



Tender Specifications UKR24001-10154

Services procurement contract for provision of EU integration consulting services for the Ministry of Health of Ukraine

Direct negotiated procedure with prior publication

Navision code: 79140000-7

Submission deadline August 29, 2025, 15:00 (CEST, Brussel)

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1 General provisions

1.1 Contracting authority

The contracting authority of this public procurement contract is Enabel, the Belgian development agency, public-law company with social purposes, with its registered office at Rue Haute 147, 1000 Brussels in Belgium (enterprise number 0264.814.354, RPM/RPR Brussels). Enabel has the exclusive competence for the execution, in Belgium and abroad, of public service tasks of direct bilateral cooperation with the partner countries. Moreover, it may also perform other development cooperation tasks at the request of public interest organisations, and it can develop its own activities to contribute towards realisation of its objectives.

For this procurement contract, Enabel is represented by Dirk Deprez, Head of the Representative Office in Ukraine

1.2 Institutional setting of Enabel

The general framework of reference in which Enabel operates is:

- The Belgian Law on Development Cooperation of 19 March 2013¹;
- The Belgian Law of 21 December 1998 establishing the Belgian Technical Cooperation as a public-law company²;
- The Belgian Law of 23 November 2017 changing the name of the Belgian Technical Cooperation and defining the missions and functioning of Enabel, the Belgian development agency, published in the Belgian Official Gazette on 11 December 2017.

The following initiatives are also guiding Enabel in its operations: In the field of international cooperation: the United Nations Sustainable Development Goals and the Paris Declaration on the harmonisation and alignment of aid;

- In the field of the fight against corruption: the Law of 8 May 2007 approving the United Nations Convention against Corruption, adopted in New York on 31 October 2003³, as well as the Law of 10 February 1999 on the Suppression of Corruption transposing the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions;
- In the field of Human Rights: the United Nations' Universal Declaration of Human Rights (1948) as well as the 8 basic conventions of the International Labour Organisation⁴ on Freedom of Association (C. n°87), on the Right to Organise and Collective Bargaining (C. n°98), on Forced Labour (C. n°29 and 105), on Equal Remuneration and on Discrimination in Respect of Employment (C. n°100 and 111), on Minimum Age for Admission to Employment (C. n°138), on the Prohibition of the Worst Forms of Child Labour (C. n°182);
- In the field of environmental protection: The Climate Change Framework Convention in Paris, 12 December 2015;

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

³ Belgian Official Gazette of 18 November 2008.

⁴ <http://www.ilo.org/ilolex/french/convdsp1.htm>.

- The first Management Contract concluded between Enabel and the Belgian federal State (approved by the Royal Decree of 17.12.2017, Belgian Official Gazette 22.12.2017) that sets out the rules and the special conditions for the execution of public service tasks by Enabel on behalf of the Belgian State.
- Enabel's Code of Conduct of January 2019, Enabel's Policy regarding sexual exploitation and abuse of June 2019 and Enabel's Policy regarding fraud and corruption risk management of June 2019;

1.3 Rules governing the procurement contract

- The following, among other, applies to this public procurement contract:
- The Law of 17 June 2016 on public procurement contracts⁵;
- The Law of 17 June 2013 on justifications, notification and legal remedies for public procurement contracts and certain procurement contracts for works, supplies and services⁶;
- The Royal Decree of 18 April 2017 on the award of public procurement contracts in the classic sectors⁷;
- Royal Decree of 14 January 2013 establishing the General Implementing Rules for public procurement contracts and for concessions for public works⁸;
- Circulars of the Prime Minister with regards to public procurement contracts.
- All Belgian regulations on public procurement contracts can be consulted on www.publicprocurement.be.
- Enabel's Policy regarding sexual exploitation and abuse – June 2019;
- Enabel's Policy regarding fraud and corruption risk management – June 2019;
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation – 'GDPR'), and repealing Directive 95/46/EC.
- Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data;
- [Enabel's Code of Conduct](#); , [Enabel's Policy on sexual exploitation and abuse – June 2019](#); and [Enabel's Policy on fraud and corruption risk management – June 2019](#);

1.4 Definitions

The following definitions apply to this procurement contract:

The tenderer: An economic operator submitting a tender;

⁵ Belgian Official Gazette 14 July 2016.

⁶ Belgian Official Gazette of 21 June 2013.

⁷ Belgian Official Gazette 9 May 2017.

⁸ Belgian Official Gazette 27 June 2017.

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

The contracting authority: Enabel, represented by the Resident Representative of Enabel in Ukraine

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

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: 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 procurement contract, which is introduced either at the demand of the contracting authority, or at the initiative of the tenderer;

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

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

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 any person as an inducement or reward for performing or refraining from any act relating to the award of a procurement contract or performance of a procurement contract already concluded with the contracting authority;

Litigation: Court action.

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

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

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

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

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

1.5 Processing of personal data by the contracting authority and confidentiality

1.5.1 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.

1.5.2 Confidentiality

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

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

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

1.6 Deontological obligations

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

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

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

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

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

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

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

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

1.7 Applicable law and competent courts

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

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

In case of litigation or divergence of opinion between the contracting authority and the contractor, the parties will consult each other to find a solution.

If agreement is lacking, the Brussels courts are the only courts competent to resolve the matter.

In case of court action, correspondence must (also) be sent to the following address:

Enabel S.A.

Global ContractFIN & Legal

To the attention of Ms Isabel Lastra

Rue Haute 147

1000 Brussels

Belgium

Any litigation regarding this public contract is the exclusive competence of the Brussels legal

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district courts and tribunals. French or Dutch are the languages of proceedings.

2 Subject-matter and scope of the procurement contract

2.1 Type of procurement contract

This procurement contract is a services procurement contract.

2.2 Subject-matter of the procurement contract

This service procurement contract consists in the provision of legal consultancy and expert services to support the harmonization of Ukrainian healthcare legislation with the European Union acquis, in conformity with the conditions of these Tender Specifications.

The main objective of the contract is to support the Ministry of Health of Ukraine and other public authorities by preparing a set of draft regulatory acts, legal analyses, and related documentation necessary for the implementation of EU health-related legislation in Ukraine, with a focus on:

- Substances of human origin (SoHO)
- Cross-border healthcare
- Medical devices and medicinal products

2.3 Lots

This is a single-lot service contract. The tender procedure does not foresee division into lots. The contract will be awarded in full to one successful bidder

2.4 Items

The procurement contract consists of the following service items (deliverables), which are pooled into one single contract. It is not possible to tender for individual items. The tenderer must submit a complete technical and financial offer covering all items listed below:

1. Comparative legal analysis between Ukrainian legislation and EU acts in specific areas (by 1 Dec 2025), and a concrete calendar plan for drafting
2. Draft regulatory acts (in accordance with paragraph 4:
 - a) Law on Amendments to Certain Laws of Ukraine concerning the Regulation of Substances of Human Origin;
 - b) Law on Amendments to Certain Laws of Ukraine concerning Cross-Border Health Care;
 - c) Law on Medical Devices and In Vitro Diagnostic Medical Devices;

- d) Law on Amendments to the Law of Ukraine “On Medicinal Products.”

with a full package of accompanying documents (explanatory notes, comparative tables, etc.).

3. Consultations with key stakeholders (representatives of the Ministry of Health, state authorities, committees of the Verkhovna Rada of Ukraine, public organizations, business associations, international partners). – NB: applicant should state the number of consultation meetings (with identified format: online or in-person) and expected number of participants

4. Written recommendations on further stages of implementation of the EU acquis in the field of healthcare, regarding substances of human origin (SoHO), cross-border healthcare, medical devices, and medicinal products

5. Draft application (including twinning fitch) prepared for Twinning on the formation of a safety and quality assurance system for substances of human origin in Ukraine

All items are interdependent and form a single assignment. Partial bids or incomplete submissions will not be considered

2.5 Term of the procurement contract

This procurement contract starts upon award notification and lasts for a fixed term of twelve (12) months, expected from September 2025 to August 2026, unless otherwise agreed in writing between the contracting authority and the contractor.

All deliverables must be completed within this fixed duration, in line with the implementation schedule set out in the Terms of Reference.

However, the contracting authority reserves the right to extend the contract duration solely for the purpose of finalizing outstanding deliverables, provided that such extension is duly justified and agreed upon by both parties in writing.

The extension shall not alter the overall nature or scope of the contract.

2.6 Variants

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

2.7 Option

There are neither required nor permitted options. Free options are not permitted.

2.8 Maximum contract value

Taking into account the obligation to ensure fair competition among economic operators, the contracting authority will closely monitor all deliverables under this contract. Once the estimated budget of EUR 221,000.00 VAT excluded has been reached, the contract will be terminated automatically, without prior notice

3 Procedure

3.1 Award procedure

Direct Negotiated Procedure with Prior Publication in application of Article 41 of the Law of 17 June 2016.

The tenders submitted by the selected tenderers will be evaluated as to formal and material regularity.

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

The formally and materially regular tenders will be evaluated as to content by an evaluation commission. The contracting authority will restrict the number of tenders to be negotiated by applying the award criterion stated in the procurement documents. This evaluation will be conducted on the basis of the award criteria 'price/cost', 'team expertise' and 'methodology' given in these Tender Specifications and aims to setting a shortlist of tenderers with whom negotiations will be conducted.

Then, the negotiation phase follows. In view of improving the contents of the tenders, the contracting authority may negotiate with tenderers the initial tenders and all subsequent tenders that they have submitted, except final tenders. The minimum requirements and the award criteria are not negotiable. However, the contracting authority may also decide not to negotiate. In this case, the initial tender is the final tender.

When the contracting authority intends to conclude the negotiations, it will so advise the remaining tenderers and will set a common deadline for the submission of any BAFOs. Once negotiations have closed, the BAFO will be compared with the exclusion, selection and 'price/cost', 'team expertise' and 'methodology' award criteria. The tenderer whose regular BAFO is the the most economically advantageous tender will be appointed the service provider for this procurement contract.

The BAFOs of the tenderers with whom negotiations have been conducted will be evaluated as to their regularity. Irregular BAFOs will be excluded as it's forbidden to regularise the final offers.

Only the regular BAFOs will be considered and assessed against the award criteria.

The contracting authority reserves the right to review the procedure set out above in line with the principle of processing equality and transparency.

3.2 Publication

3.2.1 Official publication

This procurement contract is officially advertised in the e-Procurement platform [BOSA - eProcurement](#)

3.2.2 Further notification

These Tender Specifications are published on the Enabel website (www.enabel.be).

3.3 Further information

The awarding of this contract is coordinated by:

Name: Svitlana Korol

Function: Contract and administration expert

Email: svitlana.korol@enabel.be

Any question about this procurement contract will be raised exclusively through the 'forum' related to the contract notice accessible on the site [BOSA - eProcurement](#)

by August 22, 2025) at the latest.

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

3.4 Tender

3.4.1 Data to be included in the tender

Tenderers are strongly advised to use the attached tender form and other forms in [PART 6- Forms](#). If not, they are fully responsible for ensuring consistency with the form.

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

Confidential information or technical/commercial secrets must be clearly marked and cannot be disclosed by the contracting authority.

Tenderers must attach to their offer:

- a. These tender specifications with the required forms completed;
- b. Supporting documents requested as part of the selection;
- c. The documents requested as part of the minimum requirements and award criteria;
- d. Document proving the competence of the signatory(s);
- e. Registration documents

A comprehensive summary of the required forms, attachments, and annexes that must be included with the submitted tenders is provided in [ANNEX \(1\) Summary of documents to be included in tender](#).

3.4.2 Period the tender is valid

The tenderers are bound by their tender for a period of 90 calendar days from the reception deadline date.

The validity of the tender will be negotiated, before the deadline is overrun.

3.4.3 Determination of prices

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

This procurement contract is a lump sum contract with milestone-based payments, where the fixed price covers the entire performance of the contract, encompassing all five

predefined tasks as outlined in the tender documents.

The price is established for the complete execution of the contract, covering all predefined consulting tasks (comparative legal analysis, drafting regulatory acts, stakeholder consultations, recommendations, and Twinning application preparation), in accordance with Article 36 of the Law of June 17, 2016.

Payments shall be made upon successful completion and acceptance of each of the five predefined tasks by the Ministry of Health of Ukraine, as specified in the tender documents, in accordance with Article 65 of the Law of June 17, 2016. Each payment will be contingent on the submission and approval of the corresponding act of completed work for each task.

The prices are submitted in accordance with Article 32, § 3 of the Royal Decree of April 18, 2017, which ensures clarity and transparency.

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

3.4.3.1 Elements included in the price

(Art. 32 §3 Royal Decree 18.04.2017)

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

The following are in particular included in the prices:

The administrative management and secretariat;

The translation and interpretation from Ukrainian into English and vice versa;

Travel, transportation and insurance;

Documentation pertaining to the services;

The delivery of documents or of pieces related to the performance;

The packaging;

Training required for operation;

Where applicable, the measures imposed by occupational safety and worker health legislation;

Customs and excise duties for equipment and products used;

Acceptance costs

3.4.4 Submission of tenders

3.4.4.1 Submission deadline

Tenders must be submitted to the contracting authority before **August 29, 2025 at 15:00 (CEST, Brussel)**

3.4.4.2 Submission procedure




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

In accordance with the rules applicable to the means of communication, only offers submitted by electronic means are accepted. Therefore, the submission of the tender on

paper is not allowed and the contracting authority will only take into account the tenders submitted electronically.

Electronic tenders must be sent via the Platform e-Procurement <https://www.publicprocurement.be/> which guarantees compliance with the conditions established in article 14 § 6 and 7 of the law of June 17, 2016.

To be submit a your Tender, Tenderers shall follow the instructions below:

	Step 1: Registrations via e-Procurement Tenderers must first register as a new user . After registering as a supplier, tenderers still need to create/add your enterprise . If already registered, tenderer may log in immediately.
	Step 2: Consulting the tender publication For reconsulting the tender publication in in the BDA (Bulletin of Tenders/Bulletin of Procurement) of the e-procurement platform, follow steps explained here: Searching the BDA and Information about the tender .
	Step 3: Submit For submitting your Tender, tenderers should follow the steps detailed here: How do I submit an offer / request for participation?

More information about the use of e-procurement platform can be obtained from the website: [e-Procurement Help Center](#).

3.4.4.3 Electronic signature

Submissions via the e-procurement platform must be electronically signed with a qualified electronic signature by the authorized person(s). After completing your submission, you are required to sign the “**Submission Report**” generated within your submission space on the e-procurement platform.

Individual signing of each and every submitted document and annex is not required when they are uploaded to the electronic platform. These documents are signed globally by affixing a signature to the relevant submission report.

The e-Procurement platform offers several options for signing the submission report, including the use of external tools. The Tenderer may download the submission report in PDF format, sign it using a Qualified Electronic Signature (QeS) with a preferred application (e.g., Adobe Acrobat), and then upload the signed document back to the platform. It is essential that the signature meets the requirements of a Qualified Electronic Signature (QeS).

A qualified electronic signature is an “advanced electronic signature that is created using a qualified electronic signature creation device, and which is based on a qualified electronic signature certificate”. To be advanced, the signature must:

- be linked to the signatory in an unequivocal manner;
- allow identification of the signatory;
- be created using electronic signature creation data that the signatory can, with a high level of confidence, use under their exclusive control and;
- be linked to the data to which it relates in such a way that any subsequent modification of the data is detected (article 26 of the eIDAS Regulation).

3.4.4.4 Withdrawal, substitution, and modification of tenders

When a tenderer wants to change or withdraw a tender already sent or submitted this must be done in accordance with the provisions of Articles 43 and 85 of the Royal Decree of 18 April 2017. The subject-matter and the scope of the changes must be indicated in detail. The withdrawal must be pure and simple.

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 paragraph 1.

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

3.4.5 Selection of tenderers

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

3.4.5.1 Exclusion grounds

Articles 52 and 69 of the Law; Article 51 of the Royal Decree of 18.04.2017

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

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

The contracting authority will verify the exactitude of this [FORM \(3\) Declaration on honour](#) for the tenderer with the best tender

For that purpose, the contracting authority will ask the tenderer concerned to provide information or documents allowing the contracting authority to verify the tenderer's personal situation by the fastest means and within the term set by the contracting authority.

The contracting authority is required to verify that there are no grounds for exclusion on the basis of the following documents:

- An **extract from the criminal record** issued in the name of the tenderer (legal entity) or its representative (natural person), **confirming the absence of criminal records for legal entities**. Note: For Ukrainian companies, we request the extract only for the legal representative(s) (natural person) regarding criminal liability, the absence (or presence) of a criminal record, or any restrictions as provided by the criminal procedural legislation of Ukraine (full version of the extract);
- A document certifying that the tenderer **is compliant with social security contribution payments**.
- A document certifying that the tenderer **is compliant with tax and levy payments**.
- A document certifying that the tenderer **is not subject to bankruptcy, liquidation, cessation of business, or judicial reorganization**

These documents do not need to be attached to the tender, as the sworn declarations [FORM \(3\) - Declaration on honour – Exclusion grounds](#), [FORM \(4\) - Integrity Statement for the tenderers](#) and [FORM \(5\) - Declaration on Honour Regarding Potential Links with Russia](#) are accepted by the contracting authority as proof *a priori* in lieu of these documents. The contracting authority will subsequently verify the accuracy of the information contained in these documents.

For documents that are NOT accessible via a free national database in a member state of the European Union, the tenderer must be capable of providing the supporting documents within 3 working days of the contracting authority's request.

Tenderers are therefore strongly advised not to wait for the contracting authority's request and to request the necessary documents from the competent authorities of the country in

which they are based as soon as possible. The waiting times for obtaining certain documents can indeed be long.

3.4.5.2 Qualitative selection

The tenderer must demonstrate having legal capacity to exercise the professional activity targeted by the public contract (listed in relevant trade of vocation register, social security registration, VAT number, establishment permit, etc.) in accordance with the legislation of the country where they are established.

Supporting document(s):

A copy of registration in vocation or trade register or any other official document showing a registration number and VAT number namely:

- **Copy of Extract/Excerpt from the Unified State Register of Legal Entities, Individual Entrepreneurs and Public Organizations**
- **A copy of the VAT registration certificate and/or an extract from the register of VAT payers (for VAT payers) or a certificate of a single tax payer and/or an extract from the register of a single tax payer (for single tax payers);**

3.4.5.3 Overview of the procedure

In a first phase, the tenders submitted by the selected tenderers will be evaluated as to formal and material regularity. Irregular tenders will be rejected. Proposals that do not achieve the minimum requirements and the minimum acceptable score for the methodology (15 points) or for the required qualifications and expertise of the proposed team (15 points), as stipulated in the tender documents, will be excluded from further evaluation and rejected. This ensures compliance with the principles of transparency, fairness, and quality assurance, as required by Article 6 of the Law of June 17, 2016, and the tender evaluation process outlined in Article 32, § 3 of the Royal Decree of April 18, 2017.

The contracting authority reserves the right to have the irregularities in the tenderers' tender regularised during the negotiations. The contracting authority also reserves the right to reject any proposal that does not meet the minimum standards for methodology and team composition, without prejudice to the right of participants to seek clarification in accordance with the procedures specified in the tender documents.

In a second phase, the formally and materially regular tenders will be evaluated as to content by an evaluation commission. The contracting authority will restrict the number of tenders to be negotiated by applying the award criteria stated in the procurement documents. This evaluation will be conducted on the basis of the award criteria given in these Tender Specifications and aims to setting a shortlist of tenderers with whom negotiations will be conducted. Maximum three tenderers may be included in the shortlist.

Then, the negotiation phase follows. In view of improving the contents of the tenders, the contracting authority may negotiate with tenderers the initial tenders and all subsequent tenders that they have submitted, except final tenders. The minimum requirements and the award criteria are not negotiable. However, the contracting authority may also decide not to negotiate. In this case, the initial tender is the final tender.

When the contracting authority intends to conclude the negotiations, it will so advise the remaining tenderers and will set a common deadline for the submission of any BAFOs. Once negotiations have closed, the BAFO will be compared with the exclusion, selection and award criteria. The tenderer whose regular BAFO is the most economically advantageous tender will be appointed the contractor for this procurement contract.

The BAFOs of the tenderers with whom negotiations have been conducted will be evaluated as to their regularity. Irregular BAFOs will be excluded.

Only the regular BAFOs will be considered and assessed against the award criteria.

The contracting authority reserves the right to review the procedure set out above in line with the principle of processing equality and transparency.

3.4.5.4 Award criteria

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

3.4.5.4.1 First criterion – The price (maximum 40 points)

Tenderers must indicate the proposed unit prices for each item in the [FORM \(2\) Tender Form Price](#). The total price of the offer will be calculated as the sum of all proposed items. The tender with the lowest total price will be awarded the maximum score of 40 points. The price scores for all other tenders will be calculated using the following proportional formula:

$$\text{Price Points (Tender A)} = (\text{Amount of lowest Tender} / \text{Amount of Tender A}) \times 40$$

3.4.5.4.2 Second criterion – The team expertise (maximum 30 points)

The maximum available score for team expertise is 30 points. Evaluation will be based on the relevance of qualifications, depth of professional experience, and evidence of prior work, including legal analyses, draft legislation, and references. Teams will be rated as *Excellent*, *Good*, *Acceptable*, or *Unsatisfactory* according to the criteria listed in the table below

Score, points	Evaluation level	Requirements
25-30	Excellent	<p>- Team Qualifications: Three or more experts (including Team Lead) meet or exceed:</p> <ul style="list-style-type: none"> • SoHO and CBHC lawyers: ≥5 years of experience in relevant fields. • Pharma Lawyer: ≥10 years of experience in pharmaceutical law. • Team Lead: ≥7 years of experience in legal project management. • All: Master's in Law or International Law, English proficiency at B2+ level (certified or demonstrated) <p>- Reports: ≥6 legal analyses (≥2 per technical area: SoHO, CBHC, Pharma) submitted to health-related authorities, each with documented positive feedback (e.g., emails, reference letters, or public records from authorities)</p> <p>- Draft Legislation: ≥2 examples of EU acquis-aligned draft laws (e.g., compliant with Regulation (EU) 2024/1938), each with documented positive feedback from international development partners (e.g., EU Delegation, WHO, World Bank) or state/governmental authorities of relevant countries (e.g., Ukraine, EU member states, or other</p>

		<p>jurisdictions)</p> <p>- References: ≥2 reference letters or emails from international development partners (e.g., EU Delegation, WHO, World Bank) or state/governmental authorities of relevant countries (e.g., Ukraine, EU member states, or other jurisdictions), confirming expertise and successful delivery</p>
20-24	Good	<p>- Team Qualifications: Three experts (including Team Lead) meet:</p> <ul style="list-style-type: none"> • SoHO and CBHC lawyers: ≥3 years of experience in relevant fields. • Pharma Lawyer: ≥5 years of experience in pharmaceutical law. • Team Lead: ≥5 years of experience in legal project management. • All: Master's in Law or International Law, English proficiency at B1+ level (certified or demonstrated) <p>- Reports: 3 legal analyses (1 per technical area: SoHO, CBHC, Pharma) submitted to health-related authorities, each with documented positive feedback (e.g., emails or reference letters)</p> <p>- Draft Legislation: 2 examples of EU acquis-aligned draft laws, each with documented feedback from international development partners (e.g., EU Delegation, WHO, World Bank) or state/governmental authorities of relevant countries (e.g., Ukraine, EU member states, or other jurisdictions)</p> <p>- References: ≥2 reference letters or emails from international development partners (e.g., EU Delegation, WHO, World Bank) or state/governmental authorities of relevant countries (e.g., Ukraine, EU member states, or other jurisdictions) confirming submission or delivery</p>
15-19	Acceptable	<p>- Team Qualifications: At least two experts meet:</p> <ul style="list-style-type: none"> • SoHO and CBHC lawyers: ≥3 years of experience in relevant fields. • Pharma Lawyer: ≥5 years of experience in pharmaceutical law. • Team Lead: ≥4 years of experience in legal project management. • All: Master's in Law or International Law, English proficiency at B1 level (certified or demonstrated). <p>- Reports: 2 legal analyses in any of the three technical areas (SoHO, CBHC, or Pharma) submitted to health-related authorities, with documented submission records.</p> <p>- Draft Legislation: 2 examples of EU acquis-aligned draft laws, with documented submission to international development partners (e.g., EU Delegation, WHO, World Bank) or state/governmental authorities of relevant countries (e.g., Ukraine, EU member states, or other jurisdictions).</p> <p>- References: ≥2 reference letters or emails from international development partners (e.g., EU Delegation, WHO, World Bank) or state/governmental authorities of relevant countries (e.g., Ukraine, EU member states, or other jurisdictions), confirming submission or delivery</p>
<15	Unsatisfactory	<p>- Team Qualifications: Fewer than two experts meet the minimum experience or qualification requirements (SoHO/CBHC: ≥3 years, Pharma: ≥5 years, Team Lead: ≥4 years, Master's in Law, B1 English).</p> <p>- Reports: <2 legal analyses submitted to health-related authorities, or no submission records provided.</p> <p>- Draft Legislation: <2 examples of EU acquis-aligned draft laws, or no documented submission to international development partners or state/governmental authorities of relevant countries.</p> <p>- References: No reference letters or emails from international development partners or state/governmental authorities of relevant countries.</p>

3.4.5.4.3 Third criterion – Methodology (maximum 30 points)

The maximum available score for the proposed methodology is 30 points. Proposals will be evaluated based on the clarity, feasibility, and comprehensiveness of the approach, as well as demonstrated understanding of the EU acquis and the Ukrainian healthcare legal context. The evaluation will also consider stakeholder engagement, timeline alignment, risk mitigation, and quality control. Methodologies will be rated as *Excellent*, *Good*, *Acceptable* or *Unsatisfactory* according to the criteria outlined in the table below

Score, points	Evaluation level	Requirements
25-30	Excellent	Comprehensive methodology with detailed plans for all tasks and deliverables, including legal mapping, gap analysis, and Twinning application preparation, fully aligned with EU acquis (e.g., Regulation (EU) 2024/1938, Directive 2011/24/EU) and Ukrainian healthcare legal framework. - Stakeholder Engagement: Specific methods outlined (e.g., ≥3 workshops with Ministry of Health, ≥3 focus group with civil society, consultations with parliamentary committees). - Timeline: Fully aligned with tender deadlines (e.g., EU acquis analysis by October 1, 2025; draft regulatory acts by July 1, 2026). - Risk Mitigation and Quality Control: ≥2 risk mitigation strategies (e.g., contingency plans for stakeholder delays) and ≥2 quality control measures (e.g., internal audits, expert validation).
20-24	Good	Clear methodology addressing all tasks and deliverables (e.g., legal mapping, gap analysis, Twinning application), with good alignment to EU acquis and Ukrainian context. - Stakeholder Engagement: At least 2 workshop with Ministry of Health and 2 consultation with parliamentary committees. - Timeline: Aligned with tender deadlines, with minor clarifications needed (e.g., stakeholder consultations scheduled by September 1, 2026). - Risk Mitigation and Quality Control: 1 risk mitigation strategy and 1 quality control measure (e.g., peer review or compliance check)
15-19	Acceptable	Methodology addresses key tasks (e.g., legal mapping, draft legislation), with basic alignment to EU acquis and Ukrainian context. - Stakeholder Engagement: At least 2 consultation with any stakeholder (e.g., Ministry of Health or civil society). - Timeline: Provided, but may require adjustments to meet tender deadlines (e.g., EU acquis analysis by October 1, 2025). - Risk Mitigation and Quality Control: 1 basic risk mitigation or quality control measure (e.g., internal review).
<15	Unsatisfactory	Methodology is vague, incomplete, or unrealistic, failing to adequately address tasks, deliverables, or EU acquis requirements. It lacks a clear timeline, effective risk mitigation strategies, or quality control measures, rendering it unlikely to meet tender requirements.

3.4.5.5 Final score

The scores for three award criteria will be added up. The procurement contract will be awarded to the tenderer with the highest final score, after the contracting authority has verified the accuracy of the Declaration on honour of this tenderer and provided the control shows that the Declaration on honour corresponds with reality.

3.4.5.6 Awarding the procurement contract

Articles 41 and 81 of the Law

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

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

3.4.6 Concluding the procurement contract

Art. 88 of the Royal Decree Award

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

Notification is via digital platforms, e-mail or fax and, on the same day, by registered post.

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

- These Tender Specifications and its annexes;
- The approved BAFO of the contractor and all of its annexes;
- The registered letter of notification of the award decision;
- Any later documents that are accepted and signed by both parties, as appropriate.

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

4 Special contractual provisions

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

These Tender Specifications do not derogate from the General Implementing Rules – GIR established in the Royal Decree of 14.01.2013.

4.1 Managing official (Art. 11)

The managing official is

Mrs. Paola Pavlenko, National Health Expert Enabel,

e-mail: paola.pavlenko@enabel.be

Once the procurement 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 procurement contract will be addressed to him/her, unless explicitly mentioned otherwise in these Tender Specifications.

The managing official is responsible for the follow-up of the performance of the contract.

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

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

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

4.2 Confidentiality (art. 18)

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

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

The tenderer is therefore bound by the duty of discretion.

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

Therefore, he undertakes to:

- Respect and enforce the strict confidentiality of these elements and to take all necessary precautions in order to preserve their secrecy (these precautions cannot in any case be inferior to those taken by the tenderer for the protection of his own confidential information);
- Consult, use and/or exploit, directly or indirectly, all of the above elements only to the extent strictly necessary to prepare and, if necessary, to carry out this public contract (particularly in accordance with the privacy legislation with respect to personal data processing);
- Not reproduce, distribute, disclose, transmit or otherwise make available to third parties the above elements, in whole or in part, and in any form, unless having obtained prior and written consent of the contracting authority;
- Return, at the first request of the contracting authority, the above elements;
- In general, not disclose directly or indirectly to third parties, whether for advertising or any other reason, the content of this public contract.

4.3 Protection of personal data

4.3.1 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.

4.4 Intellectual property (Art. 19 to 23)

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

4.5 Performance bond (Art. 25 to 33)

For this procurement contract no performance bond is required.

4.6 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.

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

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

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

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

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

4.7.2 Adjusting the prices (Art. 38/7)

For this procurement contract, price reviews are not permitted.

4.7.3 Unforeseen circumstances

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

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

4.8 Performance modalities (Art. 146 et seq.)

The services must be performed in accordance with Ukrainian legislation terms, Enabel internal rules and regulations.

This Tender Specification, together with the Awarding Decision issued by the Contracting Authority, shall constitute the binding contract between the parties. Submitting an offer is considered acceptance of all terms and conditions set out in this Tender Specification. The service provider's acceptance of the Awarding Decision and commencement of services shall further confirm acceptance of these terms.

All communication regarding the execution of services under this contract shall be conducted by email and considered valid proof of agreement and instructions.

4.9 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.

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

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

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

4.11 Zero tolerance Sexual exploitation and abuse

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

4.12 End of the procurement contract

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

The Managing Official will closely monitor the performance of services throughout the contract implementation.

The Contractor shall submit monthly progress reports detailing the services provided. These reports shall be reviewed and approved by the Managing Official in coordination with the Ministry of Health of Ukraine (MoH).

The contract shall be considered completed only upon full delivery of the scope of services as defined in the Terms of Reference (ToR)

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

The services will be invoiced upon the submission and formal acceptance of deliverables by the Managing Official in coordination with the Ministry of Health of Ukraine (MoH). The acceptance of each deliverable will be confirmed via email, indicating that the deliverable has been received, reviewed, and approved. Only after formal acceptance, as documented in the approved deliverables, shall the Contractor be entitled to submit an invoice for the respective deliverable. Payments shall be made within the agreed timeframe following approval, in accordance with the contract's financial terms

The contractor sends invoices along with the interim contract acceptance report to the following address:

paola.pavlenko@enabel.be Paola Pavlenko, National Health Expert

svitlana.korol@enabel.be Svitlana Korol, ECA

veronika.pineha@enabel.be Veronika Pineha, Financial controller

Only services that have been performed correctly may be invoiced.

The contracting authority shall verify and pay the amount due to the service provider within a processing period of thirty days from the date on which it is established that the services have been fully or partially completed, which shall take place according to terms set out in the contract documents. However, payment can only be made if the contracting authority is in possession of the duly issued invoice, the approved deliverables, the list of services provided and any other documents required

The invoice must be in EUROS.

4.13 Litigation (Art. 73)

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

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

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

Enabel S.A.

Global ContractFIN & Legal

To the attention of Ms Isabel Lastra

Rue Haute 147

1000 Brussels

Belgium

5 Terms of Reference

Terms of reference

Project: Support to European integration in the healthcare sector

On June 25, 2024, the first Intergovernmental Conference between Ukraine and the EU took place in Luxembourg, marking the official start of negotiations on Ukraine's accession to the European Union. Bilateral meetings with the European Commission are currently underway as part of the official screening of Ukrainian legislation for compliance with European Union law (EU acquis), where Ukraine presents its regulations and the status of alignment of national legislation with EU legislation in various negotiating chapters.

A cross-cutting area in many negotiating chapters is healthcare, which covers public health issues (infectious diseases, cross-border threats, antimicrobial resistance, safe living environment, protection of the population from the harmful effects of tobacco); regulation of the pharmaceutical market (medicines for human use, cosmetics, medical devices); non-communicable diseases; mental health, etc. In particular, the Ministry of Health of Ukraine is involved in 23 of 37 working (negotiating) groups (according to the Resolution of the Cabinet of Ministers of Ukraine No. 987 of August 27, 2024, "Some Issues of Ensuring the Negotiation Process on Ukraine's Accession to the European Union").

On February 10-12, 2025, a screening meeting was held with the European Commission on the relevant negotiating chapter 28, "Consumer Protection and Health Care." Further screening meetings are also expected:

- June 16-20, 2025 – on negotiating chapter 27 "Environment, climate change, and civil protection" (among health issues: bathing water; drinking water; biocides; pesticides);
- September 15-16, 2025 – on negotiation chapter 12 "Food security, veterinary and phytosanitary policy" (among health issues: phytosanitary measures; food processing).

Overall, Ukraine demonstrates a high level of alignment with EU standards. At the same time, some EU legislation still needs to be implemented, so the development of the entire necessary national regulatory framework for European integration in the field of healthcare is scheduled for 2027. Therefore, to strengthen the capacity of the Ministry of Health of Ukraine and other public authorities in the healthcare sector during the European integration process, a team of experts is required.

Project objective: To develop draft healthcare regulations necessary for the implementation of the European Union's acquis communautaire (EU acquis).

Tasks:

By October 1, 2025, analyze the relevant EU acquis acts, in particular with regard to:

Substances of human origin (SoHO): [Regulation \(EU\) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC \(Text with EEA relevance\)](#)

Cross-border healthcare: [Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare](#)

Medical devices and medicinal products:

[Regulation \(EU\) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation \(EC\) No 178/2002 and Regulation \(EC\) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC \(Text with EEA relevance\)](#)

[Regulation \(EU\) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU \(Text with EEA relevance\)](#)
[Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use](#)

By December 1, 2025, conduct a comparative legal analysis between Ukrainian legislation and EU acts in specific areas.

By January 1, 2026, identify gaps (gap analysis) and formulate proposals for harmonization.

By July 1, 2026, develop draft regulatory acts considering compliance with EU legislation:

Law on Amendments to Certain Laws of Ukraine concerning the Regulation of Substances of Human Origin;

Law on Amendments to Certain Laws of Ukraine concerning Cross-Border Health Care;

Law on Medical Devices and In Vitro Diagnostic Medical Devices;

Law on Amendments to the Law of Ukraine “On Medicinal Products.”

By July 1, 2026, prepare a complete set of accompanying documents for draft regulatory acts (explanatory notes, comparative tables, etc.).

By September 1, 2026, hold consultations with key stakeholders (representatives of the Ministry of Health, government authorities, committees of the Verkhovna Rada of Ukraine, public organizations, business associations, international partners).

By September 1, 2026, ensure the finalization of draft regulatory acts in consultation with key stakeholders.

By September 1, 2026, develop recommendations for further stages of implementation of the EU acquis in the field of healthcare.

Expected results (deliverables):

Written report with a comparative legal analysis between Ukrainian legislation and EU acts in specific areas

Appendix to the report with identified gaps (gap analysis) and formulated proposals for harmonization.

Draft regulatory acts with a full package of accompanying documents (explanatory notes, comparative tables, etc.).

Consultations with key stakeholders (representatives of the Ministry of Health, state authorities, committees of the Verkhovna Rada of Ukraine, public organizations, business associations, international partners).

Written recommendations on further stages of implementation of the EU acquis in the field of healthcare, regarding substances of human origin (SoHO), cross-border healthcare, medical devices, and medicinal products.

Draft application (including twinning fish) prepared for Twinning on the formation of a safety and quality assurance system for substances of human origin in Ukraine

6 Forms

6.1 Identification form

PRIVATE/PUBLIC LAW BODY WITH LEGAL FORM	
OFFICIAL NAME	
ABBREVIATION	
BUSINESS NAME (if different)	
LEGAL FORM ORGANISATION TYPE (FOR PROFIT OR NOT FOR PROFIT, NGO)	
MAIN REGISTRATION NUMBER /SECONDARY REGISTRATION NUMBER (if applicable)	
PLACE OF MAIN REGISTRATION CITY COUNTRY	
DATE OF MAIN REGISTRATION: DD/MM/YYYY	
VAT NUMBER	
ADDRESS HEAD OFFICE POSTCODE, P.O. BOX CITY COUNTRY	
CONTACT PERSON PHONE EMAIL	

Done at:		Date:	
By (Tenderer):		Represented by (Full name)	
Signature of authorised representative:			

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/ – and explicitly declares accepting all conditions listed in the Tender Specifications and renounces any derogatory provisions such as his own general sales conditions.

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

The value added tax is dealt with on a separate line in the summary bill of quantities or the inventory, to be added to the tender's value.

The tenderer commits to performing the public contract in accordance with the provisions of the Tender Specifications for the following prices, given in euros and exclusive of VAT:

No.	Deliverable Name	Person/ hours	Price (EUR, excl. VAT)
1	Comparative legal analysis between Ukrainian legislation and EU acts in specific areas (by 1 Dec 2025). Includes concrete calendar plans for drafting. Appendix to the report with identified gaps (gap analysis) and formulated proposals for harmonization.		
2	Draft regulatory acts including: a) Law on Amendments to Certain Laws of Ukraine concerning the Regulation of Substances of Human Origin; b) Law on Amendments to Certain Laws of Ukraine concerning Cross-Border Health Care; c) Law on Medical Devices and In Vitro Diagnostic Medical Devices; d) Law on Amendments to the Law of Ukraine “On Medicinal Products.” Includes full accompanying documentation (explanatory notes, comparative tables, etc.		
3	Consultations with key stakeholders (Ministry of Health, state authorities, Verkhovna Rada committees, public organizations, business associations, international partners). Includes consultation meetings (online and in-person) and expected number of participants		
4	Written recommendations on further stages of implementation of the EU acquis in healthcare, covering substances of human origin (SoHO), cross-border healthcare, medical devices, and medicinal products		
5	Draft application (including twinning fiche) for Twinning on the formation of a safety and quality assurance system for substances of human origin in Ukraine		
Total (excl. VAT):			
VAT (... %):			
Total (incl. VAT):			

Done at:		Date:	
By (Tenderer):		Represented by (Full name)	
Signature of authorised representative:			

6.3 Declaration on honour – exclusion criteria

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

- 1) The tenderer or one of its 'directors[1]' was found guilty following a conviction by final judgement for one of the following offences:
 - 1° involvement in a criminal organisation
 - 2° corruption
 - 3° fraud
 - 4° terrorist offences, offences linked related to terrorist activities or incitement to commit such offence, collusion or attempt to commit such an offence
 - 5° money laundering or terrorist financing
 - 6° child labour and other trafficking in human beings
 - 7° employment of foreign citizens under illegal status
 - 8° creating a shell company.
- 2) The counterparty which fails to fulfil his obligations relating to the payment of taxes or social security contributions for an amount in excess of EUR 3 000, except if the counterparty can demonstrate that a contracting authority owes him one or more unquestionable and due debts which are free of all foreseeable liabilities. These debts are at least of an amount equal to the one for which he is late in paying outstanding tax or social charges.
- 3) The counterparty who is in a state of bankruptcy, liquidation, cessation of activities, judicial reorganisation or has admitted bankruptcy or is the subject of a liquidation procedure or judicial reorganisation, or in any similar situation resulting from a procedure of the same kind existing under other national regulations;
- 4) When Enabel can demonstrate by any appropriate means that the counterparty or any of its directors has committed serious professional misconduct which calls into question his integrity.

Are also considered such serious professional misconduct:

- a. A breach of Enabel's Policy regarding sexual exploitation and abuse – June 2019
- 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 counterparty was seriously guilty of misrepresentation or false documents when providing the information required for verification of the absence of grounds for exclusion or the satisfaction of the selection criteria, or concealed this information

e. Where Enabel has sufficient plausible evidence to conclude that the counterparty has committed acts, entered into agreements or entered into arrangements to distort competition

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

- 5) When a conflict of interest cannot be remedied by other, less intrusive measures;
- 6) When significant or persistent failures by the counterparty were detected during the execution of an essential obligation incumbent on him in the framework of a previous contract, a previous contract placed with another contracting authority, when these failures have given rise to measures as of right, damages or another comparable sanction.

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

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

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

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

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

<https://finances.belgium.be/fr/tresorerie/sanctions-financieres/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_en

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

For Belgium:

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

- 8) << If Enabel executes a project for another funder or donor, other grounds for exclusion may be added.

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.

Done at:		Date:	
By (Tenderer):		Represented by (Full name)	
Signature of authorised representative:			

6.4 Integrity Statement for the tenderers

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

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

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

- In order to avoid any impression of risk of partiality or connivance in the follow-up and control of the performance of the public contract, it is strictly forbidden to the public contractor (i.e. members of the administration and workers) to offer, directly or indirectly, gifts, meals or any other material or immaterial advantage, of whatever value, to the employees of Enabel who are concerned, directly or indirectly, by the follow-up and/or control of the performance of the contract, regardless of their hierarchical rank.
- Any (public) contract will be terminated, once it appears that contract awarding or contract performance would have involved the obtaining or the offering of the above-mentioned advantages appreciable in cash.
- Any failure to comply with one or more of the deontological clauses is considered a serious mistake which may lead the contracting authority to take action such as excluding the contractor from this and other public contracts for Enabel, the Belgian development agency.
- 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.

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

Done at:		Date:	
By (Tenderer):		Represented by (Full name)	
Signature of authorised representative:			

6.5 Declaration on Honour Regarding Potential Links with Russia

I, the undersigned, in my capacity as a representative of the tenderer, hereby declare on my honour that there is no Russian involvement in the contract of the tenderer I represent that exceeds the limits set out in Article 5 duodecies of Council Regulation (EU) No 833/2014 of 31 July 2014 on restrictive measures in view of Russia's actions destabilizing the situation in Ukraine, as amended by Council Regulation (EU) No 2022/578 of 8 April 2022.

In particular, I declare that:

The service provider I represent (as well as the companies within our consortium) is not a Russian national, nor a natural or legal person, entity, or body established in Russia;

The service provider I represent (as well as the companies within our consortium) is not a legal person, entity, or body of which more than 50% of the ownership rights are held, directly or indirectly, by an entity referred to in point (a) of this paragraph;

Neither I nor the tenderer I represent is a natural or legal person, entity, or body acting on behalf of or under the instruction of an entity referred to in point (a) or (b) above;

No subcontractor, supplier, or entity whose capacities I use for more than 10% meets the criteria in (a), (b), or (c).

Done at:		Date:	
By (Tenderer):		Represented by (Full name)	
Signature of authorised representative:			

6.6 GDPR

Obligations of the contractor ('subcontractor or processor') vis-à-vis the contracting authority ('personal data controller')

The subcontractor undertakes to:

1. Process the personal data **only for the purpose(s)** stipulated in the contract;
2. Process the personal data **only on documented instructions** from the controller mentioned in attachment to this contract. Where the subcontractor considers an instruction constitutes a violation of European regulations in relation to data protection or any other legal Union or Member State provision in relation to data protection, he shall immediately notify the controller thereof. Furthermore, where the subcontractor is to proceed to the transfer of personal data to a third country or an international organisation in accordance with Union or Member State law to which he is subject, in such a case, he shall inform the controller of that legal requirement before processing, unless that law prohibits such information on important grounds of public interests.
3. **Ensure the confidentiality** of the personal data processed under the framework of this contract.
4. Ensure that **persons authorised to process the personal data** pursuant to this contract:
 - have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;
 - obtain necessary training in personal data protection;
5. regarding tools, products, applications or services, principles of **data protection by design and by default** should also be taken into consideration.
6. **Subcontracting**

The subcontractor may engage another subcontractor (hereinafter, the 'subsequent subcontractor') for carrying out specific processing activities. In this case, he informs the controller in advance and in writing of any change considered with regards to adding or replacing other subcontractors. This information must clearly indicate the processing activities that are subcontracted, the identity and contact details of the subcontractor and the dates of the subcontracting contract. The controller disposes of a minimum period of [...] from the date of reception of said information to voice any objections. Such subcontracting may only be carried out if the controller has not voiced any objection during said period.

The subsequent subcontractor is to respect the obligations of this contract for the account of and following the instructions of the controller. The initial subcontractor must ensure that the subsequent subcontractor provides the same data protection guarantees to implement appropriate technical and organisational measures in such a manner that the processing will meet the requirements of the European Data Protection Regulation. Where the subsequent subcontractor fails to fulfil his data protection obligations, the initial subcontractor shall remain fully liable to the controller for the performance of that other subcontractor's obligations.

7. Information rights of data subjects

When collecting data, the subcontractor is required to inform data subjects about the data processing which will be carried out. The formulation and format of this notification must be agreed with the controller prior to data collection.

8. Data subjects exercising their rights

Where possible, the subcontractor shall assist the controller to fulfil his obligation in responding to data subject rights requests: right to access, to change, right to erasure ('right to oblivion') and opposition, right to limit processing, right to transfer data, right not to be subject to an automated individual decision (such as profiling).

The subcontractor must respond, in the name and on behalf of the controller and within the terms set by the European Data Protection Regulation, to any requests of persons concerned exercising their rights where it pertains to data that are the subject-matter of subcontracting under this contract.

9. Notification of personal data breaches

The subcontractor shall notify the controller of any personal data breach not later than [...] hours after becoming aware of it by means of [...]. This notification shall be accompanied by all useful documentation allowing the controller, where needed, to notify this breach to the competent supervisory authority.

The notification shall at least:

- describe the nature of the personal data breach including where possible, the categories and approximate number of data subjects concerned, and the categories and approximate number of personal data records concerned;
- communicate the name and contact details of the data protection officer or other contact point where more information can be obtained;
- describe the likely consequences of the personal data breach;
- describe the measures taken or proposed to be taken by the controller to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.

10. Assistance of the subcontractor in ensuring compliance by the controller of his obligations.

The subcontractor shall assist the controller in carrying out data protection impact assessments. The subcontractor assists the controller with the prior consultation of the supervisory authority.

11. Security measures

The subcontractor undertakes to implement the following security measures: [...]

12. Processing of data

The subcontractor undertakes upon completing data processing service delivery to:

- erasing all personal data, or
- sending back all personal data to the controller, or

- forwarding the personal data to the subcontractor designated by the controller. Such dispatch is accompanied by the erasure of all existing copies in the data systems of the subcontractor.

After erasure, the subcontractor shall substantiate the erasure in writing.

13. Data Protection Officer

The subcontractor shall communicate to the controller the name and contact details of his Data Protection Officer, if he has designated one in accordance to Article 37 of the European Data Protection Regulation.

14. Register of categories of processing activities

The subcontractor declares keeping written records of all categories of processing activities carried out on behalf of the controller, including:

- The name and contact details of the controller on behalf of whom he operates, of any subcontractors, and where applicable, of the Data Protection Officer.
- The categories of processing carried out on behalf of the controller;
- Where applicable, transfers of personal data to a third country or an international organisation, including the identification of that third country or international organisation and, in the case of transfers referred to in the second subparagraph of Article 49(1) of the European Data Protection Regulation, the documentation of suitable safeguards;

Where possible, a general description of the technical and organisational security measures, including inter alia as appropriate: The pseudonymisation and encryption of personal data; the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services; the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident; a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing.

15. Documentation

The subcontractor makes available to the controller all information necessary to demonstrate compliance with his obligations laid and allow for and contribute to audits, including inspections, conducted by the controller or another auditor mandated by the controller.

Done at:		Date:	
By (Tenderer):		Represented by (Full name)	
Signature of authorised representative:			

7 Summary of documents to be included in tender

FROMS		
Reference	Form	Completed & attached?
FORM (1)	Identification form	
FORM (2)	Tender form – price	
FORM (3)	Declaration on honour – Exclusion grounds	
FORM (4)	Integrity Statement for the tenderers	
FORM (5)	Declaration on Honour Regarding Potential Links with Russia	
FORM (6)	GDPR	
ATTACHMENTS		
Reference	Attachment	Attached?
All tenderers shall submit the following attachments with tender:		
1.	Document proving the competence of the signatory(s)	
2.	A copy of registration showing a registration number: Copy of Extract/Excerpt from the Unified State Register of Legal Entities, Individual Entrepreneurs and Public Organizations.	
3.	A copy of the VAT registration certificate and/or an extract from the register of VAT payers (for VAT payers) or a certificate of a single tax payer and/or an extract from the register of a single tax payer (for single tax payers);	
4.	CVs of the team members clearly indicating education, qualifications, professional experience, and level of English proficiency	
5.	Reports submitted to health-related authorities, accompanied by positive feedback such as emails, reference letters, or web posts	
6.	Examples of draft laws aligned with the EU acquis, accompanied by evidence of positive feedback	
7.	Reference letters or emails from governmental authorities of relevant countries (e.g., Ukraine, EU member states, or other jurisdictions) and/or	

	international development partners (e.g., EU Delegation, WHO, World Bank)	
8.	Detailed methodology and implementation plan	

Successful tenderer shall provide the contacting authority with the following documents:		
8.	A document confirming the absence of criminal records for managing official of legal entities	
9.	A document certifying compliance social security contribution payments	
10.	A document certifying compliance with tax and levy payments	
11.	A document certifying that the tenderer is not subject to bankruptcy, liquidation, cessation of business, or judicial reorganization	