Enabel

Tender Specifications BEL21003-10024

Open procedure

Public services contract for recruitment of external technical expertise for a short-term intervention under TESS MAV+ project framework

Framework agreement with several economic operators

Belgian development agency

enabel.be

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1 General remarks

1.1 Derogations from the Royal Decree of 14 January 2013

Section 1.5, '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 contract by way of derogation from the Royal Decree of 14 January 2013 or as a complement or an elaboration thereof.

These Tender Specifications derogate Article 26 of the GIR (Royal Decree of 14 January 2014): 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 reserves the right to accept or refuse the posting of the bond through that institution. The tenderer mentions 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 public contract.

1.2 The contracting authority

The contracting authority of this public contract is Enabel, 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), called 'Enabel' pursuant to the entry into force of the 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.

Enabel has the exclusive competence for the execution, in Belgium and abroad, of public service tasks of direct bilateral cooperation with 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 public contract Enabel is represented by Jean Van Wetter, Managing director, and Danny Verspreet, Director of Finances & IT.

1.3 Institutional framework 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 company[2];

- 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.

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

The following initiatives are also guiding Enabel in its operations and are given 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 2003[3], 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;
- 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 Organization4 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 of Paris, of 12 December 2015;
- The first Management Contract contracting Enabel and the Belgian federal State (approved by the Royal Decree of 17 December 2017, Belgian Official Gazette of 22 December 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 public contract

The following, among other things, apply to this public contract:

- The Law of 17 June 2016 on public procurement[5];
- The Law of 17 June 2013 on justifications, notification and legal remedies for public contracts and certain contracts for works, supplies and services[6];
- The Royal Decree of 18 April 2017 on the awarding of public contracts in the classic sectors;
- The Royal Decree of 14 January 2013 establishing the General Implementing Rules for public procurement[7];
- Circulars of the Prime Minister with regards to public procurement;

[3] Belgian Official Gazette of 18 November 2008.
[4] https://www.ilo.org/global/standards/lang--en/index.htm
[5] Belgian Official Gazette of 14 July 2016
[6] Belgian Official Gazette of 21 June 2013.
[7] Belgian Official Gazette of 27 June 2017

- Enabel's Policy regarding sexual exploitation and abuse – June 2019;
- Enabel's Policy regarding fraud and corruption risk management – June 2019.

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

The following also apply to this contract:

- 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, hereinafter referred to as 'the GDPR'), and repealing Directive 95/46/EC;
- The Law of 3 December 2017 establishing the Data Protection Authority;
- The Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

1.5 Definitions

The following definitions apply to this contract:

- The tenderer: The natural person (m/f) or legal entity that submits a tender;
- The contractor/ service provider: The tenderer to whom the public contract is awarded;
- The awarding/contracting authority: Enabel;
- The tender: The commitment of the tenderer to perform the public contract under the conditions that he has submitted;
- Electronic signature: Data in electronic form, which is logically attached or associated with other data in electronic form and which the signatory uses to sign;
- Days: 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;
- Procurement documents: Contract notice and Tender Specifications including the annexes and the documents they refer to;
- Technical specifications: 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;
- Variant: 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;
- Option: A minor and not strictly necessary element for the performance of the contract, which is introduced either at the demand of the contracting authority, or at the initiative of the tenderer;

- Inventory: The procurement document, in a public supply or public service contract, which splits up the performance in different items and specifies the quantity or the method to determine the price for each of them;
- BDA: Belgian Public Tender bulletin;
- OJEU: Official Journal of the European Union;
- OECD: Organisation for Economic Cooperation and Development;
- General Implementing Rules (GIR): Rules laid down in the consolidated version of the Royal Decree of 14 January 2013 establishing the General Implementing Rules for public procurement and for concessions for public works;
- The Tender Specifications (Cahier spécial des charges/CSC): This document and its annexes and the documents it refers to;
- Corrupt practices: The offer of a bribe, gift, gratuity or commission to a person as an inducement or reward for performing or refraining from an act relating to the award of a contract or performance of a contract already concluded with the contracting authority;
- Litigation: Court action.

1.6 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

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 contracts for Enabel.

For the duration of the 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 Organization (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.

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.

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.

Any tender will be rejected and any (public) contract will be cancelled once it appears that contract awarding or contract performance induced the transfer of 'extraordinary commercial expenditure'. Extraordinary commercial expenditure is any commission that is not mentioned in the main contract or that does not result from a contract in good and due form referring to that contract, any commission that is paid for no actual legal service, any commission transferred into a fiscal paradise, any commission transferred to a beneficiary that is not clearly identified or to a company that obviously merely serves as a façade.

Moreover, 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 contractor to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to appointees of the contracting authority who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the contract, regardless of their hierarchical rank.

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 https://www.enabelintegrity.be website.

1.8 Applicable law and competent courts

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

The parties commit to sincerely perform their engagements to ensure the good performance of the public 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.

See also point 4.15 Litigation (Article 73 of the Royal Decree of 14 January 2013).

2 Subject-matter and scope of the public contract

2.1 Type of contract

This public contract is a public contract for services in the meaning of Article 2, 21° of the Law of 17 June 2016 on public procurement.

2.2 Subject-matter of procurement

Within the framework of the TESS MAV+ output 1 and in coordination with International Partnerships Group 4 (INTPA G4), Enabel has to set up a Short-Term Expert Pool (STEP). The main objectives of this flexible pool are to mobilize short-term support upon request in the pharmaceutical sector for all outputs, and to mobilize international, regional and national experts in access to health products (additional funding). This will contribute to strengthen local actors and institutions to improve access to quality health products.

The current consultation concerns the signing of a Framework Agreement with the aim to provide technical, managerial, institutional and/or transversal support. The type of support and the level of responsibility linked to it will depend on the specific requests made by the project actors and beneficiaries through TESS MAV+ project's Intervention Manager: they may take the form of either one-off or regular missions, as well as remote assistance (home based). The extent of the needs to be covered is described in the specifications below.

Main CPV code(s), description: 72224000-1 - Project management consultancy

Framework Agreement

This public contract is awarded as a framework agreement with several economic operators (maximum number of operators per lot: 4) in accordance with Article 43 of the Law of 17 June 2016.

This public contract establishes the terms governing public contracts to be concluded during the validity period of the framework agreement.

The framework agreement does not define all conditions governing the services concerned. The framework agreement is executed following renewed competition between the economic operators party to the framework agreement.

2.3 Lots

The contract has 15 lots, each of which is indivisible. The tenderer may submit a tender for all lots. A tender for part of a lot is inadmissible.

The lots are :

- Lot 1: Regulation strengthening;
- Lot 2: Market Authorization (MA);
- Lot 3: Intellectual Property (IP);
- Lot 4: Quality Control (QC);

- Lot 5: Pharmacovigilance (PV) and drug / vaccine safety;
- Lot 6: Technology transfer;
- Lot 7: Market shaping, Demand & Trade facilitation;
- Lot 8: Supply Chain Management;
- Lot 9: Research & Development (R&D);
- Lot 10: Higher education and Skills;
- Lot 11: Access to finance and partnership;
- Lot 12: Industrialization;
- Lot 13: Private sector development & mobilization;
- Lot 14: Monitoring & Evaluation
- Lot 15: Managerial, Institutional and ancillary support.

2.4 Items

Each lot of this public contract contains one item:

- Experts : Unit price per man/day

These items are pooled and form one single lot. It is not possible to tender for one or several items and the tenderer must submit price quotations for all items of a same lot.

2.5 Duration of the framework agreement

The public contract starts upon award notification and expires after a maximum of 48 months. This pool will normally be constituted for a fixed period until the end of the project (end of 2025).

Each party may, however, terminate the agreement at the end of the first, second or third year, provided the other party is notified at least 90 calendar days prior to the end of the first, second or third year of the framework agreement In this case, the party may not claim damages based on this termination.

If the contracting authority terminates the framework agreement, it will apply for all participants and, consequently, all participants will be notified by registered mail. Participants may not claim damages based on this termination.

Where the framework agreement is terminated in application of a measure taken as of right or when the participant is in one of the situations mentioned in Article 62 of the Royal Decree of 14 January 2013, termination of the framework agreement is limited solely to the participant against whom the measure as of right is taken.

If one of the participants takes the initiative to terminate the framework agreement, he will be barred from participating as from the second, third or fourth year, depending on the case. Once a participant is barred as a participant, he is not taken into consideration any more for procurement arising from the framework agreement.

2.6 Variants

Each tenderer may submit only one tender. Variants are forbidden.

2.7 Options

No mandatory or authorized options have been foreseen.

Free options are forbidden.

2.8 Quantities

This public contract is a price-schedule contract, i.e. a contract in which only the unit prices are flat fee prices. The price to be paid will be obtained by applying the unit prices given in the inventory to the quantities actually performed.

Quantities will be determined in Purchase Orders. The presumed quantities below are given for information purposes only.

Therefore, the contracting authority does not commit in any way as to quantities that will actually be ordered under the framework of this framework contract.

The presumed maximum yearly quantities for this tender, all lots together, are 750 man-days and around 50 missions.

3 Procedure

3.1 Award procedure

This public contract is awarded in accordance with Article 36 of the Law of 17 June 2016 via an open procedure.

3.2 Publication

3.2.1 Official notification

This public contract is published in the Belgian Public Tender bulletin and in the Official Journal of the European Union.

3.2.2 Further publication

These Tender Specifications are posted on the website of Enabel: https://www.enabel.be/public-procurement/

This public contract is officially advertised on the OECD website.

3.3 Information

The awarding of this public contract is coordinated by John Tallon.

Until 12 days before the tender submission deadline, prospective tenderers may ask questions about these Tender Specifications and the public contract. Therefore, they will make use of the forum of e-procurement. A global answer to these questions will be provided at the same time the latest 7 days before the deadline for the submission of the tenders.

The tenderer is to submit his tender after reading and taking into account any corrections made to the tender notice or Tender Specifications that are published in the Official Journal of the European Union and in the Belgian Public Tender bulletin. They are strongly advised to ask about any changes or additional information.

In accordance with Article 81 of the Royal Decree of 18 April 2017, the tenderer is required to report immediately any gap, error or omission in the procurement documents that precludes the establishment of his price or the comparison of 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

Tenderers are advised to consult the general principles set out under Heading 1 of the Law of 17 June 2016, which are applicable to this award procedure.

The tenderer must use the forms in annex. Failure to use these forms will result in him assuming full liability for any shortcomings.

The following forms must be used:

- Form 6.1 - Identification of the tenderers form
- Form 6.2 - Price quotation form (per lot)
- Form 6.3 - List of subcontractors
- Form 6.4 - Declaration on honour – Exclusion grounds
- European Single Procurement Document (ESPD)

The European Single Procurement Document is a self-declaration by economic operators providing preliminary evidence replacing the certificates issued by public authorities or third parties. As provided in Article 73 of the Law of 17 June 2016, it is a formal statement by the economic operator that it is not in one of the situations in which economic operators shall or may be excluded; that it meets the relevant selection criteria.

In accordance with Article 76 § 1 °2 of the Royal Decree of 18 April 2017, failure to comply with the obligation to submit a ESPD constitutes a substantial irregularity causing the tender to be null and void.

The tenderer also attaches the following to his tender:

- All documents demanded for qualitative selection and award criteria (per lot);
- A detail of the prices quoted, listing for each item the various elements that are included in the price and the applicable VAT rate;
- The statutes and any other document required to establish the power of attorney of the signer(s);
- If possible, the documents regarding the grounds for exclusion.

Where the tender is submitted by a group of economic operators, it must include a copy of the following documents for each of the participants in the group:

- Form 6.1 - Identification of the tenderers form
- Form 6.4 - Declaration on honour – Exclusion grounds
- European Single Procurement Document (ESPD)
- The statutes and any other document required to establish the power of attorney of the signer(s);
- The association agreement signed by each participant, clearly showing who represents the association;
- If possible, the documents regarding the grounds for exclusion.

In accordance with Article 73 of the Royal Decree of 18 April 2017, where an economic operator wants to rely on the capacities of other entities (particularly subcontractors or independent subsidiaries) for economic and financial capacity criteria and technical and vocational capacity criteria (see 3.5.3 Selection criteria), it shall prove to the contracting authority that it will have at its disposal the resources necessary, for example, by producing a commitment by those entities to that effect.
Where a candidate or tenderer relies on the capacity of other entities in the meaning of paragraph 1, the candidate or tenderer, as appropriate, answers the question given in part II, C, of the ESPD referred to in Article 38 of the Royal Decree of 18 April 2017. He also mentions for which part of the public contract he will rely on such capacity and which other entities he proposes.
The tender also comprises a separate ESPD for the entities in the meaning of paragraph 1.
The documents regarding the grounds for exclusion may also be added for these entities.

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.

The following information will be included in the tender:

- The name, first name, capacity or profession, nationality and domicile of the tenderer or, in the case of a legal person, its social purpose or corporate name, its legal form, its nationality, its registered office, its e-mail address and, where applicable, its enterprise number;
- The lump-sum unit price / the lump-sum unit prices in words and figures (excluding VAT)
- The VAT percentage
- The name of the person or persons, depending on the case, who has or have a mandate (power of attorney) for signing the tender
- The function of the person or persons, depending on the case, who signs/sign the tender
- The number and name of the account opened with a financial institute on which payment under the public contract must be made;
- The full registration number of the tenderer with the Enterprise Crossroads Bank (Banque Carrefour des Entreprises) for Belgian tenderers or with an equivalent institution for foreign tenderers.
- Participants in a group of economic operators must designate one member of the group who will represent the group vis-à-vis the contracting authority. When the ESPD must be filled out, this is indicated in part II.B of the ESPD.

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 tender draws up his tender in French, Dutch or English. The contracting authority may request from the tenderer that documents, certificates and other attachments to the tender drawn up in another language are translated.

3.4.2 Period the tender is valid

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

3.4.3 Tender submission modalities

3.4.3.1 Via e-Procurement

The tenderer may only submit one tender per public contract.

In accordance to applicable regulations for means of communication only tenders submitted by electronic means are accepted.

Consequently, tenders submitted on paper are not allowed and the contracting authority will only consider tenders submitted by digital means.

For this public contract, electronic submission of a tender is by means of the internet applications of Belgium's federal e-Procurement service (https://www.publicprocurement.be/).

For more information on registration or the connection with the platform please consult the manual via this link: https://bosa.service-now.com/eprocurement?lang=en

Documents must be in the .pdf format or equivalent.

For instructions on submitting tenders, please consult the following link: https://bosa.service-now.com/eprocurement?id=kb_article_view&sys_kb_id=3cb17cea1b7479503ff06421b24bcbac

By transferring his tender by electronic communication means the tenderer accepts that the data of his tender are registered by the reception device.

The contracting authority draws the attention of the tenderer to the fact that submitting a tender by mail does not meet the conditions of Article 14 §6 and 7 of the Law of 17 June 2016. A tender submitted by mail will be discarded.

3.4.3.2 Electronic signature of the tender

The tenderer must not sign the tender, its annexes and the ESPD individually when they are uploaded to the electronic e-Procurement platform.

The documents are signed globally by affixing a signature to the relevant submission report. It must be signed with the qualified electronic signature of the legal representative (or mandatary) of the tenderer.

Signatures are placed by the person(s) empowered or mandated to commit the tenderer. This obligation applies to each participant when the tender is submitted by a group of economic operators. These participants are jointly liable.

When the submission report is signed by a mandatary, he or she must clearly indicate whom he or she represents. The mandatary attaches the original electronic deed or private document that transfers these powers to him or her or a scanned copy of that proxy.

The contracting authority reminds tenderers that a signature on paper that has been scanned is not an admissible electronic signature.

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

When the tender is submitted via e-tendering, the tender is modified or withdrawn in accordance with Article 43, §2 of the Royal Decree of 18 April 2017.

Thus, modifying or withdrawing a tender after the submission report has been signed requires a new submission report to be signed in accordance with the preceding point.

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

The withdrawal must be pure and simple.

Where the submission report issued following modification or withdrawal is not signed as referred to in paragraph 1 of the Royal Decree of 18 April 2017, the modification or withdrawal is automatically void. This nullity applies only to the modifications or withdrawal, not to the tender itself.

3.4.3.4 Deadline date for submission and opening of initial tenders

The tenders must be in the possession of the contracting authority **before** the date given in the publication. The tenders are opened via the e-Procurement platform.

Late tenders will not be accepted[8].

3.4.4 Prices

3.4.4.1 Determination of prices

All prices given in the tender form must obligatorily be quoted in euro.

This public contract is a price-schedule contract, i.e. a contract in which only the unit prices are flat fee prices. The price to be paid will be obtained by applying the unit prices given 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 perform on-the-spot checks with a view of verifying the correctness of the indications supplied.

3.4.4.2 Elements included in the price

The tenderer is to include in his unit prices any charges and taxes generally applied to the services, with the exception of the value-added tax.

The service provider quotes his rates in euros, VAT excluded. The applicable VAT is quoted separately. Tenderers are informed that Enabel is not subjected in the meaning of Articles 21 and 21 bis of the Belgian VAT Code and in the meaning of Article 59 of Directive 2006/112/EC. This usually means that the service provider will have to charge VAT as applicable in his own country of residence (not necessarily Belgian VAT).

The prices quoted will be considered as maximum prices for the duration of the framework agreement.

The following are in particular included in the prices:

- Honorary fees;
- Insurance;
- Documentation pertaining to the services;
- Delivery of documents or records associated with performance;
- Where applicable, the measures imposed by occupational safety and worker health legislation;

As well as communication costs (including internet), administrative and secretariat costs, costs for photocopying and printing, costs of documentation of the services that can be required by the contracting authority, the production and delivery of documents or records associated with the performance of the services, any costs and charges for staff or equipment needed for the performance of this public contract, the copyright fees, the purchase or leasing of third-party services needed for the performance of the contract.

[8] Article 83 of the Royal Decree on Awarding

The following costs must not be included in the unit prices proposed and will be reimbursed on the basis of supporting documents:

For costs that can be reimbursed upon presentation of supporting documents, agreement from Enabel prior to the engagement is always required; otherwise the expense cannot be reimbursed upon presentation of supporting documents:

- **International travel:** Flight and/or international train tickets between the expert's country of domicile and the country of performance (partner country), the service provider may invoice maximum € 1,500 incl. VAT economy class return trip.
- **Domicile-airport travel expenses**: For the journey towards and from the airport or linking railway station to the airport (Brussels-Midi, for instance), several costs can be recuperated:
  1) Personal means of transportation: For this specific case, the kilometre allowance applied by the federal state (annual index on 30 June) is paid for both the outward-bound and return journey for the fastest (round-trip) journey. Please, always attach a copy of the itinerary taken if you travel by your own means of transportation (using the mapping software Mappy.com, for instance).

     Costs incurred for parking your vehicle during the assignment are NOT reimbursed. Any parking costs for dropping off or picking up the expert are not reimbursed either; such expenses are considered to be covered by the kilometre allowance.
  2) Public transportation: The train fares towards the airport (or from a linking railway station towards an airport abroad) are reimbursed.
  3) Taxi shuttles: A taxi may be used to cover part or the whole of the itinerary (in combination with public transportation) towards and/or from the airport (or the linking railway station towards an airport). The amount per itinerary is capped at 37 euros, with a maximum of two itineraries (outward-bound and return journey per assignment). This 37-euro cap may only be exceeded when check-in (two hours prior to flight departure) and arrival times fall outside the working hours schedule of Enabel. Taxi bills and the flight ticket reservation or itinerary (or any other document confirming the departure and arrival times) must be attached to the invoice as supporting documents.
- **Travel in partner country**: Where needed, travel in the partner country will be organised and paid for by Enabel.
- **The perdiems (daily allowance)**: Perdiems (daily allowances) is a flat-rate payments covering all additional costs incurred for professional reasons (so not for private reasons) and linked to the assignment, such as meals, drinks, short local trips (where applicable) and other small expenses (all phone calls, internet, snacks, tips…).

  Daily allowances are granted only for service delivery in partner countries. They pertain only to the effective time of the assignment, including weekend days and holidays.

  For travel days, the amount of the perdiem is calculated as follows: If

departure (hour of take-off at the national airport or departure of the Thalys) is after 15:00 or the return (landing or arrival) is before 17:00, the perdiem is limited to 50% of the daily allowance. If the departure is before 15:00 or the return is after 17:00, a full per diem is granted.

Where costs for accommodation comprise certain meals (for instance, breakfast) or where certain meals are borne by Enabel, the perdiems must, on a daily basis and as appropriate, reduced by:

-15% of the daily stay lump-sum allowance, for breakfast

-35% of the daily stay lump-sum allowance, for lunch

-45% of the daily stay lump-sum allowance, for the evening meal.

The amount of the daily allowance is the one set by Belgium's FPS Foreign Affairs: https://www.ejustice.just.fgov.be/eli/arrete/2018/07/02/2018040199/moniteur

- **Visa costs** are reimbursed. However, costs for issuance of a passport are not reimbursed.
- **Vaccination costs**: Vaccinations scheduled following WHO and ITM standards (including, possibly, vaccination against Japanese encephalitis) in function of the country or countries of travel, are reimbursed. However, costs for unnecessary vaccinations (not in the recommended 'package') are borne by the service provider.

Mind:

- The day rate is paid for all effective working days, even if it concerns a weekend day or a holiday. The work planning will be attached to the invoice.
- For international travel, 50% of the daily allowance is paid per day of travel.

Where applicable, the following costs are borne by Enabel:

- Costs related to the organisation of training and/or workshops:

training room, snacks, copies of training materials, writing pads and pens for participants, equipment such as a beamer, board, flipchart paper and markers.

3.5 Selection of tenderers

3.5.1 European Single Procurement Document (ESPD)

By submitting his tender together with the completed European Single Procurement Document (ESPD) the tenderer declares officially on his honour that:

- he is not in one of the mandatory or facultative exclusion cases, which must or may lead to his exclusion;
- he fulfils the selection criteria established by the contracting authority in this public contract

The European Single Procurement Document (ESPD) is a self-declaration by economic operators providing preliminary evidence replacing the certificates issued by public authorities or third parties. As provided in Article 73 of the Law of 17 June 2016, it is a formal statement by the economic operator that it is not in one of the situations in which economic operators shall or may be excluded; that it meets the relevant selection criteria.

The tenderer generates the ESPD via https://dume.publicprocurement.be/ and then attaches it to his tender.

A ESPD service manual (in French), including guidelines for enterprises, is available through:
https://bosa.belgium.be/sites/default/files/documents/DUME_man_espd_entreprise_fr_200.pdf

Where the tender is submitted by a group of economic operators, it must include an ESPD for each of the participants in the group. In this case, the candidates or tenderers answer, as appropriate, the question under part II, A of the ESPD: " Is the economic operator participating in the procurement procedure together with others?"

Where a candidate or tenderer relies on the capacity of other entities. (particularly subcontractors or independent subsidiaries) for economic and financial capacity criteria and technical and vocational capacity criteria (see 3.5.3 Selection criteria) in the meaning of paragraph 1 of Article 73 of the Royal Decree of 18 April 2017, the candidate or tenderer, as appropriate, answers the question in part II, C, of the ESPD referred to in Article 38 of the Royal Decree of 18 April 2017. He also mentions for which part of the public contract he will rely on such capacity and which other entities he proposes.

The tender also comprises a separate ESPD for the entities in the meaning of paragraph 1 of Article 73 of the Royal Decree of 18 April 2017.

For other entities that will perform part of the contract, but whose capacity the economic operator does not call upon as regards the criteria relating to economic and financial capacity and the criteria relating to technical and professional capacity (see 3.5.3 Selection criteria) within the meaning of paragraph 1 of Article 73 of the R.D. of 18 April 2017, the candidate or tenderer, as the case may be, shall answer the question in Part II, D.In accordance with Article 38 §2 of Article 73 of the Royal Decree of 18 April 2017, regarding part IV of the ESPD on the selection criteria, the contracting authority has decided to limit the information to be filled out to one single question, namely whether the economic operator fulfils the required selection criteria, in accordance with the section "Global indication for all selections criteria". So, only this section must be completed.

The contracting authority will ask the tenderer, if necessary, at any time during the procedure, to provide all or part of the supporting documents, if necessary to ensure the smooth proceeding of the procedure. The tenderer is not required to submit any supporting documents or other evidence if and to the extent that the contracting authority has the possibility to directly obtain certificates or relevant information by accessing a free national database in a Member State.

With the exception of the exclusion grounds relating to tax and social security, the tenderer that is in one of the mandatory or optional exclusion situations can prove on his own initiative that he has paid or undertaken to pay compensation for any prejudice caused by the criminal offence or the fault, clarified totally the facts and circumstances by collaborating actively with the authorities in charge of the enquiry and taken concrete specific technical, organisational and personnel measures to prevent a new criminal offence or a new fault

3.5.2 Exclusion grounds

The mandatory and facultative grounds for exclusion are given in the ESPD and the declaration on honour regarding the exclusion grounds.

The grounds for exclusion apply to :

- 1° all participants who submit a joint request to participate and who intend, in the event of selection, to form a group of economic operators ;
- 2° all participants who, as a group of economic operators, jointly submit a tender; and
- 3° third parties (in particular subcontractors or independent subsidiaries) whose capacity is called upon with regard to the criteria relating to economic and financial capacity and the criteria relating to technical and professional capacity (see 3.5.3 Selection criteria) within the meaning of paragraph 1 of Article 73 of the R.D. of 18 April 2017.

The contracting authority is to check the Declaration on honour and the ESPD on the basis of the following documents:

1) An **extract from the criminal record** made out to the name of the tenderer (legal person) or of his representative (natural person) where no criminal records exist for legal entities;
2) The document certifying that the tenderer is in order with the **payment of social contributions**, except where the contracting authority has the possibility to directly obtain certificates or relevant information by accessing a free national database in a European Union Member State.
3) The document certifying that the tenderer is in order with the **payment of levies and taxes**, except where the contracting authority has the possibility to directly obtain certificates or relevant information by accessing a free national database in a Member State.
4) The document certifying that the tenderer is not in a state of bankruptcy, liquidation, cessation of activities or judicial reorganisation, except where the contracting authority can directly obtain certificates or relevant information by accessing a free national database in a European Union Member State.

The tenderer may attach these documents directly to his tender.

If the documents are not attached, the tenderer must be able to provide the documents listed above within 5 working days following the contracting authority's request.

If the tenderer does not submit the document(s) requested within the term set, the contracting authority reserves the right to exclude the tenderer.

Tenderers are strongly advised not to wait until the contracting authority files the request and to apply as quickly as possible with the competent authorities of the country where they are established any documents that they may not have attached to their tender. The waiting times for obtaining certain documents can indeed be long.

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. This is the case for Belgian tenderers (via the Telemarc platform), except for the extract from the criminal record, which must be requested by the tenderer himself.

3.5.3 Selection criteria

Moreover, by means of the documents requested below, the tenderer must prove that he is sufficiently capable, from an economic and financial as well as from a technical point of view, to successfully perform this public contract.

- In order to satisfy the criteria relating to economic and financial capacity, and those relating to technical and professional capacity, the tenderer may call on the capacity of :all participants who submit a joint request to participate and who intend, in the event of selection, to form a group of economic operators ;
- all participants who, as a group of economic operators, jointly submit a tender; and

other entities (in particular subcontractors or independent subsidiaries) regardless of the legal nature of the link between it and these entities, pursuant to § 1 of article 73 of the Royal Decree of 18 April 2017.A separate ESPD (see point 3.5.1 European Single Procurement Document) must be attached for each participant or entity called upon to satisfy the criteria relating to economic and financial capacity and those relating to technical and professional capacity.

For all these participants and entities, the contracting authority must check that no grounds for exclusion are applicable. In accordance with Article 73 of the Royal Decree of 18 April 2017, where an economic operator wants to rely on the capacities of other entities (particularly subcontractors or independent subsidiaries) for economic and financial capacity criteria and technical and vocational capacity criteria, it shall prove to the contracting authority that it will have at its disposal the resources necessary, for example, by producing a commitment by those entities to that effect.

3.5.3.1 Criteria of financial capacity

Not applicable.

3.5.3.2 Criteria of technical capacity:

For each lot for which he submits a tender, the tenderer must provide a list of similar services performed in the last three years.

- This list must include at least 3 similar services of comparable complexity to those for which the tenderer is submitting a tender. The minimum total value of services delivered during the 3 years must exceed or equal EUR 75.000 per lot.

3.6 Evaluation of tenders

3.6.1 Regularity of the tenders

Before starting the evaluation and comparison of the tenders, the contracting authority examines their regularity and verifies the prices.

The tenders must be drawn up in such a way that the contracting authority can make a selection without starting negotiations with the tenderer. For this reason, and in order to be able to assess the tenders fairly, it is essential that the tenders be completely in conformity with the provisions of the Tender Specifications, both formally and materially.

The substantially irregular tenders are excluded.

A substantial irregularity is such as to give a discriminatory advantage to the tenderer, to distort competition, to prevent the evaluation of the tenderer's tender or its comparison with the other tenders, or to render non-existent, incomplete or uncertain the commitment of the tenderer to perform the contract under the conditions laid down.

The following irregularities are deemed substantial:

1° failure to comply with environmental, social or labour law, provided that such non-compliance is punishable by law;
2° failure to comply with the requirements of Articles 38, 42, 43, §1, 44, 48, §2, clause 1, 54, §2, 55, 83 and 92 of the Royal Decree of 18 April 2017 and of Article 14 of the Law, insofar as they contain obligations vis-à-vis the tenderers;
3° failure to comply with the minimum requirements and the requirements that are indicated as substantial in the procurement documents;

The contracting authority will also declare void any tender that is affected by several non-substantial irregularities which, by reason of their accumulation or combination, are capable of having the same effect as described above (in accordance with Article 76 of the Royal Decree of 18 April 2017).

3.6.2 Award criteria

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

3.6.2.1 Quality of the Curriculum Vitae (45%)

The tenderer is required to attach the CV(s) of the expert(s) who will be (or are likely to be) entrusted with an assignment.

The expert(s) may not be expert(s) proposed by another EO party to the framework agreement of the lot concerned. However, one or more experts may be proposed for several lots.

There will be a maximum of 5 CVs per lot.

For evaluating this criterion, the contracting authority takes into account the following elements in addition to the minimum requirements specified in 5.2

(Specific requirements by lot / expert profile).

These elements differ for each lot and are presented as follows:

3.6.2.1.1 Lot 1: Regulation strengthening

- Direct work experience with National / Supranational Regulatory Authorities;
- Experience with the private pharmaceutical sector;
- Familiarity with AUDA-NEPAD / AMRH activities and the African Medicine Agency (AMA) project;
- Work experience in Africa;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …);

- Good command of Dutch.
- Solid regulatory background and good knowledge of international pharmaceutical regulatory systems, functions and reliance principles;
- Depending on the specific need, a sound knowledge of one or several other key regulatory functions: clinical trial oversight, product marketing authorization (MA) and registration, licensing establishments, regulatory inspections, testing products, post-marketing surveillance, and vigilance activities may be additionally required;
- Good knowledge of GMP, ISO IDMP standards, ISO 9004, WHO's Global Benchmarking Tool (GBT) and Maturity Levels (ML);
- Good knowledge of the EMA regulations and activities;
- Excellent knowledge of pharmaceutical systems, National Drug Policies, legislations, system strengthening and policy dialogue in LMIC settings;
- Organizational and institutional capacity development skills;
- Ability to use new health technologies;

3.6.2.1.2 Lot 2: Market Authorization

- Work experience with National / Supranational Regulatory Authorities;
- Experience with the private pharmaceutical sector;
- Familiarity with AUDA-NEPAD / AMRH activities and the African Medicine Agency (AMA) project;
- Work experience in Africa;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …);
- Good command of Dutch.
- Solid regulatory background;
- Excellent knowledge of MA mechanisms (especially file preparation and review, initial submission, MA renewal and/or modification and product registration) and procedures and, more globally, of international pharmaceutical regulatory systems and functions;
- Depending on the specific need, a sound knowledge of one or several other key regulatory functions: regulation strengthening, clinical trial oversight, licensing establishments, regulatory inspections, testing products, post-marketing surveillance, and vigilance activities may be additionally required;
- Good knowledge of GMP and ISO IDMP standards;
- Proven knowledge of the EMA regulations, namely the Directive 2001/83/EC and the Regulation EC No 726/2004;
- Good knowledge of the EMA procedures : ASMF/EDMF, submission channels (CESP, common repository) and formats (eCTD);
- Familiarity with National Drug Policies and legislations;
- Organizational and institutional capacity development skills;
- Ability to use new health technologies;

3.6.2.1.3 Lot 3: Intellectual Property

- Good knowledge of the EMA procedures, namely ASMF/EDMF;
- Familiarity with medicine and vaccine MA and new health technologies;

- Familiarity with AUDA-NEPAD, ARIPO, OAPI, PAIPO or national IP offices in Africa;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …);
- Work experience in Africa.
- Solid regulatory background and good knowledge of international pharmaceutical regulatory systems and functions;
- Good knowledge of the health / pharmaceutical regulation, organizational and institutional context in developing countries, and familiarity with health / pharmaceutical legislations and national drug policies (especially in African countries);
- Sound knowledge of the mechanisms and terminology of IP related processes (patent filing, deposit, prosecution, freedom-to-operate, invalidation, enforcement, protection certificates, etc.);
- Excellent knowledge and skills in negotiating complex agreements in life sciences and/or pharma manufacturing, identifying licensing agreement's restrictive practices, drafting, reviewing, and revising contracts (rights and obligations) relating to in- and out-licensing of IP;
- Sound expertise in representing consumers and local governments in competition law, regulatory affairs or intellectual property matters and in using competition law and policy in LMIC settings;
- Organizational and institutional capacity development skills and capacity to help improving effectiveness and efficiency of IP related activities and processes;
- Proven abilities in advocacy and dialogue within and between public authorities and institutions;
- Excellent communication, interpersonal and relational skills;

3.6.2.1.4 Lot 4: Quality Control

- Work experience in knowledge transmission;
- Familiarity with AUDA-NEPAD / AMRH activities and the African Medicine Agency (AMA) project;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …);
- Work experience in Africa
- Solid QC background and good knowledge of international pharmaceutical QC systems and functions;
- Excellent knowledge of planification and organization of QC projects and activities and management & control of equipment and technical / financial resources;
- Deep knowledge of the WHO's ISO9001/MQAS for pharmaceutical procurement agencies: general requirements, prequalification, purchasing, receiving and storage, distribution and reassessment;
- Sound knowledge of the other quality repositories, tools and standards related to pharmaceutical industry and distribution (GMP, GDP, QHSE, etc.);
- Very good knowledge of QC performance, efficacy, result measurement, performance indicators, annual reviews, problem resolution and continuous improvement plans;
- Familiarity with the African national medicine procurement, storage and distribution systems and with the functioning of national procurement agencies of essential medicine;
- Project management skills and strategic thinking;
- High levels of adaptability to diverse educational and cultural background;
- Good priority setting, respect of deadlines and autonomy skills;

- Strong organizational, data management, analytical and problem solving abilities;
- Excellent communication, interpersonal and relational skills;

3.6.2.1.5 Lot 5: Pharmacovigilance and medicine / vaccine safety

- Professional training in Clinical Trials (e.g. Clinical Research Associate or CRA);
- Familiarity with clinical trials within pharmaceutical industries or Clinical Research Organizations (CROs);
- Work experience in Africa;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …);
- Good command of Dutch
- Solid vigilance and regulatory background;
- Sound knowledge of the main PV notions and principles: pre- and post-marketing vigilance, imputability method, B/R sign detection and evaluation, risk management plans and periodic reporting;
- In-depth / expert knowledge of relevant PV regulation, repositories, actors, databases, processes, coding, activities, AE reporting procedures and requirements, communication channels and PV quality management systems;
- Good knowledge of GVP and familiarity with international PV institutions, requirements and terminology (ICSR, ICH, MedDRA, CIOMS initiatives, etc.);
- Experience with PV audits and/or PV Health Competent Authority Inspections;
- Depending on the specific need, a sound knowledge of one or several other key regulatory functions: clinical trial oversight, product marketing authorization (MA) and registration, licensing establishments, regulatory inspections and testing products may be additionally required;
- Good knowledge of medicine development and pharmaceutical / vaccine clinical trials and Good Clinical Practices (GCP);
- Proven knowledge of the EMA regulations and procedures and the EU relevant directives;
- Organizational and institutional capacity development skills;
- Ability to use new health technologies;

3.6.2.1.6 Lot 6: Technology transfer

- Experience in R&D, QA or production of medicines, vaccines or health products in the industrial private sector (preferably in LMIC settings);
- Knowledge of European funding rules and experience within an European funded projects or programs;
- Advanced statistical knowledge;
- Familiarity with the pharmaceutical industry projects in LMIC (Africa in particular);
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …);
- Work experience in Africa/LMICs
- Solid technology transfer / process background in pharmaceutical, vaccine, laboratory diagnostic reagents / kits, and/or API industry;
- Sound understanding of industry approaches for Scale-up, Technology Transfer guidelines and protocols, and applying of QbD principles during process development;

- Good regulatory, planning and execution insights & guidance on how to realize Technology Transfers;
- Proven theoretical and practical knowledge of best practices in Scale-up for solid dose manufacturing processes;
- Good knowledge of principles, notions and terminology of technology transfer in pharmaceutical industry: Scale-Up of granulation and tableting processes, process validation, new guidance and requirements (ICH Q9/10/11, FDA, WHO, ISPE, etc.), process design stage (key input for product and process quality, process performance qualification), continuous process verification, process risk assessment, critical process parameters, critical quality attribute, change control for health products, etc.;
- Experience in technology transfer stages: identification of critical control points, experimental design and acceptance criteria for analytical methods, information on trial production batches, qualification batches, process validation, change control for potential process deviation, assessment of the end product, arrangements for retaining samples of active ingredients, intermediates, and finished products;
- Good knowledge of manufacturing process and validation principles according to the cGMP;
- Familiarity with fostering a network of regional entities to assist in technology transfer;
- Good statistical knowledge (a minimum is mandatory);
- Good knowledge of pro-active multi-actor partnership building / coordination and knowledge management / sharing;
- High level of autonomy and strong organizational, analytical and problem solving skills with pragmatic approach;
- A team player with excellent communication, interpersonal and relational skills;

3.6.2.1.7 Lot 7: Market shaping, Demand & Trade facilitation

- Experience with global or regional pooled procurement mechanisms for health products;
- Proven knowledge of pharmaceutical trade, procurement and purchase in African context;
- Existing network with key procurement decision makers, actors and stakeholders active in the African market;
- Familiarity with pharmaceutical supply chain management mechanism and processes;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …);
- Work experience in Africa
- Solid business, economy, marketing and/or trade background;
- Sound knowledge of international procurement and purchase management of pharmaceuticals (including vaccines), estimation of need and quantification, tendering mechanisms, rules and processes;
- Good understanding of the legal, reglementary and institutional status and environment related to the health / Pharmaceutical trade and procurement;
- Deep understanding of the various international, regional and national actors and stakeholders and their roles in the continental medicine and vaccine market;
- Good knowledge of the national procurement systems and of the medicine National Procurement Agencies (NPA) in LMIC;
- Familiarity with the WHO Medicines Quality Assurance (MQAS), rules and procedures;

- Strategic mindset with great business and technical acumen;
- Demonstrable technical expertise and experience in conducting market analysis, developing strategies for introduction and/or upscaling;
- Strong negotiation skills (persuasion and influencing, knowledge of the psychology of persuasion in business, organizational politics, networking and coalitions, assertiveness, managing emotions, etc.) with proven track record of tactical trade-offs to ensure best outcome;
- Project management skills and strategic thinking;
- High levels of adaptability to diverse educational and cultural background;
- Good priority setting, respect of deadlines and autonomy skills;
- Strong organizational, data management, analytical and problem solving abilities;
- Excellent communication, interpersonal, intercultural and relational skills;

3.6.2.1.8 Lot 8: Supply chain management

- Experience with a NPA in LMIC settings;
- Proven knowledge of pharmaceutical trade in African context;
- Familiarity with health products procurement mechanism and processes;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …);
- Work experience in Africa.
- Solid business background (especially SCM and logistics);
- Sound knowledge of supply chain management phases for health products (medicine / vaccine procurement, primary and secondary storage and distribution, dispensation, QC and QA);
- Good understanding of the legal, reglementary and institutional status and environment related to the pharmaceutical sector in LMIC settings;
- Good knowledge of the national PSM systems and actors (namely the medicine NPA in LMIC context);
- Sound knowledge of CMT processes;
- Familiarity with health product GSP / GDP;
- Familiarity with the WHO's Model fir Quality Assurance system (MQAS) for procurement agencies principles, rules and procedures;
- Deep understanding of the SC actors and stakeholders and their roles in the continental medicine and vaccine supply and distribution;
- Familiarity with the supply chain's (SC) main intrinsic challenges in Africa: legal and reglementary deficiencies, managerial, technical and financial weaknesses of some actors, difficulties of coordination, multitude of vertical actors and funders with different agendas, lack of availability, completeness, promptitude and/or liability of health and logistic data, unavailability of essential medicine at different health pyramid levels, logistical difficulties (namely regarding medicine storage and distribution), lack of rational use of medicine, unavailability of finance for some subsectors, etc.;
- Project management skills and strategic thinking;
- High levels of adaptability to diverse educational and cultural background;
- Good priority setting, respect of deadlines and autonomy skills;
- Strong organizational, data management, analytical and problem solving abilities;
- Excellent communication, interpersonal, intercultural and relational skills;

3.6.2.1.9 Lot 9: Research & Development (R&D)

- Familiarity with the establishing of a research unit in private, public or combined settings;
- Complementary training in finance and/or in planification;
- Familiarity with quality and risk management;
- Work experience in Africa.
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …).
- Demonstrated experience in fundamental and/or clinical research;
- Sound knowledge of medicine R&D processes and techniques: conception, synthesis, design in silico, modeling, screening, pharmacological evaluation, natural bioactive molecules, valorization, PK/PD model analysis and optimization, etc.;
- Demonstrated experience in R&D gaps assessment (including equipment, materials and consumables, facility, staff, supply chain, QC and QA);
- Strong knowledge of regulatory (GCP, GLP, GCLP and cGMP) and ethics requirement for clinical trials;
- Familiarity with research advances in medicine and vaccine development in Africa;
- Familiarity with the sector constraints: health product regulation, IP, information and health economy;
- Excellent knowledge of African and global medicine and vaccine R&D ecosystem and innovation processes;
- Excellent knowledge of policies and funding mechanisms fostering R&D and access to health products;
- Coordination of multi-actor partnerships;
- High levels of adaptability to diverse educational and cultural background;
- Good priority setting, respect of deadlines and autonomy skills;
- Strong organizational, data management, analytical and problem solving abilities;
- Excellent communication, interpersonal, intercultural and relational skills;

3.6.2.1.10 Lot 10: Higher education and skill building

- Working experience in health products research institutions and laboratories or in private sector;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …);
- Work experience in Africa.
- Solid scientific and academic background;
- Strong didactic and teaching skills;
- Demonstrated experience in assessing and developing curricula in the field of research, pharmaceutical manufacturing and/or regulation;
- Good knowledge of medicine R&D and manufacturing processes and techniques
- Excellent knowledge of African and global academic and schools of excellence in the research and pharmaceutical sector;
- Excellent knowledge of policies and funding mechanisms needed for the research and pharmaceutical workforce;
- Strong knowledge of the workforce profiles and competences required in the research and pharma sector;
- Strong knowledge on adult learning theory and instructional design, including competency frameworks;
- Excellent communication, interpersonal, intercultural and relational skills;

- High levels of adaptability to diverse educational and cultural background;
- Good priority setting, respect of deadlines and autonomy skills;
- Strong organizational, data management, analytical and problem solving abilities;

3.6.2.1.11 Lot 11: Access to finance and partnership

- Work experience in Africa.
- Previous experience in management;
- Complementary training in finance and/or in planification;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …)
- Solid business, managerial and/or financial background;
- Excellent knowledge of international finance and accounting law and regulatory standards (GAAP, IFRS);
- Sound knowledge of the major international, multilateral, regional and bilateral health funders acting in LMIC / African context (like IMF, WB, GF, USAID, etc.);
- Good knowledge of European funding rules and experience in European funded projects or programs;
- Sound knowledge in innovative financing;
- Familiarity with international and regional health interventions and initiatives in Africa;
- Good knowledge of the major areas for stronger financial systems: country ownership, domestic consensus, assessment of current practices, setting priorities, political dialogue and commitments, monetary, financial, and fiscal policy transparency, corporate governance, market integrity, regulation and supervision;
- Good knowledge of multi-actor and public-private partnership and initiatives in the pharmaceutical sector and of private finance mobilization mechanisms for sustainable development in LMICs;
- Familiarity with key standards for sound financial systems: codes of good practices, SDDS, GDDS, IAS, ISA, BCBS, etc.) and with compliance tools (FSAP, ROSCs, IFIs etc.);
- High levels of adaptability to diverse educational and cultural background;
- Good priority setting, respect of deadlines and autonomy skills;
- Strong organizational, data management, analytical and problem solving abilities;
- Excellent communication, interpersonal, intercultural and relational skills;

3.6.2.1.12 Lot 12: Industrialization

- Work experience in LMIC / Africa;
- Familiarity with quality and risk management;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …).
- Solid technical, managerial and business background;
- Excellent knowledge of pharmaceutical / Vaccine / Laboratory reagents and diagnostic products / kits / chemical / biomanufacturing / API industry strategies, methods and processes : Specification analysis, feasibility studies, risk analysis, conception of production processes, normative and legal monitoring, performance reporting and optimization;

- Sound understanding of industry approaches and best practices for Scale-up, Technology Transfer, and applying of QbD principles during process development;
- Good knowledge of notions and terminology of technology transfer in pharmaceutical industry;
- Perfect knowledge of cGMP and validation principles;
- Sound knowledge of medicine R&D processes and techniques and good knowledge of fundamental and clinical research;
- Excellent knowledge of African and global medicine and vaccine industrial ecosystem and innovation processes;
- High levels of expertise and creativity;
- Broad and in-depth understanding of the diverse aspects of development cooperation and sustainable development;
- High levels of adaptability to diverse educational and cultural background;
- Good priority setting, respect of deadlines and autonomy skills;
- Strong organizational, data management, analytical and problem solving abilities;
- Excellent communication, interpersonal, intercultural and relational skills;

3.6.2.1.13 Lot 13: Private sector development & mobilization

- Work experience with the public health / pharmaceutical sector in Africa;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …).
- Solid business, health policy and economy background;
- Good knowledge of multi-actor and public-private partnership, dialogue and initiatives in the pharmaceutical sector and of private finance mobilization mechanisms for sustainable development in LMICs;
- Familiarity with the legal, reglementary and institutional ecosystem of the health / pharmaceutical sector in Africa;
- Good experience in public / private quality Assurance for local production;
- Work experience in Africa and good knowledge of the private health sector in Africa;
- Sound knowledge of the main pharmaceutical sector challenges in African context : legal and reglementary deficiencies, managerial, technical and financial weaknesses of some public actors, difficulties of coordination, weakness of public-private partnership in health sector and mutual mistrust, lack of specialized HR, prevalence of informal sector and predominance of substandard / falsified drugs, etc.;
- High levels of adaptability to diverse educational and cultural background;
- Good priority setting, respect of deadlines and autonomy skills;
- Strong organizational, data management, analytical and problem solving abilities;
- Excellent communication, interpersonal, intercultural and relational skills;

3.6.2.1.14 Lot 14: Monitoring & Evaluation

- Relevant working experience in Africa;
- Familiarity with the institutional, organizational and the operational aspects of African pharmaceutical systems;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …).
- Solid public health and pharmaceutical background;

- Demonstrable technical expertise and experience in project / program management, monitoring & evaluation, accountability and lesson-learned (including in consulting positions);
- Strong knowledge of public health studies and research, data collection & statistical analysis and project / program evaluation;
- Excellent knowledge of M&E methods, techniques and tools;
- Proven capacity to develop and manage an M&E system (including strategy, plan, responsibilities, continuous monitoring of activities, repository of indicators, reporting and periodicity, intermediary and final evaluations, etc.);
- Mastering of epidemiological / biostatistical software (Epi Info, SPSS, Epi Data, etc.), cartography, and databases (Access, SQL Server, Sybase, etc.);
- High levels of adaptability to diverse educational and cultural background;
- Good priority setting, respect of deadlines and autonomy skills;
- Strong organizational, data management, analytical and problem solving abilities;
- Excellent communication, interpersonal, intercultural and relational skills;

3.6.2.1.15 Lot 15: Managerial, Institutional and ancillary support

- Complementary training in finance and/or in planification;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …).
- Solid business, economy, administration and/or HR background;
- Demonstrable technical expertise and experience in project management;
- Deep understanding of the various stakeholders and actors relevant for developing local medicines and vaccine manufacturing infrastructure;
- HR management tools proficiency;
- High levels of adaptability to diverse educational and cultural background;
- Good priority setting, respect of deadlines and autonomy skills;
- Strong organizational, data management, analytical and problem solving abilities;
- Excellent communication, interpersonal, intercultural and relational skills;

3.6.2.2 Number of CV's (5%)

Le soumissionnaire introduit entre 1 et 5 CV.

The following formula will be used:

Points tender X = Number of CV of tender X * 5 / Tender with the highest number of CV's

3.6.2.3 Price (50%)

The following formula will be used:

Points tender X = Amount of lowest tender * 50 / Amount of tender X

3.6.2.4 Final score

Scores for the award criteria will be added up to obtain the final score out of 100.

3.6.3 Awarding the public contract

For each lot, the public contract will be awarded to the four tenderers with the highest final score, after the contracting authority has verified the accuracy of the ESPD of these tenderers and provided the check shows that the Declaration on honour corresponds with reality..

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 public contract.

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

3.7 Concluding the public contract

3.7.1 Concluding the framework agreement

In accordance with Art. 88 of the Royal Decree of 18 April 2017, the public contract occurs through the notification to the selected tenderer of the approval of his tender.

The public contract is notified via digital platforms, e-mail and, on the same day, by registered post.

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

- These Tender Specifications and its annexes;
- The approved tender of the contractor and all of its annexes;
- The registered letter of notification of the award decision;
- The retained tenderers of the subsequent public contracts and the award mails of the subsequent public contracts;
- Any later documents that are accepted by both parties, as appropriate.

3.7.2 Concluding subsequent public contracts

Public contracts arising from the framework agreement are awarded by having economic operators (EOs) party to the framework agreement compete again.

For each order (subsequent public contract) the terms of reference will be issued and sent by e-mail simultaneously to all the EOs party to the relevant lot of the framework agreement (day X) by the managing official (MO) of the framework contract.
The service provider has to introduce a bid the latest 7 days following the first calendar day after the invitation (day X+7) and the mission has to start (Initial briefing / Kick-off meeting) the latest 30 days following the first calendar day after the invitation (day X+30). These deadlines can be shortened if needed for urgent missions.

The terms of reference will specify or include following information:

a) Title of the request
b) Contact person for the request
c) Background and rationale of the request for expertise
d) Objectives and expected results of the request
e) Profil of the expert(s) (qualifications, work experience, knowledge and skills)
   The expert proposed must be one of the experts included in the initial tender. If one or more experts are replaced, the provisions of 4.9.2 apply.
f) Delivrables
g) Planning
   - Location
   - Time Frame & Deadline from the start of the mission (=Initial briefing / Kick-off meeting)
   - Man/days of work
   - Logistical Info
h) Max. pages for the methodology

The bid has to provide in following topics:

a) The list containing the Team composition / the name(s) of the experts(s) who will carry out the mission among those proposed in the bidder's initial offer.
   The contracting authority (Enabel) will verify if the names match with the ones mentioned in the initial bid.
   If one or more experts are replaced, the provisions of 4.9.2 apply.

b) The proposed intervention methodology and a planning.
   A travers la méthodologie, le soumissionnaire devra démontrer sa compréhension des Termes de référence.

c) The price

The price is based on the unit prices of the initial tender. The unit prices proposed cannot exceed the unit prices of the initial tender.

The public contract is awarded on the basis of an evaluation of the proposals received. Evaluation takes into account the following awarding criteria:

- Methodology (including planning): 35 %
- Prices: 40 %
- Quality of CV's: 25%

The public contract is notified by e-mail on the basis of a reasoned decision.

All other EOs are informed by e-mail of the result of the procedure.

4 Specific contractual and administrative conditions

This chapter of these Tender Specifications holds the specific provisions that apply to this public contract by way of derogation from the 'General Implementing Rules for public procurement and for concessions for public works' 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.

The derogations are mentioned under point 1.1 Derogations from the General Implementing Rules.

4.1 Correspondence with the service provider (Art. 10)

The contracting authority imposes the use of digital means for the purpose of exchanging written documents.

Whether digital means are used or not, information is communicated, shared and stored in such a way that the integrity and confidentiality of data is ensured.

4.2 Managing official (Art. 11)

The management and control of the performance of the public contract are entrusted to Zaïha AREZKI, Intervention Manager Team Europe Support Structure on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (TESS MAV+):

Enabel

Rue Haute 147,

1000 Brussels

E-mail: zaiha.arezki@enabel.be

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

The managing official is fully competent for the follow-up of the satisfactory performance of the public contract, including issuing service orders, drawing up reports and states of affairs, approving the services, progress reports and reviews. He or she may order any modifications to the public 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 contract are not part of the competence of the managing official. For such decisions the contracting authority is represented as stipulated under the point 1.2 Contracting authority.

Under no circumstances is the managing official allowed to modify modalities (e.g. delivery deadlines) of the contract, even if the financial impact is nil or negative. Any commitment, change or agreement derogating 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 undertakes to having the public 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 public contract. Any replacements must be approved by the contracting authority.

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 service provider and its employees are bound by a duty of reserve concerning the information which comes to their knowledge during performance of this public contract. This information may not under any circumstances be communicated to third parties without the written consent of the contracting authority. The service provider may, nevertheless, list this contract as a reference, provided that the status is correctly indicated (e.g. 'in performance') and that the contracting authority has not withdrawn this consent due to poor contract performance.

4.5 Personal data protection

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 the contractor

Where during contract performance, the contractor processes 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, the following provisions apply:

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)

The contracting authority does not acquire the intellectual property rights created, developed or used during performance of the public contract.

Without prejudice to clause 1 and unless otherwise stipulated in the procurement documents, when the subject-matter of the public 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 contract, the contracting authority also acquires the right to register and protect them, unless otherwise stipulated in the procurement documents.

Where 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)

The performance bond is posted per subsequent public contract concluded following the modalities below.

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

No performance bond is required if the performance period of the contract concluded does not exceed 45 calendar days or if the value of the contract concluded is below EUR 50 000, excluding VAT.

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).

By way of 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 reserves the right to accept or refuse the posting of the bond through that institution. The tenderer mentions 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 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 bank account number of the Deposit and Consignment Office Fill out the following form as completely as possible:https://finances.belgium.be/sites/default/files/01_marche_public.pdf (PDF, 1.34 Mo), and forward it by e-mail toinfo.cdcdck@minfin.fed.be

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;

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

4° in the case of a guaranty, by the deed of undertaking of the credit institution or the insurance company.

Proof is provided, as appropriate, by submission to the contracting authority of:

1° the deposit receipt of the Deposit and Consignment Office or of a public institution with an equivalent function; or

2° a debit notice issued by the credit institution or the insurance company; or

3° the deposit certificate issued by the State Cashier or public institution with an equivalent function; or

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° 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 contract and a reference to the procurement documents, as well as the name, first names 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 'mandatary', 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.

The contractor's demand to proceed to final acceptance of a subsequent contract equals a request to release the complete performance bond.

4.8 Conformity of performance (Art. 34)

The works, supplies and 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.

The contractor of the public 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 desk review or on-the-spot check 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 his contract cancelled or to be permanently excluded.

4.9 Changes to the public 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 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 the services already delivered, 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 contract.

4.9.2 Replacement of the experts

An economic operator party to the framework agreement may propose to replace the expert provided the following conditions and modalities are respected.

The EO submits to the framework agreement's managing official the expert's CV and the agreement of the expert to work for the account of the EO concerned.

The expert proposed:

- Must have similar competences and comply with the specifications set out in point 5.2

- May not be the expert proposed by another EO party to the framework agreement of the lot concerned.

For the change to be accepted, the new expert must fulfil the 2 conditions above.

The contracting authority maintains the right to accept or refuse the new expert proposed even if she or he fulfils the 2 above conditions.

If the new expert is not accepted, the EO party to the framework agreement can either maintain the initial expert or the EO will be barred as a participant to the framework agreement for the lot concerned. For a request the EO may propose maximum 2 different experts.

4.9.3 Revision of prices (Art. 38/7)

The prices are adjusted annually on the anniversary date of public contract conclusion based on the health index.

The price revision is calculated by means of the following formula:

Price revision = (revision coefficient (k) - 1) * revisable part

k = 1 * is\gi/IS\GI

IS = health index ('Indice Santé') on the day the tenders are opened.

is = same index, on date of invoicing.

As from the second year, the contractor may submit a new price quote at the beginning of the year. The revised prices will only apply when they have been approved by the contracting authority.

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

The **contracting authority** reserves the right to suspend the performance of the contract for a given period, mainly when it considers that the 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 period and at least ten working days or two calendar weeks, depending on whether the performance period is expressed in working days or calendar days;
- The suspension is not owing 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 contract.

4.9.5 Possible addition of country where Enabel starts operating

This public contract provides for the contractor to be entrusted with performing new services to the extent that it regards similar services to those performed under the framework of this public contract, to be carried out in a new country where Enabel would operate (either a new partner country of the Belgian Development Cooperation or a new country of operation for a third-party donor).

In other words, the contracting authority will be able to acquire similar services.

4.9.6 Unforeseen circumstances (Art. 38/11)

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 public contract, Enabel will do everything reasonable to agree a maximum compensation figure.

4.9.7 Taxation having an effect on the value of the public contract:

For this public contract, a price revision as provided for under Article 38/8 of the GIR, resulting from a change in taxation, is possible if the case occurs in Belgium or in the

country of performance concerned by this public contract and has an incidence on the value of procurement.

Such price revision is only possible if both the following conditions apply:

1. The change entered into force after the tenth day preceding the deadline for submission of tenders, and

2. Either directly, or indirectly by means of an index, such taxation is not included in the revision formula provided for in procurement documents in application of Article 38/7.

In the event of a rise in taxes, the contractor must prove that it has actually borne the additional costs that he has claimed and that they relate to services inherent to performance of the contract.

In the event of a fall, there will be no revision if the contractor can prove that it has paid the taxes at the old rate.

If the procurement documents do not contain a review clause as provided for in paragraph 1, the rules laid down in paragraphs 2 to 4 will be deemed to apply automatically.

4.9.8 Submission conditions (Art. 38/14)

The contracting authority or contractor that wants to use one of the re-examination provisions as described in Articles 38/09 to 38/12, must report the facts or circumstances on which it bases itself in writing within 30 days of their occurrence or the date on which the contractor or the contracting authority would normally have become aware of them.

4.10 Follow-up of services

The contracting authority reserves the right to request an activity report at any time of the assignment from the service provider (problems encountered and unresolved issues, deviations from the planning and deviations from the ToR…).

The contracting authority may carry out annual evaluations of the services provided and/or the quality of the relationship with the contractor.

4.11 Performance modalities (Art. 146 et seq.)

4.11.1 Deadlines and terms (Art. 147)

For each order (subsequent public contract) the mission has to start (Initial briefing / Kick-off meeting) the latest 30 days following the first calendar day after the invitation (day X+30).

The terms of reference will specify or include the man/days of work

The services must be performed within a term that will be specified in the proposal for the subsequent contract (see 3.7.2).

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

The services will be performed at the following address:

- Countries where the Belgian Development Cooperation operates in the name of the Belgian State or any other country where Enabel is asked to intervene for other donors.
- The domicile or country of residence of the expert.
- Enabel's head office.

4.11.3 Quantities to be supplied (Art. 117)

The public contract has no minimum quantities.

The estimates given below under point 2.7 Quantities are for information purposes only and regard the whole duration of the public contract The service provider must be able to deliver these quantities for the length of the public contract.

4.11.4 Inspection of the services (Art. 150)

If during contract performance irregularities are found, the contractor will be notified about this immediately by 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.

4.12 Means of action of the contracting authority (Art. 44–53 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 public 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 appointees of the contracting authority who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the 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 contract and/or the exclusion from procurement by the contracting authority for a determined duration.

4.12.1 Failure of performance (Art. 44)

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

1) when the delivery is not carried out in accordance with the conditions specified in the procurement documents;
2) at any time, when performance 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 have been given in due form by the contracting authority.

§2 Any failure to comply with the provisions of the public contract, including the non-observance 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 or by e-mail showing by equivalent means the exact date of dispatch.

The contractor must repair the defects without any delay. He may assert his right of defence by registered letter or by e-mail showing the exact date of dispatch. Such defence is to be sent within fifteen days following the day determined by the dispatch of the report. Silence on his part after this period shall be deemed acknowledgement of the reported facts.

§3 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.

4.12.1 Penalties (Art. 45)

Any failure of performance may lead to a penalty as described in Article 45 of the GIR.

4.12.2 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 period without the issuing of a report and they are automatically applied for the total number of days of delay.

Regardless of the application of any fines for delay, the contractor indemnifies the contracting authority against damages for which it is liable towards third parties due to late performance of the contract.

Fines for delay shall be calculated at 0.1% per day of delay, the maximum being fixed at 7.5% of the value of the services performed with a delay.

4.12.3 Measures as of right (Art. 47-155)

§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 detected.

The measures as of right are:

1) Unilateral termination of the 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;
2) Performance under regie of all or part of the non-performed contract;
3) Conclusion of one or more replacement contracts with one or more third parties for all or part of the 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 contract will be borne by the new contractor.

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

4.13.1 Acceptance of the framework agreement

The provisional acceptance of the last subsequent public contract equals the final acceptance of the framework agreement.

4.14 Invoicing and payment of services (Art. 66 to 72 – 160)

At the end of each subsequent public contract, the contractor must send the invoices (in a single copy) and the provisional acceptance report for the public contract (original copy) to the following address

Enabel – Belgian development agency

Rue Haute 147

1000 Brussels

However, advances may be granted in accordance with the terms and conditions set out in 4.14. In accordance with Directive 2014/55/EU and the Royal Decree of 9 March 2022 on public procurement specifying the obligation for companies to use electronic invoicing, the contractor must use an electronic invoicing system.

If the contractor is registered with the Enterprise Crossroads Bank (Banque Carrefour des Entreprises) in Belgium, he can use the Belgian Mercurius portal to receive electronic invoices in accordance with the standards and rules in force.

Non-Belgian contractors can use one of the certified access points on the international network Peppol. To access the list of service providers offering the use of these access points: https://peppol.org/members/peppol-certified-service-providers/.

Only service delivery that has been performed correctly may be invoiced.

The contracting authority disposes of a verification term of thirty days starting on the end date of service delivery, established in conformity with the modalities in the procurement documents, to carry out the technical acceptance and provisional acceptance 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.

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.

Advances

By way of derogation from the above and in accordance with Articles 12/1 to 5 of the Law of 17 June 2016, inserted by the Law of 22 December 2023 amending the public procurement regulations with a view to promoting access by SMEs to said public contracts, the contracting authority pays an advance when the contractor for a subsequent public contract proves to be an SME within the meaning of Article 163, § 3, subparagraph 2, of the Law of 17 June 2016 and the period for performance of the subsequent contract is equal to or greater than two months

The amount of the advance is calculated by applying the following percentages to a reference value determined in accordance with Article 12/5 of the Law of 17 June 2016:

1° if the contractor is a micro-enterprise, i.e. a company that employs fewer than ten people and whose annual turnover or annual balance sheet total does not exceed two million euros, the percentage to be taken into account is twenty per cent,

2° if the contractor is a small enterprise, i.e. a company that employs fewer than fifty people and whose annual turnover or annual balance sheet total does not exceed ten million euros, the percentage to be taken into account is ten per cent,

3° where the contractor is a medium-sized enterprise, i.e. a company that employs fewer than two hundred and fifty people and with an annual turnover not exceeding fifty million euros or an annual balance sheet total not exceeding forty-three million euros, the percentage to be taken into account is five per cent.

Pursuant to Art. 12/5, paragraph 2, of the Law of 17 June 2016, the reference value is calculated as follows:

- If the duration of the subsequent public contract is equal to or less than twelve months, the reference value for calculating the advance payment is equal to the initial value of the public contract, all taxes included.
- If the duration of the subsequent public contract is greater than twelve months, the reference value is an amount equal to twelve times the initial value of the public contract, including taxes, divided by the duration of the contract expressed in months.
- In the case of an open-ended subsequent public contract, the reference value is the value per month of the public contract multiplied by twelve.

The first half of the advance payment is deducted from the sums due to the contractor when the amount of the services performed reaches thirty per cent of the initial value of the public contract and the second half of the advance payment is deducted from the sums due to the contractor when the amount of the services performed reaches sixty per cent of the initial value of the public contract. The above amounts are to be understood as including the value-added tax.

4.15 Litigation (Art. 73 of the Royal Decree of 14 January 2013)

The competent courts of Brussels have exclusive jurisdiction over any dispute arising from the performance of this public 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 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 – Belgian development agency

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

To the attention of Inge Janssens

Rue Haute 147

1000 Brussels

Belgium

5 Terms of reference

5.1 General requirements

The following requirements are mandatory for all the experts / team members:

5.1.1.1 Qualifications

- Unless otherwise specified, a university diploma or equivalent higher education degree in Engineering, a Master's degree or any other recognized equivalent diploma in a field adapted to their roles and responsibilities as detailed by lot.

5.1.1.2 Work experience

- Ten (10) years of work experience, including at least five (5) years of sound professional experience in the related field;
- At least two (2) years of cumulative experience working in developing / Low & Middle Income Countries or LMIC (namely in Africa);
- Relevant consulting experience in the related fields;
- Proven experience in presenting oral communications in international congresses, conferences and seminars in the related field.

5.1.1.3 Knowledge and skills

- Excellent command of English (oral and written);
- Depending on the specific profiles, countries and/or settings, a very good command of oral and written French, Dutch, Arabic, and/or Portuguese may either be required or considered as an asset;
- IT fully iterate with excellent command of Microsoft Office package;
- Pro-active and results-oriented;
- Adaptability, flexibility positive and pragmatic attitude;
- Sound organizational skills and priority setting ability;
- Excellent oral and written communication skills;
- Very good interpersonal and relational skills;
- A team player with proven ability to build trust within the team and with the partners;
- Knowledge management and building;
- Knowledge of Theory of Change and other tools to address complexity.

5.2 Specific requirements by lot / expert profile

5.2.1 Lot 1: Regulation strengthening / WS1

5.2.1.1 Qualifications

- Pharmacy diploma or related biomedical, biotech or life science fields;
- Master's degree in pharmaceutical regulatory affairs (or equivalent experience, especially with National Regulatory Authorities / Agencies or NRAs). A PhD is considered as an asset.

5.2.1.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years of working experience in pharmaceutical regulatory affairs;
- Experience of working or directly interacting with NRAs in LMIC context on a regular basis (especially in benchmarking), in pharmaceutical system strengthening and in helping NRAs achieving maturity levels 3 and 4. Alternatively, a relevant similar experience with regional or continental pharmaceutical regulatory agencies may be considered.

5.2.1.3 Knowledge and skills

- Excellent command of English (oral and written).

5.2.2 Lot 2: Market Authorization (MA) / WS1

5.2.2.1 Qualifications

- Pharmacy diploma or related biomedical or life science fields;
- Master's degree in pharmaceutical regulatory affairs (or equivalent experience, especially with Pharmaceutical firms holders of MA). A PhD is considered as an asset.

5.2.2.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years of working experience in pharmaceutical regulatory affairs;
- Relevant experience of working in regulatory departments of pharmaceutical firms holders of MA of human drugs and vaccines, especially in the preparation and submission of MA requests to the NRAs.

5.2.2.3 Knowledge and skills

- Excellent command of English (oral and written).

5.2.3 Lot 3: Intellectual Property (IP) / WS2

5.2.3.1 Qualifications

- University diploma in law with higher education specialization in intellectual or industrial property law, coupled with a professional training or certificate in antitrust and competition laws related to the access to technology and IP;
- Master's degree / higher education specialization in relevant health, life science, biotech or biomedical domains.

5.2.3.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years of working experience in different pharmaceutical regulatory affairs, more specifically in legal counseling, licensing, competition and/or antitrust laws and regulations;
- Relevant experience of working in regulatory or legal affairs with MoHs, MoEs, MoTs or NRAs in LMIC, especially in the services dealing with pharmaceutical legislations. Alternatively, relevant experience with pharmaceutical firms in IP related processes and licensing.

5.2.3.3 Knowledge and skills

- Excellent command of English (oral and written).

5.2.4 Lot 4: Quality Control (QC) / WS1

5.2.4.1 Qualifications

- Master's degree or equivalent higher education diploma in pharmacy, pharmaceutical science, chemistry or related fields, coupled with a specialization in pharmaceutical / chemical industry;
- Master's degree / higher education specialization in quality control of medicine or chemicals;
- Alternatively, a Master's degree / higher education specialization in medicine physical, chemical and/or Microbiological analysis.

5.2.4.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years of working experience in QC;
- Relevant experience of working in medicine / vaccine QC systems, especially in project management within pharmaceutical industrial GMP laboratories and/or distribution GDP institutions;
- Sound experience in conducting quality diagnosis, inspections, audits and regular reviews. Alternatively, a proven experience in batch testing and release in pharma / vaccine industry is considered ;
- Relevant experience of working in LMIC context (preferably in Africa).

5.2.4.3 Knowledge and skills

- Excellent command of English (oral and written).

5.2.5 Lot 5: Pharmacovigilance and medicine / vaccine safety / WS1

5.2.5.1 Qualifications

- Pharmacy diploma or related biomedical, biotech, or life science fields;
- Master's degree / Higher education specialization in pharmacovigilance (PV) and/or drug safety. A PhD is considered as an asset.

5.2.5.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years of working experience in pharmacovigilance and drug surveillance services of supranational / national / regional competent authorities or pharmaceutical firms, with a PV focused role;
- Work experience in consulting / expertise in a relevant area.

5.2.5.3 Knowledge and skills

- Excellent command of English and French (oral and written).

5.2.6 Lot 6: Technology transfer / WS2

5.2.6.1 Qualifications

- Pharmacy diploma or related biomedical, biotech, or life science fields;
- Master's degree / equivalent higher education specialization (technology transfer specialists, process scientist, process engineer) or industrial relevant experience in the area of technology Transfer.

5.2.6.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years in life science / pharmaceutical technology transfer and/or in processes);
- Relevant experience of working in pharmaceutical industry.

5.2.6.3 Knowledge and skills

- Excellent command of English (oral and written).

5.2.7 Lot 7: Market shaping, Demand & Trade facilitation / WS3

5.2.7.1 Qualifications

- Master's degree in Business Administration, Economics, Demand Marketing, International Trade, procurement or related fields;
- Alternatively, a Bachelor's Degree in the same fields may be considered, if coupled with 3-year-additional relevant experience;
- Master's degree/ Higher education specialization in health or related domains will be considered as an asset;

5.2.7.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years in health / pharmaceutical sector market shaping and/or trade facilitation in supervisory and managerial positions (management consultancy, project management, market dynamics, offer/demand assessment, procurement and supply management (PSM), reimbursement and pricing policies / practices or other relevant fields);
- Relevant experience of working in LMIC context.

5.2.7.3 Knowledge and skills

- Excellent command of English (oral and written).

5.2.8 Lot 8: Supply chain management (SCM) / WS3

5.2.8.1 Qualifications

- Master's degree in Business Administration or equivalent AND a higher education specialization (e.g. M.Sc. in PSM) or a professional training (e.g. UNDP certificate) in SCM for health products ;
- Alternatively, a higher education diploma in pharmacy or related health / biomedical / scientific fields AND a Master's degree in supply chain management (or equivalent experience);

5.2.8.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years in supply chain management / logistics;
- Relevant experience of working in SCM of health products (medicine and/or vaccines), including experience in an international context (as SC specialist or consultant).

5.2.8.3 Knowledge and skills

- Excellent command of English and French (oral and written).

5.2.9 Lot 9: Research & Development (R&D) / WS4

5.2.9.1 Qualifications

- Master's degree in health science, chemistry, biotechnology engineering, or related fields. PhD considered as an key asset;
- Master's degree / higher education diploma in drug / pharmaceutical science, R&D / study engineering or pharmaceutical industry.

5.2.9.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years in medicine or vaccine R&D, drug design or therapeutic innovation;
- Relevant experience in discovery, pre-clinical and clinical development of health products in private pharmaceutical, chemical and biotech companies or within relevant research and/or academic institutions;
- Relevant international working experience in LMICs in development and/or cooperation areas.
- Any other relevant working experience in R&D with the private pharmaceutical sector may be considered.

5.2.9.3 Knowledge and skills

- Excellent command of English (oral and written).

5.2.10 Lot 10: Higher education and skill building / WS4

5.2.10.1 Qualifications

- Master's degree in pharmacy, biomedical, biotech, life science or related fields;
- Higher education diploma or relevant professional certificate / training in education/ learning design and/or competency development.

5.2.10.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years in the field of learning quality and innovation in a leading educational institution;
- Relevant experience in curriculum and competency framework development, learning assessment and credentialling, multilingualism and delivery, and impact evaluation in the field of research, pharmaceutical industry and/or regulatory systems. Alternatively, relevant experience in knowledge transmission in health product development and/or manufacturing within recognized research and/or academic institutions could be considered;
- Relevant international working experience in LMICs in development and/or cooperation areas.

5.2.10.3 Knowledge and skills

- Excellent command of English (oral and written).

5.2.11 Lot 11: Access to finance and partnership / WS5

5.2.11.1 Qualifications

- Master's degree in Business Administration, Economic science, finance or related fields;
- Higher education diploma in public health, international development, African studies or related fields.

5.2.11.2 Work experience

- Ten (10) years of relevant working experience in financial management, negotiation, audit, accounting or controlling, of which minimum five (5) years in networking, partnership negotiation, fund raising and/or public/private sector dialogue;
- Relevant experience in international finance within LMIC / limited resource settings.

5.2.11.3 Knowledge and skills

- Excellent command of English (oral and written).
- Work experience in Africa.
- Previous experience in management;
- Complementary training in finance and/or in planification;
- Good command of (an)other AU working language(s) (French, Arab, Portuguese, …).

5.2.12 Lot 12: Industrialization / WS6

5.2.12.1 Qualifications

- Master's degree in pharmacy or related domains, specialized in pharmaceutical industry;
- Alternatively, a Master's degree in industrialization engineering specialized in public health, access to quality health products, or related fields;
- Master's degree / higher education specialization in Business Administration, economy or related fields.

5.2.12.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years in the field of public health, industrialization and/or access to quality medicines, vaccines or health products;
- Experience in the implementation, capacity building and facilitation of national or supranational public-private networks in the field of pharmaceutical production and/or biomanufacturing.

5.2.12.3 Knowledge and skills

- Excellent command of English (oral and written).

5.2.13 Lot 13: Private sector development & mobilization / WS6

5.2.13.1 Qualifications

- Master's degree in Business Administration, Political or Economic science or related fields;
- Higher education diploma in public health, international development or related fields.

5.2.13.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years of experience in working or engaging with the pharmaceutical private sector;
- Experience in high-level and multi-sectoral policy dialogue with government parties and the pharmaceutical private sector in LMIC context.

5.2.13.3 Knowledge and skills

- Excellent command of English (oral and written).

5.2.14 Lot 14: Monitoring & Evaluation / Transverse

5.2.14.1 Qualifications

- Master's degree in life science or related fields (preferably in pharmacy);
- Master's degree or relevant professional certificates / trainings in development project / business management, M&E, epidemiology or biostatistics.

5.2.14.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years in management and/or monitoring & evaluation of public health projects;
- Relevant working experience in development projects funded by international / multilateral donors in LMIC context;
- Experience in working and/or collaboration with development actors and stakeholders working in African countries (including supervisory ministries, programs, implementation partners, donors, recipients, NGOs and/or civil society actors);
- Other specific experience depending of the needed support.

5.2.14.3 Knowledge and skills

- Excellent command of English (oral and written);

5.2.15 Lot 15: Managerial, Institutional and ancillary support / Transverse

5.2.15.1 Qualifications

- Master's degree in Business Administration, Economics, public administration, organizational development or related fields, with a specialization in Health / Organization / project Management, Leadership, organizational & functional audit and/or market dynamics;
- Alternatively, a bachelor degree in the above-mentioned fields may be accepted if coupled with an additional experience of three (3) years in the related fields.

5.2.15.2 Work experience

- Ten (10) years of relevant working experience, of which minimum five (5) years in administration / organization managerial and/or institutional support:
- Relevant experience in managing, evaluating and/or reinforcement of HR capabilities in public administrations;
- Specific experience in African countries in conducting organizational and/or functional audit or in supporting public administration reforms within the health sector.
- Other specific experience depending of the needed support.

5.2.15.3 Knowledge and skills

- Excellent command of English (oral and written);

6 Forms

6.1 Identification of the tenderer

Name and first name of the tenderer or name of the company and legal form	
Nationality of the tenderer and of staff (if different)	
Domicile / Registered office	
Telephone number	
National Social Security Office registration number or equivalent	
Enterprise number	
Represented by the undersigned (*) (Name, first name and function)	
Contact person (telephone number, possibly e-mail address)	
If different: Project manager (telephone number, e-mail address)	
Account number for payments Financial institution Under the name of	

(*) The tenderer shall include in his tender proof that the party/ies signing the tender is/are mandated to do so. The following are considered proof of evidence: an official document (statutes, declaration before a notary, etc.) certifying that the person signing is accredited to do so in the name of and for the account of the entity/joint enterprise/consortium.

Single person of contact during contract performance

Last name, first name:	
Function:	
Tel.:	
E-mail:	
Address:	

Person of contact in case of absence (back-up):

Last name, first name:	
Function:	
Tel.:	
E-mail:	
Address:	

6.2 Tender form - Prices

By submitting this tender the tenderer commits to performing this public contract in conformity with the provisions of the Tender Specifications BEL 21003-10024 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 are established relative to the value of these items in relation to the total amount 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 value-added tax is a special item of the inventory, to be added to the tender value. The tenderer commits to performing the public contract in accordance with the provisions of the Tender Specifications BEL 21003-10024 for the following prices, given in euros and exclusive of VAT:

6.2.1 Lot 1: Regulation strengthening / WS1

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.2 Lot 2: Market Authorization (MA)

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.3 Lot 3: Intellectual Property (IP)

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.4 Lot 4: Quality Control (QC)

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.5 Lot 5: Pharmacovigilance (PV) and drug / vaccine safety

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.6 Lot 6: Technology transfer

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.7 Lot 7: Market shaping, Demand & Trade facilitation

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.8 Lot 8: Supply Chain Management

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.9 Lot 9: Research & Development (R&D)

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.10 Lot 10: Higher education and Skills

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.11 Lot 11: Access to finance and partnership

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.12 Lot 12: Industrialization

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.13 Lot 13: Private sector development & mobilization

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.14 Lot 14: Monitoring & Evaluation

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

6.2.15 Lot 15: Managerial, Institutional and ancillary support

Item	Unit	Presumed Quantities	Unit price in euros excluding VAT	Total price exclusive of VAT	Applicable VAT rate
Expert	Man-day	50	€	€	%
Total price VAT incl.					€

Should this tender be approved, the performance bond will be constituted under the conditions and deadlines stipulated in the Tender Specifications. 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 mentioned below 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.

6.3 List of subcontractors

Name and legal form	Address / Registered office	Subject-matter	Other entity within the meaning of Article 73 §1 of the Royal Decree of 18 April 2017 (YES/NO)*.

* In accordance with Article 73 of the Royal Decree of 18 April 2017, where an economic operator wants to rely on the capacities of other entities (particularly subcontractors or independent subsidiaries) for economic and financial capacity criteria and technical and vocational capacity criteria (see 3.5.3 Selection criteria), it shall prove to the contracting authority that it will have at its disposal the resources necessary, for example, by producing a commitment by those entities to that effect.

Where a candidate or tenderer relies on the capacity of other entities in the meaning of paragraph 1, the candidate or tenderer, as appropriate, answers the question given in part II, C, of the ESPD referred to in Article 38 of the Royal Decree of 18 April 2017. He also mentions for which part of the public contract he will rely on such capacity and which other entities he proposes.

The tender also comprises a separate ESPD for the entities in the meaning of paragraph 1.

6.4 Declaration on honour – Exclusion grounds

Hereby, I / we, acting as legal representative(s) of above-mentioned tenderer declare that the tenderer is not in any of the following cases of exclusion:

1. The tenderer nor any of its directors was found guilty following an indefeasible judgement for one of the following offences:
   1° involvement in a criminal organisation
   2° corruption
   3° fraud
   4° terrorist offence, offence linked to terrorist activities or incitement to commit such offence, collusion or attempt to commit such an offence
   5° money laundering or financing of terrorism
   6° child labour and other trafficking in human beings
   7° employment of foreign citizens under illegal status
   8° creation of a shell company
   The exclusions on the basis of this criterion apply for a 5-year term from the date of judgement.

2. The tenderer has failed to fulfil his obligations to **pay taxes or social security contributions** for an amount in excess of EUR 3 000, except if the tenderer 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 tenderer 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. The tenderer or one of its directors has committed **serious professional misconduct which calls into question their integrity.**

The following are considered serious professional misconduct, among others:

a) A breach of Enabel's Policy regarding sexual exploitation and abuse – June 2019
b) 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 tenderer 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 tender has committed acts, entered into agreements or entered into arrangements to distort competition
   The presence of this tenderer 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 tenderer were detected during the execution of an essential obligation incumbent on him in the framework of a past contract concluded with another contracting authority, when these failures have given rise to measures as of right, damages or another comparable sanction. Failures to respect applicable obligations regarding environmental, social and labour rights under European Union law, national law, labour agreements or international provisions on environmental, social and labour rights are considered 'significant'.
The presence of the tenderer on the exclusion list of Enabel because of such a failure serves as evidence.

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

8. The tenderer or one of its directors are on the lists of persons, groups or entities subject to United Nations, European Union or Belgian financial sanctions:

For the United Nations, the lists can be consulted at the following address: https://finances.belgium.be/fr/tresorerie/sanctions-financieres/sanctions-internationales-nations-unies

For the European Union, the lists can be consulted at the following address: https://finances.belgium.be/fr/tresorerie/sanctions-financieres/sanctions-europ%C3%A9ennes-ue

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

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_generales/tr%C3%A9sorerie/contr%C3%B4le-des-instruments-1-2

The tenderer formally declares being able, when asked and without delay, to provide the relevant certificates and other kinds of supporting documents, except if:

a. Enabel can directly obtain the supporting documents concerned by consulting a national database in a Member State that is accessible for free, provided the tenderer has given the required information (website address, responsible authority for providing the information, specific reference of the documents) so Enabel can obtain these, with concomitant permission to access them;

b. Enabel already has said documents.

The tenderer formally agrees with Enabel accessing the supporting documents substantiating the information provided in this document.

Date

Place

Signature

6.5 Overview of the documents to be submitted

- The identification form correctly filled out (see 6.1) (for each participant for tender submitted by a group of economic operators)
- List of subcontractors (see 6.3)
- The declaration on honour – Exclusion grounds correctly filled out and signed (see 6.4) (for each participant for tender submitted by a group of economic operators)
- All documents demanded pertaining to selection criteria and award criteria
    - The eESPD (see point 3.5.1) and any annex(es) (for each participant for tender submitted by a group as well as for the entities, particularly the subcontractors, whose capacity is used for economic and financial capacity criteria and technical and vocational capacity criteria)
    - Where an economic operator wants to rely on the capacities of other entities (particularly subcontractors) for economic and financial capacity criteria and technical and vocational capacity criteria (see 3.5.3 Selection criteria), it shall prove to the contracting authority that it will have at its disposal the resources necessary, for example, by producing a commitment by those entities to that effect.
    - The list of similar services delivered during the last three years, per lot
    - CV of the expert(s) (maximum 5) for each lot
    - Tender form – Prices, correctly filled out per lot(see 6.2)
- A detail of the prices quoted, listing for each item the various elements that are included in the price and the various applicable taxes and levies;
- When the tender is signed by a mandatary (authorised representative), he or she must clearly indicate whom he or she represents. The authorised representative attaches the electronic authenticated deed or the private power of attorney or a scanned copy of the power of attorney (for each participant if the tender is submitted by a group of economic operators). Where applicable, (s)he refers to the number of the Annexe to the Belgian Official Gazette in which the excerpt of the deed concerned is published and provides the page(s) and/or passage concerned.
- Where the tender is submitted by a group of economic operators, the association agreement signed by each participant, clearly showing who represents the association
- If possible, the documents pertaining to the mandatory grounds for exclusion (see point 3.5.2) (for each participant for tender submitted by a group of economic operators).