Enabel

Tender Specifications BEL21003-10004

Public Services Contract for providing "Short-term expertise for in the field of Manufacturing and Access to Medicines, Vaccines and Health Technologies"

NEGOTIATED PROCEDURE WITHOUT PRIOR PUBLICATION

Framework contract concluded with a single operator

Agence belge de développement

enabel.be

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1.1 Derogations from the General Implementing Rules

Chapter '*Specific contractual and administrative conditions*' of these Tender Specifications (CSC/Cahier Spécial des Charges) holds the specific administrative and contractual provisions that apply to this public procurement contract as a derogation of the Royal Decree of 14.01.2013 or as a complement or an elaboration thereof.

These tender documents derogate from Art. 25-33 of the General Implementing Rules (see point 4.7 "Performance guarantee").

1.2 Contracting authority

The contracting authority of this public procurement contract is Enabel, the Belgian development agency, public-law company with social purposes, with its registered office at Rue Haute 147, 1000 Brussels in Belgium (enterprise number 0264.814.354, RPM/RPR Brussels).

Enabel has the exclusive competence for the execution, in Belgium and abroad, of public service tasks of direct bilateral cooperation with the partner countries. Moreover, it may also perform other development cooperation tasks at the request of public interest organisations, and it can develop its own activities to contribute towards realisation of its objectives.

For this procurement contract, Enabel is represented by Mr. Arnaud Leclercq, Portfolio Manager – Global Projects and Mr. Patrick Gaudissart, Operations Manager who will sign the award letter and mandated to represent the company towards third parties.

1.3 Institutional setting of Enabel

The general framework of reference in which Enabel operates is:

- The Belgian Law on Development Cooperation of 19 March 2013^{1;}
- The Belgian Law of 21 December 1998 establishing the Belgian Technical Cooperation as a public-law company2;
- The Belgian Law of 23 November 2017 changing the name of the Belgian Technical Cooperation and defining the missions and functioning of Enabel, the Belgian development agency, published in the Belgian Official Gazette on 11 December 2017.

The following initiatives are also guiding Enabel in its operations: We mention as main examples:

- In the field of international cooperation: the United Nations Sustainable Development Goals and the Paris Declaration on the harmonisation and alignment of aid;
- In the field of the fight against corruption: the Law of 8 May 2007 approving the United Nations Convention against Corruption, adopted in New York on 31 October 20033, as well as the Law of 10 February 1999 on the Suppression of Corruption transposing the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions;

¹ Belgian Official Gazette of 30 December 1998, of 17 November 2001, of 6 July 2012, of 15 January 2013 and of 26 March 2013. Belgian Official Gazette of 1 July 1999.

³ Belgian Official Gazette of 18 November 2008.

- In the field of Human Rights: the United Nations' Universal Declaration of Human Rights (1948) as well as the 8 basic conventions of the International Labour Organisation4 on Freedom of Association (C. n°87), on the Right to Organise and Collective Bargaining (C. n°98), on Forced Labour (C. n°29 and 105), on Equal Remuneration and on Discrimination in Respect of Employment (C. n°100 and 111), on Minimum Age for Admission to Employment (C. n°138), on the Prohibition of the Worst Forms of Child Labour (C. n°182);
- In the field of environmental protection: The Climate Change Framework Convention in Paris, 12 December 2015;
- The first Management Contract concluded between Enabel and the Belgian federal State (approved by the Royal Decree of 17.12.2017, Belgian Official Gazette 22.12.2017) that sets out the rules and the special conditions for the execution of public service tasks by Enabel on behalf of the Belgian State.
- Enabel's Code of Conduct of January 2019, Enabel's Policy regarding sexual exploitation and abuse of June 2019 and Enabel's Policy regarding fraud and corruption risk management of June 2019.

1.4 Rules governing the procurement contract

The following, among other things, applies to this public procurement contract:

- The Law of 17 June 2016 on public procurement contracts⁵;
- The Law of 17 June 2013 on justifications, notification and legal remedies for public procurement contracts and certain procurement contracts for works, supplies and services⁶;
- The Royal Decree of 18 April 2017 on the award of public procurement contracts in the classic sectors⁷;
- Royal Decree of 14 January 2013 establishing the General Implementing Rules for public procurement contracts and for concessions for public works8;
- Circulars of the Prime Minister with regards to public procurement contracts.
- Enabel's Policy regarding sexual exploitation and abuse June 2019;
- Enabel's Policy regarding fraud and corruption risk management June 2019;
- legislation with regards to sexual harassment at the workplace or equivalent]
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation – 'GDPR'), and repealing Directive 95/46/EC.
- Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data. ;

All Belgian regulations on public contracts can be consulted on <u>www.publicprocurement.be</u>; Enabel's Code of Conduct and the policies mentioned above can be consulted on Enabel's website via <u>https://www.enabel.be/content/integrity-desk</u>.

⁴ <u>http://www.ilo.org/ilolex/french/convdisp1.htm</u>.

⁵ Belgian Official Gazette 14 July 2016.

 ⁶ Belgian Official Gazette of 21 June 2013.
 ⁷ Belgian Official Gazette 9 May 2017.

⁸ Belgian Official Gazette 27 June 2017.

1.5 Definitions

The following definitions apply to this procurement contract:

The tenderer: An economic operator submitting a tender;

<u>The contractor/ service provider</u>: The tenderer to whom the procurement contract is awarded;

<u>The contracting authority</u>: Enabel, represented by Mr. Arnaud Leclercq, Portfolio Manager – Global Projects and Mr. Patrick Gaudissart, Operations Manager

<u>The tender</u>: Commitment of the tenderer to perform the procurement contract under the conditions that he has submitted;

<u>Days</u>: In the absence of any indication in this regard in the Tender Specifications and the applicable regulations, all days should be interpreted as calendar days;

<u>Procurement documents</u>: Tender Specifications including the annexes and the documents they refer to;

<u>Technical specifications</u>: A specification in a document defining the characteristics of a product or a service, such as the quality levels, the environmental and climate performance levels, the design for all needs, including accessibility for people with disabilities, and the evaluation of conformity, of product performance, of the use of the product, safety or dimensions, as well as requirements applicable to the product as regards the name by which it is sold, terminology, symbols, testing and test methods, packaging, marking or labelling, instructions for use, the production processes and methods at every stage in the life cycle of the supply or service, as well as the evaluation and conformity procedures;

<u>Variant</u>: An alternative method for the design or the performance that is introduced either at the demand of the contracting authority, or at the initiative of the tenderer;

<u>Option</u>: A minor and not strictly necessary element for the performance of the procurement contract, which is introduced either at the demand of the contracting authority, or at the initiative of the tenderer;

<u>Inventory</u>: The procurement document which splits up the performance in different items and specifies the quantity or the method to determine the price for each of them;

<u>General Implementing Rules (GIR)</u>: Rules laid down in the Royal Decree of 14.01.2013 establishing the General Implementing Rules for public procurement contracts and for concessions for public works;

<u>The Tender Specifications</u> (Cahier spécial des charges/CSC): This document and its annexes and the documents it refers to;

<u>Corrupt practices</u>: The offer of a bribe, gift, gratuity or commission to any person as an inducement or reward for performing or refraining from any act relating to the award of a procurement contract or performance of a procurement contract already concluded with the contracting authority;

Litigation: Court action.

<u>Subcontractor in the meaning of public procurement regulations:</u> The economic operator proposed by a tenderer or contractor to perform part of the contract. The subcontractor is understood as the economic operator with the capacity which the applicant or tenderer relies upon or to whom he entrusts all or part of his engagements.

<u>Controller in the meaning of the GDPR:</u> the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.

<u>Sub-contractor or processor in the meaning of the GDPR:</u> a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller.

<u>Recipient in the meaning of the GDPR:</u> a natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not.

<u>Personal data:</u> any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

1.6 Processing of personal data by the contracting authority and confidentiality

1.6.1 Processing of personal data by the contracting authority

The contracting authority undertakes to process the personal data that are communicated to it in response to the Call for Tenders with the greatest care, in accordance with legislation on the protection of personal data (General Data Protection Regulation, GDPR). Where the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data contains stricter provisions, the contracting authority will act in accordance with said law.

1.6.2 Confidentiality

The tenderer or contractor and Enabel are bound to secrecy vis-à-vis third parties with regards to any confidential information obtained within the framework of this public contract and will only divulge such information to third parties after receiving the prior written consent of the other party. They will disclose this confidential information only among appointed parties involved in the assignment. They guarantee that said appointed parties will be adequately informed of their obligations in respect of the confidential nature of the information and that they shall comply therewith.

PRIVACY NOTICE OF ENABEL: Enabel takes your privacy serious. We undertake to protect and process your personal data with due care, transparently and in strict compliance with privacy protection legislation.

See also: https://www.enabel.be/content/privacy-notice-enabel

1.7 Deontological obligations

1.7.1. Any failure to comply with one or more of the deontological clauses may lead to the exclusion of the candidate, tenderer or contractor from other public procurement contracts for Enabel.

1.7.2. For the duration of the procurement contract, the contractor and his staff respect human rights and undertake not to go against political, cultural or religious customs of the beneficiary country. The tenderer or contractor is bound to respect fundamental labour standards, which are internationally agreed upon by the International Labour Organisation (ILO), namely the conventions on union freedom and collective bargaining, on the elimination of forced and obligatory labour, on the elimination of employment and professional discrimination and on the abolition of child labour.

1.7.3. In accordance with Enabel's Policy regarding sexual exploitation and abuse, the contractor and his staff have the duty to behave in an irreproachable manner towards the beneficiaries of

the projects and towards the local population in general. They must abstain from any acts that could be considered a form of sexual exploitation or abuse and they must abide by the basic principles and guidelines laid down in this policy.

1.7.4. Any attempt of a candidate or a tenderer to obtain confidential information, to proceed to illicit arrangements with competitors or to influence the evaluation committee or the contracting authority during the investigation, clarification, evaluation and comparison of tenders and candidates, procedure will lead to the rejection of the application or the tender.

1.7.5. Moreover, in order to avoid any impression of risk of partiality or connivance in the followup and control of the performance of the procurement contract, it is strictly forbidden to the contractor to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to agents of the contracting authority who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the procurement contract, regardless of their hierarchical rank.

1.7.6. The contractor of the procurement contract commits to supply, upon the demand of the contracting authority, any supporting documents related to the performance conditions of the contract. The contracting authority will be allowed to proceed to any control, on paperwork or on site, which it considers necessary to collect evidence to support the presumption of unusual commercial expenditure. Depending on the gravity of the facts observed, the contractor having paid unusual commercial expenditure is liable to have its contract cancelled or to be permanently excluded from receiving funds.

1.7.7. In accordance with Enabel's Policy regarding sexual exploitation and abuse of June 2019 and Enabel's Policy regarding fraud and corruption risk management complaints relating to issues of integrity (fraud, corruption, etc.) must be sent to the Integrity desk through the <u>https://www.enabelintegrity.be</u> website.

1.8 Applicable law and competent courts

The procurement contract must be performed and interpreted according to Belgian law.

The parties commit to sincerely perform their engagements to ensure the good performance of this procurement contract.

In case of litigation or divergence of opinion between the contracting authority and the contractor, the parties will consult each other to find a solution. If agreement is lacking, the Brussels courts are the only courts competent to resolve the matter.

2.1 Type of procurement contract

This contract is a public service contract and is awarded as Framework Agreement concluded with one operator without renewed competition: Article 43, §4, al. 1 of the Law of 17 June 2016.

This public contract is awarded as a framework agreement with a single supplier. All the terms of the framework agreement determined in these Tender Specifications and the tenders are binding so the orders can be placed without any further additions to the original tenders, in accordance with Article 43 of the Law of 17 June 2016.

Conclusion of this public contract confers no exclusive rights to the service provider. The contracting authority may, even during the validity term of this contract, have other service providers or its own departments deliver services that are identical or similar to those referred to in these Tender Specifications. Consequently, the service provider may not lay claim to the payment of any sort of compensation.

2.2 Subject-matter of the procurement contract

This public supplies contract consists performance of short-term expertise, in conformity with the conditions of these Tender Specifications.

2.3 Lots⁹

(Articles 2, 52° and 58 of the Law and Articles 49 and 50 of the Royal Decree Award)

This contract is a contract with one lot which is indivisible.

2.4 Items

This contract consists of the following items:

Item 1: Services provided expert 1: Pharmaceutical Expert

Item 2: Services provided expert 2: Health Economist

2.5 Term of the procurement contract¹⁰

The contract runs from the first working day following the notification of the award until the acceptance of the services.

Enabel also reserves the right to order additional services from the service provider within a maximum period of 4 years from the notification of the award of the contract, and this within the budgetary limits authorized by this procedure.

⁹ For contracts of an amount equal to or greater than € 135 000 excl. VAT, the contracting authority is obliged to consider dividing the contract into lots unless a valid reason is given in the procurement documents.

¹⁰ Please note: term of the procurement contract not to be confused with performance period.

The service provider may not claim any compensation in the event that the number of orders does not reach the estimates mentioned above.

2.6 Variants

The tenderer may not submit a variant. Free variants are forbidden. Any variant proposed will be discarded.

Each tenderer may submit only one tender.

2.7 Option

The tenderer may not submit a variant. Free options are forbidden. The option proposed will be discarded.

2.8 Quantity

This being a framework contract, it has no minimum quantities.

Enabel estimates that it will order up to a maximum of 50 days for both types of expertise from the service provider selected under this contract, mainly in July and August 2023.

3 Procedures for the procurement contract

3.1 Award procedure

Negotiated Procedure without Prior Publication in application of Article 42, §1, al. 1, 1°, a) of the Law of 17 June 2016 on public procurement.

3.2 Semi-official notification

3.2.1 Enabel publication

This procurement contract is published on the Enabel website (www.enabel.be).

3.3 Information

The awarding of this procurement contract is coordinated by John Tallon, Expert en Contractualisation; john.tallon@enabel.be.

Throughout this procedure all contacts between the contracting authority and the (prospective) tenderers about this procurement contract will exclusively pass through this person. (Prospective) tenderers are prohibited to contact the contracting authority in any other way with regards to this contract, unless otherwise stipulated in these Tender Specifications.

Until the **21st of June at 5 pm**, tenderers may ask questions about these Tender Specifications and the procurement contract.

The complete overview of questions and answers will be provided to all tenderers the **23st of June et 12 pm (midday).**

Until the notification of the award decision no information will be given about the evolution of the procedure.

The procurement documents can be consulted free of charge at the following internet address: www.enabel.be

To be able to submit a tender in full knowledge of the facts, the tenderer may visit the website. <u>www.enabel.be</u> .

The tenderer is supposed to submit his tender after reading and taking into account any corrections made to the Tender Specifications that are published on the Enabel website or that are sent to him by e-mail. To do so, when the tenderer has downloaded the Tender Specifications, it is strongly advised that he gives his coordinates to the public procurement administrator mentioned above and requests information on any modifications or additional information.

The tenderer is required to report immediately any gap, error or omission in the procurement documents that precludes him from establishing his price or compare tenders, within ten days at the latest before the deadline for receipt of tenders.

3.4 Tender

3.4.1 Data to be included in the tender

The tenderer must use the tender form in annexe (**see point 6 "Forms**"). In case he does not use these forms, he is fully responsible for the perfect concordance between the documents he has used and the form.

The tender and the annexes to the tender form are drawn up in English.

By submitting a tender, the tenderer automatically renounces to his own general or specific sales

conditions, even if these are mentioned in any of the annexes to his tender.

The tenderer clearly designates in his tender which information is confidential and/or relates to technical or business secrets and may therefore not be divulged by the contracting authority.

3.4.2 Period the tender is valid

The tenderers are bound by their tender for a period of 120 calendar days from the reception deadline date.

The validity of the tender will be negotiated if the deadline stated above is overrun.

3.4.3 Determination of prices

All prices given in the tender form must obligatorily be quoted in **EUROS**, taxes excluded.

This procurement contract is a price-schedule contract (price man/day in EUR ex-VAT).

The price to be paid will be obtained by applying the unit prices mentioned in the inventory to the quantities actually performed.

In accordance with Article 37 of the Royal Decree of 18 April 2017, the contracting authority may for the purpose of verifying the prices carry out an audit of any and all accounting documents and an on-site audit to check the correctness of the indications supplied.

3.4.3.1. Elements included in the price

(Art. 32 §3 Royal Decree 18.04.2017)

The service provider is deemed to have included in his unit and global prices any charges and taxes generally applied to services, with the exception of the value-added tax.

The following are in particular included in the prices:

- The administrative management and secretariat;
- Documentation pertaining to the services;
- The delivery of documents or of pieces related to the performance;
- Where applicable, the measures imposed by occupational safety and worker health legislation;

The price only relates to the unit price (man-day) in EUR ex-VAT.

For each order, Enabel will specify the number of days that will be needed after having discussed it with the service provider and the incl. VAT.

In case of a mission in the field, the service provider may invoice maximum \bigcirc 1,500 incl. VAT economy class return trip on the basis of the invoice and a flat rate of \bigcirc 250 (does not need to be justified) per day worked in the field (accommodation and small expenses).

3.4.4 How to submit tenders?

Without prejudice to any variants, the tenderer may only submit only one tender.

The tenderer submits his tender before **Thursday 29th of June at 5pm (UTC+2)** the following mail address: **john.tallon@enabel.be**.

The representative must clearly state that he/she is authorised to commit the tenderer. If the tenderer is a company / association without legal body status, formed by separate natural or legal persons (temporary group or temporary partnership), the tender must be signed by each of these persons.

Any request for participation or tender must arrive before the final submission date and time. Requests for participation or tenders that arrive late will not be accepted¹¹.

3.4.5 Change or withdrawal of a tender that has already been submitted

When a tenderer wants to change or withdraw a tender already sent or submitted this must be done in accordance with the provisions of Articles 43 and 85 of the Royal Decree of 18 April 2017.

To change or withdraw a tender already sent or submitted, a written statement is required, which will be correctly signed by the tenderer or his representative. The subject-matter and the scope of the changes must be indicated in detail. Any withdrawal must be unconditional.

The withdrawal may also be communicated by fax or electronic means, if it is confirmed by registered letter deposited at the post office or against acknowledgement of receipt at the latest the day before the tender acceptance deadline.

Thus, a tender that is modified or withdrawn after the signing of the submission report means that a new submission report, signed in accordance with paragraph 1, must be sent.

The subject-matter and the scope of the changes must be indicated in detail.

The withdrawal must be pure and simple.

When the submission report drawn up following the modifications or withdrawal set out in clause 1 does not bear the signature referred to in paragraph 1, the modification or withdrawal is automatically deemed null and void. This nullity applies only to the modifications or withdrawal, not to the tender itself.

3.4.6 Opening of tenders

The tender must be in the possession of the contracting authority before the final submission date and time specified in point 3.4.4. "How to submit tenders". The tenders shall be opened behind closed doors.

3.4.7 Selection of tenderers

Articles 66 – 80 of the Law; Articles 59 to 74 Royal Decree Award

3.4.7.1 Exclusion grounds

The mandatory and optional exclusion grounds are given in attachment to these Tender Specifications.

By submitting this tender, the tenderer certifies that he is not in any of the cases of exclusion listed in the Articles 67 to 70 of the Law of 17 June 2016 and the Articles 61 to 64 of the Royal Decree of 18 April 2017.

The contracting authority will verify the accuracy of this Declaration on honour for the tenderer with the best tender on the basis of the following documents:

- Extract from the criminal record of the manager of the bidding company
- Certificate of regularity of social contributions
- Certificate of fiscal regularity

The recent nature of the documents aforementioned is established to the extent that they are less than 3 months old from the final submission date.

Art. 83 of the Royal Decree Award

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For Belgian tenderers, the contracting authority will itself ask for information or documents that it can obtain free of charge by digital means from the instances that manage the information or documents (Telemarc).

In other cases, the tenderer can attach these documents to the offer. If these documents are not attached to the offer, the tenderer must be able to provide the documents aforementioned within 5 working days from the contract authority's request. If the tenderer does not submit the requested document(s) within the deadline, the adjudicator reserves the right to exclude the tenderer.

Tenderers are strongly advised not to wait for the contract authority's request and to ask their local competent authorities as soon as possible for the documents they have not attached to their tender. Indeed, the time for obtaining certain documents can be long.

Conflicts of interest and revolving doors mechanism:

As part of the fight against conflicts of interests, in particular in view of avoiding revolving doors mechanisms as defined in the Law of 8 May 2007 approving the United Nations Convention against Corruption, adopted in New York on 31 October 2003, the tenderer shall refrain from relying on any former (internal or external) collaborators of Enabel, within two years from his/her/their resignation, retirement or any other type of departure from Enabel, for whatever reason, directly or indirectly, for the elaboration and/or submission of its tender or any other intervention under the award procedure or for tasks to be conducted as part of the performance of this procurement contract.

The above provision does however only apply when there is a direct link between the preceding activities conducted for the contracting authority by the person(s) concerned and his/her/their activities for this procurement contract.

Any breach of this measure liable to distort the normal conditions of competition is subject to a sanction in accordance with the provisions of Article 5 of the Law of 17 June 2016 on public procurement contract and certain procurement contracts works, supplies and services. In concrete terms, this sanction, depending on the case, consists of discarding the tender or terminating the procurement contract.

3.4.7.2 Selection criteria

Article 71 of the Law and Articles 65 to 74 of the Royal Decree of 18.04.2017

The tenderer must prove that he is sufficiently capable, from a technical point of view, to successfully perform this public procurement contract.

Technical aptitude: See Art. 68 of the Royal Decree of 18.04.2017				
The tenderer must show at least 3 similar assignments of services delivered over the past three years: The tenderer includes in his tender a list with the main services that have been delivered over the past three years including the amount and date as well as the public or private recipients.	List of similar assignments that have been performed by the Service Provider over the past three years (see below)			

experts	 Master's degree in pharmaceutical sciences or Health sciences Excellent knowledge of English (written/oral) Minimum 5 years of experience in the field of public 				
•	health, access to quality assured medicines, vaccines or health products; Minimum 5 years of experience in strengthening pharmaceutical systems (e.g., Regulation strengthening, Market Shaping, demand & trade facilitation) Good knowledge of the African pharmaceutical systems context and of stakeholders				
2. • •	Health Economist Master's degree in Business Administration, Economic Sciences or Political Sciences Excellent knowledge of English (written/oral) Minimum 5 years of experience in the field of public health, access to quality assured medicines, vaccines or health products; Minimum 5 years of experience in strengthening pharmaceutical systems (e.g., Regulation strengthening, Market Shaping, demand & trade facilitation) Good knowledge of the African pharmaceutical systems context and of stakeholders				

Description of the main similar supply deliveries	Delivery places	Amount involved	Relevant dates in the last 3 years	Name of the Client

3.4.7.3 Overview of the procedure

In a first phase, the tenders submitted by the selected tenderers will be evaluated as to formal and material regularity.

The contracting authority reserves the right to have the irregularities in the tenderers' tender regularised during the negotiations.

Furthermore, Enabel reserves the right to negotiate the content of the bids within the limits provided for by the regulations within the framework of this procedure.

3.4.7.4 Award criteria

The contracting authority will choose the regular bid, eventually negotiated, that it finds to be most advantageous, taking account of the following criteria:

1. Technical expertise /Qualifications and experience of assigned staff (70%)

a. Sub-criterion 1:

Any useful qualification (specialisation in the area of pharmaceutical sciences, access to quality health products) in addition to the minimum required for expert 1 (Pharmaceutical Expert)

- Specialisation in the area of pharmaceutical sciences (10%)
- Specialisation in the area of access to quality health products (10%)
- b. Sub-criterion 2 :

Any useful experience in addition to the minimum required for expert 1; Pharmaceutical Expert (minimum 5 years of experience in the field of public health, access to quality assured medicines, vaccines or health products and minimum 5 years of experience in strengthening pharmaceutical systems)

The following formula will be used to obtain the score for tender X =

Number of additional years of experience of tender X / Highest number of additional years of experience for both expertise's (*15)

c. Sub-criterion 3 :

Any useful qualification (specialisation in the area of pharmaceutical sciences, access to quality health products) in addition to the minimum required for expert 2 (Health Economist)

- Specialisation in the area of pharmaceutical sciences (10%)
- Specialisation in the area of access to quality health products (10%)
- d. Sub-criterion 4 :

Any useful experience in addition to the minimum required for expert 2; Health Economist (minimum 5 years of experience in the field of public health, access to quality assured medicines, vaccines or health products and minimum 5 years of experience in working or engaging with the pharmaceutical private sector)

With regards to the price criterion, the following formula will be used:

The following formula will be used to obtain the score for tender X =

Number of additional years of experience of tender X / Highest number of additional years of experience for both expertise's (*15)

2. Financial proposal (30%)

With regards to the price criterion, the following formula will be used: Points tender **X** = <u>Amount of lowest tender * 30</u> <u>Amount of tender X</u>

3.4.7.5 Final score

The scores for the award criteria will be considered for the ranking of the selected bidders. The procurement contracts will be awarded to the best selected tenderers following their ranking with regards to their final score, after the contracting authority has verified the accuracy of the Declaration on honour of this tenderer and provided the control shows that the Declaration on honour corresponds with reality.

3.4.7.6 Awarding the procurement contract

Articles 41 and 81 of the Law

The procurement contracts will be awarded to the tenderers who has submitted the most economically advantageous tenders.

Notice though that in accordance with Art. 85 of the Law of 17 June 2016, there is no obligation for the contracting authority to award the procurement contract.

The contracting authority may either decide not to award the procurement contract; either redo the procedure, if necessary, through another award procedure.

3.4.8 Concluding the framework agreement

A framework agreement will be concluded with the best-ranked tenderer, after the contracting authority has verified the exclusion grounds.

The framework agreement is concluded by the notification to the participant of the contracting authority's decision.

Notification is via e-mail.

Notice though that, in accordance with Art. 85 of the Law of 17 June 2016, there is no obligation for the contracting authority to conclude the framework agreement.

The contracting authority can either decide not to conclude the framework agreement, either redo the procedure, if necessary, through another award procedure

So, the full contract agreement consists of a procurement contract awarded by Enabel to the chosen tenderer in accordance with:

- These Tender Specifications and its annexes;
- if any, minutes of the information session and/or clarifications and/or the addendum,
- The approved BAFO of the contractor and all of its annexes;
- The registered letter of notification of the award decision;
- Any later documents that are accepted and signed by both parties, as appropriate.

In an objective of transparency, Enabel undertakes to publish each year a list of recipients of its contracts. By introducing his tender, the successful tenderer declares that he agrees with the publication of the title of the contract, the nature and object of the contract, its name and location, and the amount of the contract.

4 Special contractual provisions

This chapter of these Tender Specifications holds the specific provisions that apply to this public procurement contract as a derogation of the 'General Implementing Rules for public procurement contracts and for public works concessions' of the Royal Decree of 14 January 2013, hereinafter referred to as 'GIR', or as a complement or an elaboration thereof. The numbering of the articles below (between brackets) follows the numbering of the GIR articles. Unless indicated, the relevant provisions of the General Implementing Rules (GIR) apply in full.

These tender documents derogate from Art. 25-33 of the General Implementing Rules (see point 4.7 "Performance guarantee").

4.1 Definitions (Art. 2)

- <u>Contract manager</u>: The official or any other person who manages and controls the performance of the contract;
- <u>Performance bond</u>: Financial guarantee given by the successful tenderer to cover its obligations until final and good performance of the contract;
- <u>Acceptance</u>: Observation by the contracting authority that the performance of all or part of the works, supplies or services is in compliance with good practice and with the terms and conditions of the contract;
- <u>Progress payment</u>: Payment of an instalment under the contract after service delivery is accepted;
- <u>Advance</u>: Payment of part of the contract before service delivery (if accepted);
- <u>Amendment</u>: Agreement established between the contracting parties during contract performance in view of changing documents applicable to the contract.

4.2 Managing official (Art. 11)

The managing official is **Catherine Dujardin**, « Experte en Stratégie et Politique Programme en Santé Publique », **catherine.dujardin@enabel.be**

Once the procurement contract is concluded, the managing officials are the main contact point for the service provider. Any correspondence or any questions with regards to the performance of the procurement contract will be addressed to him/her, unless explicitly mentioned otherwise in these Tender Specifications.

The managing officials are responsible for the follow-up of the performance of the contract.

The managing officials are fully competent for the follow-up of the satisfactory performance of the procurement contract, including issuing service orders, drawing up reports and states of affairs, approving the services, progress reports and reviews. She may order any modifications to the procurement contract with regards to its subject-matter provided that they remain within its scope.

However, the signing of amendments or any other decision or agreement implying derogation from the essential terms and conditions of the procurement contract are not part of the competence of the managing official. For such decisions the contracting authority is represented as stipulated under the contracting authority.

Under no circumstances is the managing official allowed to modify the terms and conditions (e.g. performance deadline) of the contract, even if the financial impact is nil or negative. Any commitment, change or agreement that deviates from the conditions in the Tender Specifications and that has not been notified by the contracting authority, will be considered null and void.

4.3 Subcontractors (Art. 12 to 15)

The fact that the contractor entrusts all or part of his commitments to subcontractors does not relieve him of liability to the contracting authority. The latter does not recognise any contractual relation with third parties.

The contractor remains, in any case, solely liable to the contracting authority.

The service provider commits to having the procurement contract performed by the persons indicated in the tender, except for force majeure. The persons mentioned or their replacements are all deemed to effectively be involved in the performance of the procurement contract. Any replacements must be approved by the contracting authority.

Art. 12/3 § 2 of the Royal Decree of 14 January 2013:

3° when this involves a service contract in a sector susceptible to fraud, the subcontracting chain may only have two levels at most, namely the contractor's direct subcontractor and the second level subcontractor.

When the contractor uses a subcontractor to carry out specific processing activities on behalf of the contracting authority, the same data protection obligations as those of the contractor are imposed on that subcontractor by contract or any other legal act.

In the same way, the contractor will respect and enforce to his subcontractors, the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation, GDPR). The contracting authority may conduct an audit of the processing carried out in order to validate compliance with this legislation.

4.4 Confidentiality (art. 18)

The knowledge and information gathered by the tenderer under the framework of this public contract is strictly confidential.

Under no circumstances can the information collected, regardless of its origin and nature, be transferred to third parties in any form.

The tenderer is therefore bound by the duty of discretion.

In accordance with Article 18 of the Royal Decree of 14 January 2013 establishing the general rules for public procurement, the tenderer undertakes to consider and process in a strictly confidential manner any information, all facts, any documents and/or any data, whatever their nature and support, which have been communicated to him, in any form and by any means, or to which he has access, directly or indirectly, in the context or on the occasion of this public contract. Confidential information covers, in particular, the very existence of this public contract, without this list being limited.

Therefore, he undertakes to:

- Respect and enforce the strict confidentiality of these elements and to take all necessary precautions in order to preserve their secrecy (these precautions cannot in any case be inferior to those taken by the tenderer for the protection of his own confidential information);
- Consult, use and/or exploit, directly or indirectly, all of the above elements only to the extent strictly necessary to prepare and, if necessary, to carry out this public contract (particularly in accordance with the privacy legislation with respect to personal data processing);

- Not reproduce, distribute, disclose, transmit or otherwise make available to third parties the above elements, in whole or in part, and in any form, unless having obtained prior and written consent of the contracting authority;
- Return, at the first request of the contracting authority, the above elements;
- In general, not disclose directly or indirectly to third parties, whether for advertising or any other reason, the content of this public contract.

4.5 Protection of personal data

4.5.1 Processing of personal data by the contracting authority

The contracting authority undertakes to process the personal data that are communicated to it in response to the Call for Tenders with the greatest care, in accordance with legislation on the protection of personal data (General Data Protection Regulation, GDPR). Where the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data contains stricter provisions, the contracting authority will act in accordance with said law.

4.5.2 PROCESSING OF PERSONAL DATA BY A SUBCONTRACTOR

During contract performance, the contractor may process personal data of the contracting authority exclusively in the name and on behalf of the contracting authority, for the sole purpose of performing the services in accordance with the provisions of the Tender Specifications or in execution of a legal obligation.

For any processing of personal data carried out in connection with this public contract, the contractor is required to comply with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR) and the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

By simply participating in the contracting process, the tenderer certifies that he will strictly comply with the obligations of the GDPR for any processing of personal data conducted in connection with that public contract.

The personal data that will be processed are confidential. The contractor will therefore limit access to data to the strictly necessary personnel for the performance, management and monitoring of the public contract.

For the performance of the public contract, the contracting authority will determine the purposes and means of processing personal data. In this case, the contracting authority will be responsible for the processing and the contractor will be its processor, within the meaning of Article 28 of the GDPR.

Processing carried out on behalf of a controller must be governed by a contract or other legal act that is binding on the processor with regard to the personal data controller and that sets out that the subcontractor acts only on the instruction of the person in charge of the processing and that the confidentiality and security obligations regarding the processing of personal data are also the responsibility of the subcontractor (Article 28 §3 of the GDPR).

4.6 Intellectual property (Art. 19 to 23)

§1 the contracting authority acquires the intellectual property rights created, developed or used during performance of the contract.

Without prejudice to clause 1 and unless otherwise stipulated in the procurement documents, when the subject-matter of the procurement contract consists of the creation, manufacture or the development of designs or of logos, the contracting authority acquires the intellectual property thereof, as well as the right to trademark them, to have them registered and to have them

protected.

For domain names created under the procurement contract, the contracting authority also acquires the right to register and protect them, unless otherwise stipulated in the procurement documents.

When the contracting authority does not acquire the intellectual property rights, it obtains a patent licence of the results protected by intellectual property law for the exploitation modes that are mentioned in the procurement documents.

4.7 Performance bond (Art. 25 to 33)

For this procurement contract no performance bond is required.

The performance bond is set at 5 % of the total value, excluding VAT, of the procurement contract. The value thus obtained is rounded up to the nearest 10 euros.

In accordance with the legal and regulatory provisions, the performance bond may be constituted either of cash or of public funds or may take the form of a joint performance bond.

The performance bond may also take the form of a surety bond issued by a credit institution meeting the requirements of the law on the statute and control of credit institutions, or by an insurance company meeting the requirements of the law on control of insurance companies and approved for branch 15 (bonds).

As a derogation from Article 26, the performance bond may be posted through an establishment that has its registered office in one of the countries of destination of the services. The contracting authority maintains the right to accept or refuse the posting of the bond through that institution. The tenderer shall mention the name and address of this institution in the tender.

This derogation is founded on the idea of providing possible local tenderers with an opportunity to submit a tender. This measure is made essential by the specific requirements of the contract.

The contractor must, within 30 calendar days from the day of procurement contract conclusion, furnish proof that he or a third party has posted the bond in one of the ways set out below:

- 1° in the case of cash, by transfer of the amount to the bpost account number of the Deposit and Consignment Office Fill out the form https://finances.belgium.be/sites/default/files/01_marche_public.pdf as completely as possible and return it to the e-mail address: info.cdcdck@minfin.fed.be
- 2. After reception and validation of said form, an agent of Belgium's Deposit and Consignment Office (Caisse des Dépôts et Consignations) will communicate to you the payment instructions (account number + communication) for posting the bond in cash;
- 3. 2° in the case of public funds, by depositing such funds, for the account of the Deposit and Consignment Office, with the State Cashier at the head office of the National Bank in Brussels or at one of its provincial agencies or with a public institution with an equivalent function;
- 4. 3° in the case of a joint surety, by deposit via an institution that lawfully carries out this activity of a deed of joint surety with the Deposit and Consignment Office or with a public institution with an equivalent function;
- 5. 4° in the case of a guaranty, by the deed of undertaking of the credit institution or the insurance company.

This proof must be provided as applicable by submission to the contracting authority of:

- 1. 1° the deposit receipt of the Deposit and Consignment Office or of a public institution with an equivalent function; or
- 2. 2° a debit notice issued by the credit institution or the insurance company; or

- 3. 3° the deposit certificate issued by the State Cashier or public institution with an equivalent function; or
- 4. 4° the original copy of the deed of joint surety stamped by the Depot and Consignment Office or by a public institution with an equivalent function; or
- 5. 5° the original copy of the deed of undertaking issued by the credit institution or the insurance company granting a guaranty.

These documents, signed by the depositor, must state why the performance bond was posted and its precise usage, consisting of a concise indication of the subject-matter of the procurement contract and a reference to the procurement documents, as well as the name, first name and full address of the contractor and, where relevant, that of the third party that made the deposit on the contractor's account, bearing the statement 'lender' or 'mandatory', as appropriate.

The period of 30 calendar days specified above is suspended during the period of closure of the contractor's business for paid annual holidays and the days off in lieu stipulated by regulation or by a collective binding labour agreement.

Proof that the required performance bond has been posted must be sent to the address that will be mentioned in the contract conclusion notification.

Request by the contractor for the acceptance procedure to be carried out:

- 1. For the provisional acceptance: This is equal to a request to release the first half of the performance bond;
- 2. For the final acceptance: This is equal to a request to release the second half of the performance bond, or, in case no provisional acceptance applied, to release the whole of the performance bond.

4.8 Conformity of performance (Art. 34)

The services must comply in all respects with the procurement documents. Even in the absence of technical specifications in the procurement documents, the works, supplies and services must comply in all aspects with good practice.

4.9 Changes to the procurement contract (Art. 37 to 38/19)

4.9.1 Replacement of the contractor (Art. 38/3)

Provided that he meets the selection and exclusion criteria set out in this document, a new contractor may replace the contractor with whom the initial procurement contract was agreed in cases other than those provided for in Art. 38/3 of the General Implementing Rules (GIR).

The contractor submits his request as quickly as possible by registered post, stating the reasons for this replacement and providing a detailed inventory of the state of supplies and services already performed, the new contractor's contact details and the documents and certificates which the contracting authority cannot access free of charge.

The replacement will be recorded in an amendment dated and signed by all three parties. The initial contractor remains liable to the contracting authority for the performance of the remainder of the procurement contract.

4.9.2 Adjusting the prices (Art. 38/7)

For this procurement contract, price reviews are not permitted.

4.9.3 Indemnities following the suspensions ordered by the contracting authority during performance (Art. 38/12)

<u>The contracting authority</u> reserves the right to suspend the performance of the procurement contract for a given period, mainly when it considers that the procurement contract cannot be performed without inconvenience at that time.

The performance period is extended by the period of delay caused by this suspension, provided that the contractual performance period has not expired. If it has expired, the return of fines for late performance will be agreed.

When activities are suspended, based on this clause, the contractor is required to take all necessary precautions, at his expense, to protect the services already performed and the materials from potential damage caused by unfavourable weather conditions, theft or other malicious acts.

The contractor has a right to damages for suspensions ordered by the contracting authority when:

- The suspension lasts in total longer than one twentieth of the performance time and at least ten working days or two calendar weeks, depending on whether the performance time is expressed in working days or calendar days;
- The suspension is not due to unfavourable weather conditions;
- The suspension occurred during the contract performance period.

Within thirty days of their occurrence or the date on which the contractor or the contracting authority would normally have become aware of them, the contractor reports the facts or circumstances succinctly to the contracting authority and describes precisely their impact on the progress and cost of the procurement contract.

4.9.4 Unforeseen circumstances

As a rule, the contractor is not entitled to any modification of the contractual terms due to circumstances of which the contracting authority was unaware.

A decision of the Belgian State to suspend cooperation with a partner country is deemed to be unforeseeable circumstances within the meaning of this article. Should the Belgian State break off or cease activities which implies therefore the financing of this procurement contract, Enabel will do everything reasonable to agree a maximum compensation figure.

4.10 Preliminary technical acceptance (Art. 42)

The contracting authority reserves the right to demand an activity report at any time of the assignment to the service provider (meetings held, persons met, institutions visited, summary of results, problems encountered and unresolved issues, deviations from the planning and deviations from the ToR...).

4.11 Performance modalities (Art. 146 et seq.)

4.11.1 Deadlines and terms (Art. 147)

The order form is addressed to the service provider by mail.

The services must start within 7 calendar days from the day after the date on which the service provider received the mail and must be performed as soon as possible.

The order form will specify the number of man's days and the expected deadline.

The closure of the service provider's business for annual holidays is not included in this calculation.

Enabel estimates that it will order up to a maximum of 50 days for both types of expertise from the service provider selected under this contract, mainly in July and August 2023. For each order, the service provider specifies the number of days that will be needed and the incl. VAT.

In case of a mission in the field, the service provider may invoice \bigcirc 1,500 incl. VAT economy class return trip on the basis of the invoice and a flat rate of \bigcirc 250 (does not need to be justified) per day worked in the field (accommodation and small expenses).

4.11.2 Place where the services must be performed and formalities (Art. 149)

The services will be performed remotely or might be performed on the field in an African country.

In this case, the service provider may invoice $\\mathcal{C}$ 1,500 incl. VAT economy class return trip on the basis of the invoice and a flat rate of $\\mathcal{C}$ 250 (does not need to be justified) per day worked in the field (accommodation and small expenses).

4.11.3 Evaluation of the services performed

If during contract performance irregularities are found, the contractor shall be notified about this immediately by fax or e-mail, which shall be confirmed consequently. The contractor is bound to perform the non-complying services again.

When the services have been performed, the quality and conformity of the services shall be evaluated. A report of this evaluation shall be drawn up. The original copy of this report will be sent to the contractor. Any services that have not been performed correctly or in conformity with the requirements of these tender specifications shall not be paid.

4.12 Inspection of the services (Art. 150)

If during contract performance irregularities are found, the contractor will be notified about this immediately by fax or e-mail, which will be confirmed consequently by registered letter. The contractor is bound to perform the non-complying services again.

The service provider advises the managing official by registered post or e-mail showing the exact date of dispatch, at which date the services can be controlled.

4.13 Liability of the service provider (Art. 152-153)

The service provider takes the full responsibility for mistakes and deficiencies in the services provided.

Moreover, the service provider indemnifies the contracting authority against damages for which it is liable towards third parties due to late performance of the services or due to failure of the service provider.

4.14 Zero tolerance Sexual exploitation and abuse

In application of Enabel's Policy regarding sexual exploitation and abuse of June 2019 there will be zero tolerance towards any misconduct that could impact the professional credibility of the tenderer.

4.15 Means of action of the contracting authority (Art. 44-51 and 154-155)

The service provider's default is not solely related to services as such but also to the whole of the service provider's obligations.

In order to avoid any impression of risk of partiality or connivance in the follow-up and control of the performance of the procurement contract, it is strictly forbidden to the service provider to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to the employees of the contracting authority who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the procurement contract, regardless of their hierarchical rank.

In case of violation, the contracting authority may impose a lump-sum fine to the service provider for each violation, which can be to up to three times the amount obtained by adding up the (estimated) values of the advantage offered to the employee and of the advantage that the contractor hoped to obtain by offering the advantage to the employee. The contracting authority will decide independently about the application and the amount of this fine.

This clause is without prejudice to the possible application of other measures as of right provided in the GIR, namely the unilateral termination of the procurement contract and/or the exclusion of procurement contracts of the contracting authority for a determined duration.

4.15.1 Failure of performance (Art. 44)

§1 The contractor is considered to be in failure of performance under the procurement contract:

1° when the delivery is not carried out in accordance with the conditions specified in the procurement documents.

2° at any time, when the delivery has not progressed in such a way that it can be fully completed on the due dates;

3° when he does not observe written orders, which are given in due form by the contracting authority.

§2 Any failure to comply with the provisions of the procurement contract, including the nonobservance of orders of the contracting authority, is recorded in a report ('process verbal'), a copy of which will be sent immediately to the contractor by registered mail.

The contractor must repair the defects without any delay. He may assert his right of defence by registered letter addressed to the contracting authority within fifteen days from the date of dispatch of the report (process verbal). Silence on his part after this period shall be deemed as acknowledgement of the reported facts.

Any defects detected that can be attributed to the contractor render him liable to one or more of the measures provided for in Articles 45 to 49, 154 and 155.

4.15.2 Fines for delay (Art. 46 and 154)

The fines for delay differ from the penalties referred to in Article 45. They are due, without the need for notice, by the mere lapse of the performance term without the issuing of a report and they are automatically applied for the total number of days of delay.

Without prejudice to the application of fines for delay, the contractor continues to guarantee the contracting authority against any damages for which it may be liable to third parties due to late performance of the procurement contract.

4.15.3 Measures as of right (Art. 47 and 155)

§1 When, upon expiry of the term given in Article 44, §2, the contractor has not taken action or has presented means deemed unjustified by the contracting authority, the contracting authority may apply the measures as of right described in paragraph 2.

However, the contracting authority may apply measures as of right without waiting for the expiry of the term given in Article 44, §2, when the contractor has explicitly recognised the defects found.

§2 The measures as of right are:

1° Unilateral termination of the procurement contract. In this case the entire performance bond, or if no bond has been posted an equivalent amount, is acquired as of right by the contracting authority as lump sum damages. This measure excludes the application of any fine for delay in performance in respect of the terminated part;

2º Performance under regie of all or part of the non-performed procurement contract;

3° Conclusion of one or more replacement procurement contracts with one or more third parties for

all or part of the procurement contract remaining to be performed.

The measures referred to in 1°, 2° and 3° will be taken at the expense and risk of the defaulting contractor. However, any fines or penalties imposed during the performance of a replacement procurement contract will be borne by the new contractor.

4.16 End of the procurement contract

4.16.1 Acceptance of the services performed (Art. 64-65 and 156)

The managing official will closely follow up the services during performance.

The services will not be accepted until after fulfilling audit verifications, technical acceptance and tests.

The contracting authority disposes of a verification term of thirty days starting on the final or partial end date of the services, set in conformity with the modalities in the procurement documents, to carry out the acceptance formalities and to notify the result to the service provider. This term commences provided that the contracting authority possesses, at the same time, the list of services delivered or the invoice. Upon expiry of the thirty-day term following the date stipulated for completion of the entirety of the services, depending on the case, an acceptance report or a refusal of acceptance report may be drawn up.

Where the services are completed before or after this date, it is the responsibility of the service provider to notify the managing official by registered letter, and at the same time to ask for the acceptance procedure to be carried out. Within thirty days after the date of receipt of the service provider's request, an acceptance or a refusal of acceptance report may be drawn up, depending on the case.

The acceptance specified above is final.

4.16.2 Invoicing and payment of services (Art. 66 to 72 - 160)

The contractor shall send one copy of the invoice with the original the service order to the address mentioned in the specific service order.

Only services that have been performed correctly may be invoiced.

The contracting authority disposes of a verification term of thirty days starting on the end date for the services, set in conformity with the modalities in the procurement documents, to carry out the acceptance & approval formalities and to notify the result to the service provider.

The amount owed to the service provider must be paid within thirty days with effect from the expiry of the verification term or with effect from the day after the last day of the verification term, if this is less than thirty days. And provided that the contracting authority possesses, at the same time, the duly established invoice and any other documents that may be required.

When the procurement documents do not provide for any separate debt claim, the invoice will constitute the debt claim.

The invoice must be in EUROS.

No advance may be asked by the contractor and the payment will be made after provisional/final acceptance of each service delivery of a same order.

4.17 Modifications to the contract (Art. 37-38 and 151)

The contracting authority has the right to change the initial tender unilaterally, if the following conditions are respected:

1° the scope of the contract remains unaltered.

2° the modification is limited to 10 % of the initial awarded amount.

The essential terms and conditions can only be modified with reasons, to be mentioned in an amendment.

4.18 Litigation (Art. 73)

The competent courts of Brussels have exclusive jurisdiction over any dispute arising from the performance of this procurement contract. French or Dutch are the languages of proceedings.

The contracting authority will in no case be held liable for any damage caused to persons or property as a direct or indirect consequence of the activities required for the performance of this procurement contract. The contractor indemnifies the contracting authority against any claims for compensation by third parties in this respect.

In case of 'litigation', i.e. court action, correspondence must (also) be sent to the following address:

Enabel, public-law company

Legal unit of the Logistics and Acquisitions service (L&A)

To the attention of Mrs Inge Janssens

rue Haute 147

1000 Brussels

Belgium

5 Terms of Reference

1. Background: Team Europe Support Structure

Ensuring healthy lives and promoting well-being at all ages is essential to sustainable development (SDG 3). The COVID-19 pandemic has shown large inequalities in access to quality health services and demonstrated the need for strong health systems and better pandemic preparedness all over the world. Universal health coverage can only be achieved when there is affordable access to safe, effective, and quality medicines and health products.

The African Union intends to have 60% of the continent's vaccines produced locally by 2040. The Partnership for African Vaccine Manufacturing (PAVM) aims to have 5 research & manufacturing hubs in Africa in the next 10-15 years.

In 2021, the EU Commission presidency announced the launch of a Team Europe Initiative (TEI) for the production and access to vaccines, medicines and health products (MAV+). This TEI MAV+ aims at boosting local manufacturing capacities in Africa and strengthening pharmaceutical systems in Africa. The TEI operates at continental and national levels on 3 dimensions: supply side, demand and enabling ecosystem. The TEI MAV+ works in close collaboration with African Union, particularly Africa CDC and the recently created Partnership for African Vaccine Manufacturing (PAVM).

Belgium is committed to improve access to quality essential medicines as an integrated component to the Universal right to health. This commitment includes the strengthening of local capacities and the insurance of quality health products supplies. Belgium is also a very active member of the TEI MAV+ and a keen advocate for supporting Africa call for a new Public Health Order.

In the scope of this TEI, EU has identified a budget of 10.5 Mi Euros to set up a technical support service (TESS) that will assist the EU as well as PAVM and foster coordination between members states and institutions in Europe and Africa to effectively collaborate towards achieving AU health objectives with regards to health products in Africa. Additional funding Belgium (3 Mi EUR) and from Germany (2 Mi EUR) complement the EU initiative funding.

The overall objective of this project is to facilitate access to safe, effective, quality and affordable essential vaccines, medicines and health technologies for all, in alignment with SDG 3.8 and in the context of promoting universal health coverage (UHC).

The specific objective of the project is to enhance TEI MAV+ coordination, technical expertise, progress monitoring and communication.

The project will last three years (36 months) and includes four outputs as follows:

- Operational support to the EC to facilitate the overall coordination of Team Europe members and the TEI monitoring, evaluation and communication
- Technical Support to TEI-MAV+ workstreams

- Technical Support to PAVM Secretariat
- Technical Support to strengthen equitable access to quality health products in Africa

2. Short-Term Expertise

In the framework of the Output 1, the TESS has to "mobilise short-term expertise upon request (in broad areas – technical, managerial, transversal) for all outputs, namely :

- Technical Support to TEI-MAV+ workstreams
- Technical Support to PAVM Secretariat, and
- Technical Support to strengthen equitable access to quality health products in Africa

The technical support might focus on:

- Regulation strengthening
- Technology transfer, knowledge exchange & IP
- Market Shaping, demand & trade facilitation
- R&D, higher education and skills
- Access to finance
- Industrialization & private sectors

The tasks might be to :

- Contribute to INTPA work by developing technical and strategic policy recommendations, supporting in decision making and strategy setting
- Contribute evidence based technical and strategic guidance to Team Europe Initiatives
- Provide strategic inputs for policy dialogue to INTPA and EU Member States in the context of international initiatives, the PAVM and other institutions (EMA, AMA, AMRH, WHO, etc.)
- Provide Multi-country support building on lessons learned and experiences, particularly to TEI MAV+ members.
- Provide technical inputs to joint programming planning and other forms of collaboration among EU Member States.
- 3. Objectives and expected results
- General Objective : cover technical support requests from TEI, PAVM and AMA in the field of Manufacturing and Access to Medicines, Vaccines and Health Technologies with short-term expertise
- Specific Objectives: respond to Short-term experts requests
- Expected Results: the Short-term experts requests are fully covered by expertise

Forms 6

6.1. Identification forms

6.1.1 Natural person

To fill the form, please click here :

https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:e15a7f59-9a3c-4072-89acdeb89f513e1c

I. PERSONAL DATA					
FAMILY NAME(S)(1)					
FIRST NAME(S)(1)					
DATE OF BIRTH					
JJ MM YY	<i>T</i> YY				
PLACE OF BIRTH (CITY, VILLAGE)	COUNTRY OF B	IRTH			
TYPE OF IDENTITY DOCUME	ENT				
IDENTITY CARD	PASSPORT	DRIVING LICENCE ⁽²⁾	OTHER(3)		
ISSUING COUNTRY					
IDENTITY DOCUMENT NUM	BER				
PERSONAL IDENTIFICATION	NUMBER(4)				
PERMANENT PRIVATE ADRESS					
POSTCODE	P.O. BOX		CITY		
REGION (5) COUNTRY					
PRIVATE PHONE					
PRIVATE E-MAIL					
II. BUSINESS DATA		If YES, please provid official supporting de	le business data and attach copies of ocuments		
Do you run your own business without a separate legal	BUSINESS NAME (if applicable)				
personality (e.g. sole traders, self-employed etc.) and you	VAT NUMBER				
provide as such services to the Commission, other Institutions,	REGISTRATION NUMBER				
Agencies and EU-Bodies ? PLACE OF REGISTRATION		RATION			
YES NO		CITY			
	COUNTRY				
DATE SIGNATURE					

Failing other identity documents: residence permit or diplomatic passport.

See table with corresponding denominations by country.

¹⁰³⁴⁵ As indicated on the official document.

Accepted only for Great Britain, Ireland, Denmark, Sweden, Finland, Norway, Iceland, Canada, United States and Australia.

To be completed with Region, State or Province by non EU countries only, excluding EFTA and candidate countries.

6.1.2 Legal person entity private/public legal body

To fill the form, please click here :

https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:fcf7423f-7287-4cbb-9c7b-645ab60734a3

OFFICIAL NAME 2					
ABREVIATION					
MAIN REGISTRATION NUMBER③					
SECONDARY REGISTRATION NUMB (if applicable)	ER				
PLACE OF MAIN REGISTRATION	CITY		COUNTRY		
DATE OF MAIN REGISTRATION	DD	MM	YYYY		
VAT NUMBER					
OFFICIAL ADDRESS					
POSTCODE P.O. BOX			CITY		
COUNTRY			PHONE		
E-MAIL					
	STAMP				
DATE					
SIGNATURE OF AUTHORISED REPRESENTATIVE					

① Public law body WITH LEGAL PERSONALITY, meaning a public entity being able to represent itself and act in its own name, i.e. being capable of suing or being sued, acquiring and disposing of property, entering into contracts. This legal status is con- firmed by the official legal act establishing the entity (a law, a decree, etc.).

2 National denomination and its translation in EN or FR if existing.

③ Registration number in the national register of the entity.

6.1.3 Public law entity

To fill the form, please click here :

https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:fcf7423f-7287-4cbb-9c7b-645ab60734a3

National denomination and its translation in EN or FR if existing.
 NGO = Non Governmental Organisation, to be completed if NFPO is indicated.

⁽³⁾ Registration number in the national register of companies. See table with corresponding field denomination by country.

6.1.4 Subcontractors

Name and legal form	Address / Registered office	Object

6.2. Tender Forms – prices

By submitting this tender the tenderer commits to performing this public contract in conformity with the provisions of the Tender Specifications **BEL21003-10004** and explicitly declares accepting all conditions listed in the Tender Specifications and renounces any derogatory provisions such as his own general sales conditions.

The unit prices and the global prices for each item in the inventory are established relative to the value of these items in relation to the total value of the tender. All general and financial costs as well as the profits are distributed between the various items in proportion to their weight.

The tenderer commits to performing the public contract in accordance with the provisions of the Tender Specifications for the following unit prices, in EUR and inclusive of VAT and other applicable taxes (written in figures):

ITEM	DESCRIPTION	ESTIMATED DAYS	LUMP SUM- UNIT PRICE/MAN/D AY ALL TAXES EXCLUDING VAT	PRICE IN EUROS EXCLUDING
1	Expert 1 : Pharmaceutical Expert	25	€	€
2	Expert 2: Health Economist	25	€	€
TOTAL price in euros excluding VAT			€	

Percentage VAT: %

The confidential information and/or the information relating to technical or business secrets is indicated clearly in the tender.

In order to correctly compare the tenders, the duly signed information or documents included in Part 3 must be attached to the tender.

The tenderer declares on honour that the information given is accurate and correct and that it has been established while fully aware of the consequences of misrepresentation.

Name and first name:	:
----------------------	---

Place and date:

Certified true and sincere, Handwritten original signature (s):

6.3. Declaration on honour – exclusion criteria

Hereby, I / we, acting as legal representative(s) of above-mentioned tenderer, declare that the tenderer does not find himself in one of the following situations:

- 1) The tenderer or one of its 'directors [1]' was found guilty following a conviction by final judgement for one of the following offences:
 - 1° involvement in a criminal organisation
 - 2° corruption
 - 3° fraud

4° terrorist offences, offences linked related to terrorist activities or incitement to commit such offence, collusion or attempt to commit such an offence

5° money laundering or terrorist financing

6° child labour and other trafficking in human beings

7° employment of foreign citizens under illegal status

8° creating a shell company.

- 2) The counterparty which fails to fulfil his obligations relating to the payment of taxes or social security contributions for an amount in excess of EUR 3 000, except if the counterparty can demonstrate that a contracting authority owes him one or more unquestionable and due debts which are free of all foreseeable liabilities. These debts are at least of an amount equal to the one for which he is late in paying outstanding tax or social charges.
- 3) The counterparty who is in a state of bankruptcy, liquidation, cessation of activities, judicial reorganisation or has admitted bankruptcy or is the subject of a liquidation procedure or judicial reorganisation, or in any similar situation resulting from a procedure of the same kind existing under other national regulations;
- 4) When Enabel can demonstrate by any appropriate means that the counterparty or any of its directors has committed serious professional misconduct which calls into question his integrity.

Are also considered such serious professional misconduct:

- a. A breach of Enabel's Policy regarding sexual exploitation and abuse June 2019
- A breach of Enabel's Policy regarding fraud and corruption risk management June 2019
- c. A breach of a regulatory provision in applicable local legislation regarding sexual harassment in the workplace
- d. The counterparty was seriously guilty of misrepresentation or false documents when providing the information required for verification of the absence of grounds for exclusion or the satisfaction of the selection criteria, or concealed this information
- e. Where Enabel has sufficient plausible evidence to conclude that the counterparty has committed acts, entered into agreements or entered into arrangements to distort competition

The presence of this counterparty on one of Enabel's exclusion lists as a result of such an act/agreement/arrangement is considered to be sufficiently plausible an element.

5) When a conflict of interest cannot be remedied by other, less intrusive measures;

6) When significant or persistent failures by the counterparty were detected during the execution of an essential obligation incumbent on him in the framework of a previous contract, a previous contract placed with another contracting authority, when these failures have given rise to measures as of right, damages or another comparable sanction.

Also failures to respect applicable obligations regarding environmental, social and labour rights, national law, labour agreements or international provisions on environmental, social and labour rights are considered 'significant'.

The presence of the counterparty on the exclusion list of Enabel because of such a failure serves as evidence.

7) Restrictive measures have been taken vis-à-vis the counterparty with a view of ending violations of international peace and security such as terrorism, human-rights violations, the destabilisation of sovereign states and de proliferation of weapons of mass destruction.

The counterparty or one of its directors are on the lists of persons, groups or entities submitted by the United Nations, the European Union and Belgium for financial sanctions:

For the United Nations, the lists can be consulted at the following address:

https://finances.belgium.be/fr/tresorerie/sanctions-financieres/sanctionsinternationales-nations-unies

For the European Union, the lists can be consulted at the following address:

https://finances.belgium.be/fr/tresorerie/sanctions-financieres/sanctionseurop%C3%A9ennes-ue

https://eeas.europa.eu/headquarters/headquarters-homepage/8442/consolidated-listsanctions_en

https://eeas.europa.eu/sites/eeas/files/restrictive_measures-2017-01-17-clean.pdf

For Belgium:

https://finances.belgium.be/fr/sur_le_spf/structure_et_services/administrations_gen_erales/tr%C3%A9sorerie/contr%C3%B4le-des-instruments-1-2

Signature preceded by 'read and approved', in writing, and indication of name and function of

the person signing:

•••••

Place, date

6.4. Integrity statement for the tenderers

Hereby, I / we, acting as legal representative(s) of above-mentioned tenderer, declare the following:

- Neither members of administration or employees, or any person or legal person with whom the tenderer has concluded an agreement in view of performing the public contract, may obtain or accept from a third party, for themselves of for any other person or legal person, an advantage appreciable in cash (for instance, gifts, bonuses or any other kind of benefits), directly or indirectly related to the activities of the person concerned for the account of Enabel.
- The board members, staff members or their partners have no financial or other interests in the businesses, organisations, etc. that have a direct or indirect link with Enabel (which could, for instance, bring about a conflict of interests).
- I have / we have read and understood the articles about deontology and anti-corruption included in the Tender Documents (see 1.7.), as well as *Enabel's Policy regarding sexual exploitation and abuse* of June 2019 and *Enabel's Policy regarding fraud and corruption risk management* of June 2019 and I / we declare fully endorsing and respecting these articles.

If above-mentioned public contract is awarded to the tenderer, I/we declare, moreover, agreeing with the following provisions:

- In order to avoid any impression of risk of partiality or connivance in the follow-up and control of the performance of the public contract, it is strictly forbidden to the public contractor (i.e. members of the administration and workers) to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to the employees of Enabel who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the public contract, regardless of their hierarchical rank.
- Any (public) contract will be terminated, once it appears that contract awarding or contract performance would have involved the obtaining or the offering of the above-mentioned advantages appreciable in cash.
- Any failure to comply with one or more of the deontological clauses will be considered as a serious professional misconduct which will lead to the exclusion of the contractor from this and other public contracts for Enabel.
- The public contractor commits to supply, upon the demand of the contracting authority, any supporting documents related to the performance conditions of the contract. The contracting authority will be allowed to proceed to any control, on paperwork or on site, which it considers necessary to collect evidence to support the presumption of unusual commercial expenditure.

Finally, the tenderer takes cognisance of the fact that Enabel reserves the right to lodge a complaint with the competent legal instances for all facts going against this statement and that all administrative and other costs resulting are borne by the tenderer.

Signature preceded by 'read and approved', in writing, and indication of name and function of

the person signing:

.....

Place, date

Documents to be provided

• Power of attorney

The Bidder shall include in his tender the power of attorney empowering the person signing the bid on behalf of the company, joint venture or consortium. In case of a consortium or a temporary association, the joint bid must specify the role of each member of the consortium. A group leader must be designated, and the power of attorney must be completed accordingly.

- The statutes and any other document required to establish the power of attorney of the signer(s)
- Identification forms
- Tender form
- Declaration on honour
- Integrity statement for the tenderers
- List of similar assignments that have been performed by the Service Provider over the past three years
- CV of all the experts/consultant who will/might be used for the performance of the contract to be provided
- Any other document that has been required below