

Belgium-Brussels: HADEA/2023/OP/0036 – Speed up the Development of and Access to Innovative Medical Countermeasures

OJ S 183/2023 22/09/2023

Contract notice

Services

Legal Basis:

Regulation (EU, Euratom) No 2018/1046

Section I: Contracting authority

I.1. Name and addresses

Official name: European Health and Digital Executive Agency (HaDEA), HADEA.A.2 – EU4Health/SMP Food

Postal address: COV2, Place Charles Rogier 16

Town: Brussels

NUTS code: BE100 Arr. de Bruxelles-Capitale/Arr. Brussel-Hoofdstad

Postal code: 1210

Country: Belgium

E-mail: hadea-procell@ec.europa.eu

Internet address(es):

Main address: <https://hadea.ec.europa.eu>

I.3. Communication

The procurement documents are available for unrestricted and full direct access, free of charge, at: <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=14937>

Additional information can be obtained from the abovementioned address

Tenders or requests to participate must be submitted electronically via: <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=14937>

I.4. Type of the contracting authority

European institution/agency or international organisation

I.5. Main activity

General public services

Section II: Object

II.1. Scope of the procurement**II.1.1. Title**

HADEA/2023/OP/0036 – Speed up the Development of and Access to Innovative Medical Countermeasures

Reference number: HADEA/2023/OP/0036

II.1.2. Main CPV code

73000000 Research and development services and related consultancy services

II.1.3. Type of contract

Services

II.1.4. Short description

This call for tenders aims at purchasing services to speed up the development of and support the access to medical countermeasures which address HERA's priority threats. To accelerate development and support access to MCMs, the requested services include the provision of clinical and concurrent non-clinical development services and the priority right to purchase the promising products (Investigational Medicinal Product – IMP for lots 1, 2 and 3 and product for lot 4), that shall allow bringing innovative products to the market and ensure EU/EEA access to them.

II.1.5. Estimated total value

Value excluding VAT: 82 000 000,00 EUR

II.1.6. Information about lots

This contract is divided into lots: yes
Tenders may be submitted for all lots

II.2. Description

II.2.1. Title

Vaccines to Combat Antimicrobial Resistance (AMR)
Lot No: 1

II.2.2. Additional CPV code(s)

73000000 Research and development services and related consultancy services, 73300000 Design and execution of research and development

II.2.3. Place of performance

NUTS code: AT Österreich
NUTS code: BE Belgique / België
NUTS code: BG България / Bulgaria
NUTS code: CY Κύπρος / Kýpros
NUTS code: CZ Česko
NUTS code: DE Deutschland
NUTS code: DK Danmark
NUTS code: EE Eesti
NUTS code: EL Ελλάδα / Elláda
NUTS code: ES España
NUTS code: FI Suomi / Finland
NUTS code: FR France
NUTS code: HR Hrvatska
NUTS code: HU Magyarország
NUTS code: IE Éire / Ireland
NUTS code: IS Ísland
NUTS code: IT Italia
NUTS code: LI Liechtenstein
NUTS code: LT Lietuva
NUTS code: LU Luxembourg
NUTS code: LV Latvija
NUTS code: MT Malta
NUTS code: NL Nederland
NUTS code: NO Norge
NUTS code: PL Polska

NUTS code: PT Portugal
NUTS code: RO România
NUTS code: SE Sverige
NUTS code: SI Slovenija
NUTS code: SK Slovensko

Main site or place of performance: Please consult the procurement documents.

II.2.4. Description of the procurement

Lot 1 of this call aims to speed up the development of vaccine candidates targeting bacterial infections as an alternative treatment strategy to address the rising incidence of AMR. The identified vaccine candidates shall be designed to target bacteria belonging to at least one of the twelve bacterial families classified as 'priority pathogens' in the 2017 WHO Bacterial Priority Pathogens List. These families encompass *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Enterobacteriaceae*, *Enterococcus faecium*, *Staphylococcus aureus*, *Helicobacter pylori*, *Campylobacter* spp., *Salmonellae*, *Neisseria gonorrhoeae*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Shigella* spp. The tender may also target *Mycobacterium tuberculosis*. Vaccine candidates must have shown promising biological activity based on immunogenicity data of Phase I and safety data from Phase I clinical trials. Lot 1 aims at supporting the advancement of vaccine candidates that have successfully completed at least Phase I clinical studies.

II.2.5. Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.6. Estimated value

Value excluding VAT: 22 000 000,00 EUR

II.2.7. Duration of the contract, framework agreement or dynamic purchasing system

Duration in months: 48

This contract is subject to renewal: no

II.2.10. Information about variants

Variants will be accepted: no

II.2.11. Information about options

Options: no

II.2.13. Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds: yes

Identification of the project: Regulation (EU) 2021/522 establishing a programme for the Union's action in the field of health (EU4Health programme) for the period 2021-2027.

II.2.14. Additional information

Please consult the procurement documents.

II.2. Description

II.2.1. Title

Broad Spectrum Antivirals against Respiratory Diseases

Lot No: 2

II.2.2.

Additional CPV code(s)

73000000 Research and development services and related consultancy services, 73300000 Design and execution of research and development

II.2.3. Place of performance

NUTS code: AT Österreich
NUTS code: BE Belgique / België
NUTS code: BG България / Bulgaria
NUTS code: CY Κύπρος / Kýpros
NUTS code: CZ Česko
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NUTS code: SE Sverige
NUTS code: SI Slovenija
NUTS code: SK Slovensko

Main site or place of performance: Please consult the procurement documents.

II.2.4. Description of the procurement

Lot 2 will support the development of broad-spectrum antivirals targeting respiratory RNA viral families, such as Paramyxo-, Orthomyxo and Coronaviridae.

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.

Broad spectrum antivirals candidates supported under the scope of these two lots under this call for tenders have finalised pre-clinical data (proof of principle), which means that the medicine design can meet the pharmaco-therapy challenge established, as well as first-in-man studies characterising pharmacokinetics, potential effective concentration and/or dose ranges.

II.2.5. Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.6. Estimated value

Value excluding VAT: 18 000 000,00 EUR

II.2.7. Duration of the contract, framework agreement or dynamic purchasing system

Duration in months: 48

This contract is subject to renewal: no

II.2.10. Information about variants

Variants will be accepted: no

II.2.11. Information about options

Options: no

II.2.13. Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds: yes

Identification of the project: Regulation (EU) 2021/522 establishing a programme for the Union's action in the field of health (EU4Health programme) for the period 2021-2027.

II.2.14. Additional information

Please consult the procurement documents.

II.2. Description

II.2.1. Title

Broad Spectrum Antivirals Targeting Viral Families Known for Causing Viral Haemorrhagic Fever (VHF)

Lot No: 3

II.2.2. Additional CPV code(s)

73000000 Research and development services and related consultancy services, 73300000 Design and execution of research and development

II.2.3. Place of performance

NUTS code: AT Österreich

NUTS code: BE Belgique / België

NUTS code: BG България / Bulgaria

NUTS code: CY Κύπρος / Kýpros

NUTS code: CZ Česko

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NUTS code: SK Slovensko

Main site or place of performance: Please consult the procurement documents.

II.2.4. Description of the procurement

Lot 3 will support the development of broad-spectrum antivirals targeting viral families known for causing viral haemorrhagic fever (VHF), such as Arena-, Bunya-, Flavi-, Filoviridae.

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.

Broad spectrum antivirals candidates supported under the scope of these two lots under this call for tenders have finalised pre-clinical data (proof of principle), which means that the medicine design can meet the pharmaco-therapy challenge established, as well as first-in-man studies characterising pharmacokinetics, potential effective concentration and/or dose ranges.

II.2.5. Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.6. Estimated value

Value excluding VAT: 18 000 000,00 EUR

II.2.7. Duration of the contract, framework agreement or dynamic purchasing system

Duration in months: 48

This contract is subject to renewal: no

II.2.10. Information about variants

Variants will be accepted: no

II.2.11. Information about options

Options: no

II.2.13. Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds:
yes

Identification of the project: Regulation (EU) 2021/522 establishing a programme for the Union's action in the field of health (EU4Health programme) for the period 2021-2027.

II.2.14. Additional information

Please consult the procurement documents.

II.2. Description

II.2.1. Title

Point of Care Metagenomic Sequencing for Universal Pathogen Detection
Lot No: 4

II.2.2. Additional CPV code(s)

73000000 Research and development services and related consultancy services, 73300000
Design and execution of research and development

II.2.3. Place of performance

NUTS code: AT Österreich
NUTS code: BE Belgique / België
NUTS code: BG България / Bulgaria
NUTS code: CY Κύπρος / Kýpros
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NUTS code: SI Slovenija

NUTS code: SK Slovensko

Main site or place of performance: Please consult the procurement documents.

II.2.4. Description of the procurement

Lot 4 supports the development of a metagenomic next-generation sequencing (mNGS)-based test that can detect any respiratory viral pathogen, including novel and emerging, from human respiratory samples. This lot targets MGS-based solutions optimised for infectious disease diagnostics and early outbreak detection.

II.2.5. Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.6. Estimated value

Value excluding VAT: 24 000 000,00 EUR

II.2.7. Duration of the contract, framework agreement or dynamic purchasing system

Duration in months: 48

This contract is subject to renewal: no

II.2.10. Information about variants

Variants will be accepted: no

II.2.11. Information about options

Options: no

II.2.13. Information about European Union funds

The procurement is related to a project and/or programme financed by European Union funds: yes

Identification of the project: Regulation (EU) 2021/522 establishing a programme for the Union's action in the field of health (EU4Health programme) for the period 2021-2027.

II.2.14. Additional information

Please consult the procurement documents.

Section III: Legal, economic, financial and technical information

III.1. Conditions for participation

III.1.1. Suitability to pursue the professional activity, including requirements relating to enrolment on professional or trade registers

List and brief description of conditions:

Please consult the procurement documents.

III.1.2. Economic and financial standing

Selection criteria as stated in the procurement documents

III.1.3. Technical and professional ability

Selection criteria as stated in the procurement documents

III.2. Conditions related to the contract

III.2.2. Contract performance conditions

Please consult the procurement documents.

III.2.3. Information about staff responsible for the performance of the contract

Obligation to indicate the names and professional qualifications of the staff assigned to performing the contract

Section IV: Procedure

IV.1. Description

IV.1.1. Type of procedure

Open procedure

IV.1.3. Information about a framework agreement or a dynamic purchasing system

IV.1.8. Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: no

IV.2. Administrative information

IV.2.2. Time limit for receipt of tenders or requests to participate

Date: 04/12/2023 Local time: 16:00

IV.2.3. Estimated date of dispatch of invitations to tender or to participate to selected candidates

IV.2.4. Languages in which tenders or requests to participate may be submitted

Bulgarian, Czech, Danish, German, Greek, English, Spanish, Estonian, Finnish, French, Irish, Croatian, Hungarian, Italian, Lithuanian, Latvian, Maltese, Dutch, Polish, Portuguese, Romanian, Slovak, Slovenian, Swedish

IV.2.6. Minimum time frame during which the tenderer must maintain the tender

Duration in months: 6 (from the date stated for receipt of tender)

IV.2.7. Conditions for opening of tenders

Date: 05/12/2023 Local time: 11:00

Place:

Tenders will be opened electronically on the date and time indicated in the contract notice. It is possible to attend the opening by videoconference.

Information about authorised persons and opening procedure: Please consult the procurement documents.

Section VI: Complementary information

VI.1. Information about recurrence

This is a recurrent procurement: no

VI.2. Information about electronic workflows

Electronic invoicing will be accepted

Electronic payment will be used

VI.3. Additional information

Please consult the procurement documents. In case of unavailability or disruptions in the functioning of the electronic means of communication provided in Section I.3) in the last 5 calendar days before the time limit for receipt indicated in Section IV.2.2), the contracting

authority reserves the right to extend this time limit and publish the extension at the internet address provided in Section I.3), without a preceding publication of a corrigendum to this notice. Economic operators interested in this procurement are invited to subscribe to the call for tenders at the address in Section I.3) in order to get notified when new information or documents are published.

VI.4. Procedures for review

VI.4.1. Review body

Official name: General Court of the European Union

Postal address: Rue du Fort Niedergrünwald

Town: Luxembourg

Postal code: L-2925

Country: Luxembourg

Telephone: +352 4303-1

Internet address: <http://curia.europa.eu>

VI.4.3. Review procedure

Precise information on deadline(s) for review procedures:

Please consult the procurement documents.

VI.5. Date of dispatch of this notice

15/09/2023