and performance evaluation plan as required by the IVDR
- Detailed plan underpinning the submission of an application seeking EU certification

Questions can only be submitted via TED eTendering.

Exclusion of tenderers: selection criterion

Experience in research and development of diagnostics

- Tenderer must prove they are able to achieve all necessary steps to develop and certify a medical device
- At least one similar development (in scope and complexity) in last 10 years
- Evidenced by a list of past development protocols

Questions can only be submitted via TED eTendering.

Selection of awardee: criteria

- Price: 30%
- Quality: 70%

Criterion	Weight
Innovation	40%
Relevance to public health challenges	10%
Methodology	25%
Appropriateness of the organisation of work and resources	15%
Quality control	10%

Questions can only be submitted via TED eTendering.

Selection of awardee: assessing innovation

Comparing suggested solution to requirements in target product profile, especially on:

- Complexity of workflows
- Time to answer
- Per-sample cost
- Interpretability by clinicians
- Sensitivity, specificity, PPV, NPV (see details in table 1)

Questions can only be submitted via TED eTendering.

How to participate in the call for tenders on innovative MCMs

Sofia Lourenço
Legal Advisor
HaDEA A2.3 – EU4Health

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This call for tenders is divided into 4 lots:

Lot number	Lot title	Budget (EUR)
1	Vaccines to combat antimicrobial resistance (AMR)	22 000 000
2	Broad spectrum antivirals against respiratory diseases	18 000 000
3	Broad spectrum antivirals to treat viral-haemorrhagic fevers	18 000 000
4	Point of care metagenomic sequencing for universal pathogen detection	24 000 000
	Maximum total amount of all purchases	**82 000 000**

Tenders may be submitted for one or several lots.
Economic operators submitting tenders for more than one lot must submit a tender for each lot.

Questions can only be submitted via TED eTendering.

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Procurement procedure

The contracting authority has chosen to award the contracts resulting from this call for tenders through an open procedure pursuant to Article 164(1) (a) of the Financial Regulation.

Questions can only be submitted via TED eTendering.

Who may submit a tender?

Tender Specifications, Section ***2.2 Entities subject to restrictive measures and rules on access to procurement: who may submit a tender?***

General rules

- Participation in this call for tenders is open on equal terms to all natural and legal persons coming within the scope of the Treaties, as well as to international organisations.
- It is also open to all natural and legal persons established in a third country provided that it has a special agreement with the European Union in the field of public procurement on the conditions laid down in that agreement.

Questions can only be submitted via TED eTendering.

Who may not submit a tender?

- Tenderers must ensure that no involved entities nor any subcontractors, including those which do not need to be identified in the tender, are subject to **EU restrictive measures adopted under Article 29 of the Treaty on the European Union (TEU)** or **Article 215 of the Treaty on the Functioning of the EU (TFEU)**, consisting of a prohibition to make available or transfer funds or economic resources or to provide financing or financial assistance to them directly or indirectly, or of an asset freeze. The prohibition applies throughout the whole performance of the contract.

- Following the Council Implementing Decision (EU) 2022/2506, as of 16 December 2022, no legal commitments can be signed with Hungarian public interest trusts established under Hungarian Act IX of 2021 or any entity they maintain. This applies to all contractual level commitments, including subcontractors.

Questions can only be submitted via TED eTendering.

Registration in the Participant Register and Submission of the Tenders

- Any economic operator willing to participate in this call for tenders must be registered in the **Participant Register** - an online register of organisations and natural persons (participants) participating in calls for tenders or proposals of the European Commission and other EU institutions/bodies.
- Tenders are to be submitted via the **eSubmission application** according to the instructions laid down in the Invitation letter and the eSubmission Quick Guide available at the link: https://wikis.ec.europa.eu/display/FTPortal/Open+procedures_EN (*see Section 4.1)*

Questions can only be submitted via TED eTendering.

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Tender specifications: evaluation and award

The evaluation of the tenders that comply with the submission conditions will consist of the following elements:

- Check if the tenderer is not subject to **restrictive measures and has access to procurement** (*see Section 2.2*);
- Verification of **administrative compliance** (if the tender is drawn up in one of the official EU languages and the required documents signed by duly authorised representative(s) of the tenderer);
- Verification of non-exclusion of tenderers on the basis of the **exclusion criteria** (*see Section 3.1*)
- Selection of tenderers on the basis of **selection criteria** (*see Section 3.2*)
- Verification of compliance with the **minimum requirements** specified in the procurement documents (*see Section 3.3 and further details in Section 1.4.2.1*)
- Evaluation of tenders on the basis of the **award criteria** (*see Section 3.4*).

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Questions can only be submitted via TED eTendering.

Exclusion criteria (Section 3.1)

- The objective of the exclusion criteria is to assess whether the tenderer is in any of the exclusion situations listed in Article 136(1) of the Financial Regulation. Tenderers found to be in an exclusion situation will be rejected.
- As evidence of non-exclusion, each tenderer needs to submit with its tender a Declaration on Honour in the model available in Annex 2.
- Please see Section 3.1 - Exclusion criteria

<u>The documents mentioned in the Declaration on Honour as supporting evidence on non-exclusion must only be provided upon request of the Contracting Authority</u>

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Selection criteria (Section 3.2)

- The purpose of the selection criteria is to determine whether a tenderer has the necessary capacity to implement the contract.
- Selection criteria are verified on a pass/fail basis

Questions can only be submitted via TED eTendering.

Selection criteria (Section 3.2)

- ***3.2.1 Legal and regulatory capacity***

Tenderers can be natural or legal persons.

Tenderers are not obliged to take a specific legal form in order to submit their tenders.

Tenderers **need to prove specific legal and regulatory capacity** to perform the contract for the different lots, **by providing the identified evidence – to be submitted with the tender**.

Selection criteria (Section 3.2)

- ***3.2.2 Economic and financial capacity***

Please refer to Criteria F1, F2 and F3 for each Lot

Important for F1:

The minimum level of economic and financial capacity on criterion F1 for tenderers submitting tenders for two or more lots, should be the average yearly sum of turnover and other operating income (excluding variation in stocks) of the last two financial years above the aggregate of the respective lots. I.e. if applying for Lot 1 and 2, must be above EUR 8.500 000 (Lot 1 - EUR 5 000 000 and Lot 2 - EUR 3 500 000 respectively).

All the evidence on economic and financial capacity must be provided with the tender.

Questions can only be submitted via TED eTendering.

3.2.3 Technical and professional capacity

Lot 1, Lot 2 and Lot 3

Criterion T1

A list of clinical trials protocols/projects/activities meeting the minimum level of capacity is requested.

LOT 4

Criterion T1

A list of past development protocols meeting the minimum level of capacity is requested.

All the evidence on technical and professional capacity must be provided with the tender.

Questions can only be submitted via TED eTendering.

3.4 Award criteria LOT 1, 2, 3 and 4

- The objective of the award criteria is to evaluate the tenders with a view to choosing the most economically advantageous tender.
- Tenders will be evaluated on the basis of the following award criteria and their weighting:

- ***Price - 30%***

The price considered for evaluation will be the total price of the tender, covering all the requirements set out in the tender specifications.

Questions can only be submitted via TED eTendering.

3.4 Award criteria

- ***Quality - 70%***

LOT 1 - Vaccines to combat antimicrobial resistance (AMR)

Award criterion 1: Relevance and Innovation

Sub-criterion 1.1 - Relevance to Public Health Challenges and EU added value

Sub-criterion 1.2 – Innovation

Sub-criterion 1.3 - Promising Biological Activity and Safety

Award criterion 2: Methodology for conducting the clinical and concurrent non-clinical development activities

Questions can only be submitted via TED eTendering.

3.4 Award criteria

- ***Quality - 70%***

LOT 1 - Vaccines to combat antimicrobial resistance (AMR)

Award criterion 3: Appropriateness of the organisation of the work and resources

Award criterion 4: Quality of the measures implemented for a continuous high performance, including quality control and data protection

Please refer to Section 3.4 for all the details

3.4 Award criteria

- ***Quality - 70%***

LOT 2 - Broad Spectrum antivirals (respiratory RNA viral families)

LOT 3 – Broad-spectrum antivirals (VHF-associated RNA viral families)

Award criterion 1: Relevance and Innovation

Sub-criterion 1.1 - Relevance to Public Health Challenges and EU added value

Sub-criterion 1.2 – Broad-spectrum antiviral (BSA), and BSA-containing drug combinations (‘antiviral cocktails’)

Sub-criterion 1.3 - Safety profile and overall soundness of the scientific approach and technology used

Award criterion 2: Methodology for conducting the clinical and concurrent non-clinical development activities

Questions can only be submitted via TED eTendering.

3.4 Award criteria

- ***Quality - 70%***

LOT 2 - Broad Spectrum antivirals (respiratory RNA viral families)

LOT 3 – Broad-spectrum antivirals (VHF-associated RNA viral families)

Award criterion 3: Appropriateness of the organisation of the work and resources

Award criterion 4: Quality of the measures implemented for a continuous high performance, including quality control and data protection

Please refer to Section 3.4 for all the details

Questions can only be submitted via TED eTendering.

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3.4 Award criteria

- ***Quality - 70%***

LOT 4 – Point of care metagenomic sequencing for universal pathogen detection

Award criterion 1: Relevance and Innovation

Sub-criterion 1.1 - Relevance to Public Health Challenges and EU added value

Sub-criterion 1.2 – Innovation

Award criterion 2: Methodology

Questions can only be submitted via TED eTendering.

3.4 Award criteria

- ***Quality - 70%***

LOT 4 – Point of care metagenomic sequencing for universal pathogen detection

Award criterion 3: Appropriateness of the organisation of the work and resources

Award criterion 4: Quality of the measures implemented for a continuous high performance, including quality control and data protection

Please refer to Section 3.4 for all the details

4.2 Content of the tender: which documents to submit with the tender

Technical tender

- The technical tender for any lot must provide all the information needed to assess the compliance with Section 1.4 of the specifications and the award criteria

- When submitting the technical tender, it is **highly recommended** that the tenderer:

  - Limits the technical tender to a **maximum of 70 pages**, excluding evidence provided for the assessment of exclusion and selection criteria, such as CVs, past projects or profit and loss accounts, cover page and annexes, etc; and

  - Uses Times New Roman font with a minimum font size of 11, A4 page size and all margins (top, bottom, left, right) at least 15 mm (excluding any footers or headers).

Questions can only be submitted via TED eTendering.

4.2 Content of the tender: which documents to submit with the tender

Financial tender

- The Financial Model in Annex 6 shall be used.
- One Financial Form for each Lot.
- Any modification of the template of the financial tender may lead to rejection of the tender.

Questions can only be submitted via TED eTendering.

4.2 Content of the tender: what documents to submit with the tender

Tenderers willing to submit tenders for more than one lot need to upload a separate technical and financial tender for each of the lots in which they are interested.

Questions can only be submitted via TED eTendering.

Contact during the procedure

- Any request for additional information and request of clarification must be made in writing only through the TED eTendering website in the "Questions & answers" tab:

- Any other additional information will be published on the TED eTendering website

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Timeline

- 22 September: publication of the call for tenders
- **4 December, 16:00 (CET): deadline for submission of tenders**
- **5 December, 11:00 (CET):** opening of tenders

Questions can only be submitted via TED eTendering.

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Useful links

TED e-tendering to the innovative MCMs call for tenders

Funding & tender opportunities portal

Participant register

For detailed instructions on how to submit a tender

Questions can only be submitted via TED eTendering.

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Technical help

Contact the tender platform support team, from 08:00 to 20:00 CEST:

ec-funding-tender-service-desk@ec.europa.eu

+32 (0) 229 71063

The support team operates in **English only.**

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Closing remarks

Agnès Mathieu-Mendes

Head of Unit A2, EU4Health and SMP Food
European Health and Digital Executive Agency

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Thank you

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