

Belgium-Brussels: Medical practice and related services

OJ S 202/2022 19/10/2022

Contract notice

Services

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority

I.1. Name and addresses

Official name: Agence Fédérale des Médicaments et des Produits de santé

National registration number: 0884.579.424_17050

Postal address: avenue galilée 5 / 03

Town: Bruxelles

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

Postal code: 1210

Country: Belgium

E-mail: david.dekuyssche@afmps.be

Telephone: +32 25248279

Internet address(es):Main address: www.fagg.beAddress of the buyer profile: <https://enot.publicprocurement.be/enot-war/preViewNotice.do?noticeId=461457>**I.3. Communication**The procurement documents are available for unrestricted and full direct access, free of charge, at: <https://enot.publicprocurement.be/enot-war/preViewNotice.do?noticeId=461457>

Additional information can be obtained from the abovementioned address

Tenders or requests to participate must be submitted electronically via: <https://eten.publicprocurement.be/etendering/viewWorkspacesBasedOnExtUrl.do?wsName=FAGG-2022-EMA-4L+-F02>Electronic communication requires the use of tools and devices that are not generally available. Unrestricted and full direct access to these tools and devices is possible, free of charge, at: <https://enot.publicprocurement.be/enot-war/displayForum.do?forumId=47841>**I.4. Type of the contracting authority**

National or federal agency/office

I.5. Main activity

Health

Section II: Object

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

PROCEDURE OUVERTE POUR DES SERVICES DE COLLABORATION SCIENTIFIQUE DANS LE CADRE DES PROCEDURES DE L'UNION EUROPEENNE 2023-2025 POUR LE COMPTE DE L'AFMPS

II.1.2. Main CPV code

85120000 Medical practice and related services

II.1.3. Type of contract

Services

II.1.4. Short description

Lot 1 & lot 2 :

Un poste de représentation belge au Scientific Advice Working Party (SAWP) du Comité des médicaments à usage humain (CHMP) de l'Agence européenne des médicaments (EMA).

Lot 3 : pédiatrique

Un poste de représentation belge au Paediatric Committee (PDCO) de l'Agence européenne des médicaments (EMA).

II.1.5. Estimated total value

II.1.6. Information about lots

This contract is divided into lots: yes

Tenders may be submitted for all lots

Maximum number of lots that may be awarded to one tenderer: 2

II.2. Description

II.2.1. Title

Un poste de représentation belge au Scientific Advice Working Party (SAWP) du Comité des médicaments à usage humain (CHMP) de l'Agence européenne des médicaments (EMA).

Lot No: 1

II.2.2. Additional CPV code(s)

85120000 Medical practice and related services

II.2.3. Place of performance

NUTS code: NL329 Groot-Amsterdam

Main site or place of performance: amsterdam

II.2.4. Description of the procurement

rôle de représentant de l'AFMPS au sein du Scientific Advice Working Party (SAWP) du Comité des médicaments à usage humain (CHMP) de l'Agence européenne des médicaments (EMA).

Le SAWP traite les demandes d'avis scientifique introduites par les firmes pharmaceutiques auprès de l'EMA. Ces demandes peuvent porter sur diverses disciplines (qualité des médicaments, aspects précliniques, aspects cliniques, etc.). Pour les nouvelles demandes d'avis scientifique, deux coordinateurs chaque fois sont désignés parmi les membres du SAWP. Ces coordinateurs préparent une proposition d'avis scientifique avec une équipe multidisciplinaire d'experts. Cette proposition est débattue au sein du SAWP. Les avis du SAWP sont validés par le CHMP.

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

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

Start: 01/03/2023 End: 31/03/2026

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:
no

II.2.14. Additional information

II.2. Description

II.2.1. Title

Un poste de représentation belge au Scientific Advice Working Party (SAWP) du Comité des médicaments à usage humain (CHMP) de l'Agence européenne des médicaments (EMA).

Lot No: 2

II.2.2. Additional CPV code(s)

85120000 Medical practice and related services

II.2.3. Place of performance

NUTS code: NL329 Groot-Amsterdam

Main site or place of performance: amsterdam

II.2.4. Description of the procurement

rôle de représentant de l'AFMPS au sein du Scientific Advice Working Party (SAWP) du Comité des médicaments à usage humain (CHMP) de l'Agence européenne des médicaments (EMA).

Le SAWP traite les demandes d'avis scientifique introduites par les firmes pharmaceutiques auprès de l'EMA. Ces demandes peuvent porter sur diverses disciplines (qualité des médicaments, aspects précliniques, aspects cliniques, etc.). Pour les nouvelles demandes d'avis scientifique, deux coordinateurs chaque fois sont désignés parmi les membres du SAWP. Ces coordinateurs préparent une proposition d'avis scientifique avec une équipe multidisciplinaire d'experts. Cette proposition est débattue au sein du SAWP. Les avis du SAWP sont validés par le CMHP.

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

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

Start: 01/03/2023 End: 31/03/2026

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:
no

II.2.14. Additional information

II.2. Description

II.2.1. Title

Un poste de représentation belge au Paediatric Committee (PDCO) de l'Agence européenne des médicaments (EMA).

Lot No: 3

II.2.2. Additional CPV code(s)

85120000 Medical practice and related services

II.2.3. Place of performance

NUTS code: NL329 Groot-Amsterdam

Main site or place of performance: amsterdam

II.2.4. Description of the procurement

Ce médecin spécialiste en pédiatrie assumera le rôle de représentant de l'AFMPS au sein du Paediatric Committee (PDCO) de l'Agence européenne des médicaments (EMA).

Le Paediatric Committee (PDCO) évalue les plans de recherche pédiatrique (« paediatric investigation plans ») pour les médicaments en développement. Ces plans de recherche doivent apporter la garantie que suffisamment d'études sont réalisées pour les enfants avec le médicament en développement, afin qu'une quantité suffisante de données soit récoltée pour pouvoir autoriser l'utilisation du médicament chez les enfants.

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

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

Start: 01/08/2023 End: 31/08/2026

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:
no

II.2.14. Additional information

Section III: Legal, economic, financial and technical information

III.1. Conditions for participation

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.2.3. 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: yes

IV.2. Administrative information

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

Date: 01/12/2022 Local time: 11:00

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

French, Dutch

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: 01/12/2022 Local time: 11:00

Section VI: Complementary information

VI.1. Information about recurrence

This is a recurrent procurement: no

VI.3. Additional information

VI.4. Procedures for review

VI.4.1. Review body

Official name: Conseil d'Etat

Postal address: rue de la Science 33

Town: Bruxelles
Postal code: 1040
Country: Belgium
E-mail: info@conseildetat.be
Telephone: +32 2349611
Internet address: <http://www.raadvst-consetat.be>

VI.4.2. Body responsible for mediation procedures

Official name: AFMPS
Postal address: Avenue Galilée 5, Bte 3
Town: Bruxelles
Postal code: 1210
Country: Belgium
E-mail: david.dekuyssche@afmps.be
Telephone: +32 25284279

VI.4.4. Service from which information about the review procedure may be obtained

Official name: AFMPS
Postal address: Avenue Galilée 5, Bte 3
Town: Bruxelles
Postal code: 1210
Country: Belgium
E-mail: david.dekuyssche@afmps.be
Telephone: +32 25284279

VI.5. Date of dispatch of this notice

14/10/2022