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Number: 4300-45/2025-1(382)
Date: 15.04.2025

# TENDER DOSSIER

| | |
|---|---|
| **Subject of the public contract:** | **PURCHASE OF PALIVIZUMAB AND VACCINE AGAINST TUBERCULOSIS** |
| **Public contract award procedure:** | **Open procedure** (in accordance with Article 40, of the Public Procurement Act) |
| **Public procurement code:** | **56L150425** |

# CONTENTS OF TENDER DOSSIER

# I. GENERAL

The Contracting Authority, the National Institute of Public Health, has prepared the tender dossier in accordance with Article 67 of the Public Procurement Act (Official Gazette of the Republic of Slovenia, No. 91/2006, hereinafter: ‘ ZJN-3’).

The National Institute of Public Health holds the authorisation for the wholesale marketing of medicinal products for human use. The decision was issued by the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (decision No.: 801-32/2024-8 of 2.9.2024).
Authorisation No. 801-32/2024-8 for wholesale marketing of medicinal products for human use covers the following activities:

- purchase of medicinal products from legal entities and natural persons that hold the authorisation to pursue the activity of manufacture and wholesale distribution of medicinal products,
- introduction of medicinal products from other European Union Member States into the Republic of Slovenia,
- warehousing of medicinal products,
- sale of medicinal products.

| | |
|---|---|
| **SUBJECT OF THE PUBLIC CONTRACT:** | **Purchase of palivizumab and Vaccine against tuberculosis** |
| **TYPE OF PUBLIC CONTRACT**: | **Open procedure** (in accordance with Article 40, of the Public Procurement Act) |
| **A PUBLIC TENDER DIVIDED INTO LOTS:** | **YES** |
| **VALIDITY OF THE FRAMEWORK AGREEMENT**: | **From 1.10.2025 till 30.9.2027.** |
| CPV CODE | 33600000 |
| **INFORMATION ABOUT THE CONTRACTING AUTHORITY:** | **National Institute of Public Health**<br>**Trubarjeva cesta 2, 1000 Ljubljana**<br>VAT Identification Number: SI 44724535<br>Registration Number: 6462642000<br>C.A. No.: IBAN SI56 0110 0600 0043 188<br><br>**Person Responsible:**<br>Assoc. Prof. Branko Gabrovec, PhD<br>General Director<br><br>**Contact person** for technical problems related to obtaining tender documents or using tender documents:<br>Peter Ambrožič<br>Tel.: +386 1 2441656<br>E-pošta: peter.ambrozic@nijz.si |

**BIDDER:** A bidder may be any physical or legal person eligible to have the status of a bidder according to the provisions of the Public Procurement Act (ZJN-3).

The bidder shall have a valid authorisation to pursue the activity of manufacture of medicinal products which covers the medicinal product in question or a valid wholesale marketing authorisation for medicinal products which covers the medicinal product in question, pursuant to the legislation applying in the Republic of Slovenia. The request must be fulfilled by the bidder and cannot be delegated to subcontractors or partners.

Subcontractors or partners involved in the wholesale activities of medicinal products shall have a valid authorisation to pursue the activity of manufacture of medicinal products which covers the medicinal product in question or a valid wholesale marketing authorisation for medicinal products which covers the medicinal product in question, pursuant to the legislation applying in the Republic of Slovenia.

A Bidder who is not a marketing authorization holder of a medicinal product must be a business associated with a holder of marketing authorisation according to the Medicinal Products Law (Official Journal of RS, no. 17/2014 and amendments, hereafter ZZdr-2).

The indicated conditions must be met on the day of opening of bids.

# 1. INVITATION TO TENDER

Pursuant to Article 67 of ZJN-3, the Contracting Authority has sent the notice on the public contract under an open procedure (hereinafter: 'Public Contract') for publication on the Public Procurement Portal.

Pursuant to the Public Contract, we hereby invite you to submit your bid in accordance with the instructions for compiling bids.

## 1.1. METHOD AND PLACE OF ACCEPTING THE DOCUMENTATION RELATING TO THE CALL FOR TENDERS

Bidders can obtain the documents on the public procurement portal.

All potential changes, additions, corrections to tender documents and additional clarifications comprise an integral part of the documentation related to the call for tenders. Questions and responses published on the public procurement portal shall also be an integral part of the tender documents.

Instructions for using the information system for using the e-JN electronic tender submission functionality: INSTRUCTIONS FOR USING ESPD FOR BIDDERS at https://ejn.gov.si/sistem/usmeritve-in-navodila/navodila-in-obrazci.html.

## 1.2. SUPPLEMENTARY CLARIFICATIONS OF THE DOSSIER

Candidates or bidders who may have additional questions in regard to the Tender Dossier may send these to the Contracting Authority via the Public Procurement Portal www.enarocanje.si upon publication of the related public tender.

The final deadline for sending additional questions is **9:00 am on 13th May 2025.**

## 1.3. METHOD, PLACE AND DATE FOR BID RECEPTION

Bidders must submit their bids via the e-JN information system at the website https://ejn.gov.si/ in accordance with point 3 of the document Instructions for the use of the information system to utilise the functionalities of the system for the electronic submission of e-JN bids: INSTRUCTIONS FOR THE USE OF THE EUROPEAN SINGLE PROCUREMENT DOCUMENT (hereinafter: ESPD) FORM FOR BIDDERS (hereinafter: Instructions for the use of the e-JN), which is part of this tender documentation and posted on the website https://ejn.gov.si/sistem/usmeritve-in-navodila/navodila-in-obrazci.html.

Prior to submitting a bid, bidders shall register at https://ejn.gov.si/ in accordance with the Instructions for the use of the e-JN. Bidders that are already registered on the e-JN information system should log into the application at the same address.

The person at the bidder authorised to submit tenders in the e-JN information system shall submit the tender by clicking on the "Submit" button. Upon the submission of a tender, the e-JN information system logs the bidder's authorised person's identity and the time of submission of the tender. By submitting a bid, the bidder's authorised person demonstrates and declares his or her intention to submit a binding bid on behalf of the tenderer (Article 18 of the Code of Obligations). Upon submission of a bid, that bid is binding for the time stated in the bid, unless the bidder's authorised person withdraws or amends the bid before the deadline for submissions.

Bids shall be deemed to have been submitted on time if the contracting authority receives them via the e-JN system (https://ejn.gov.si/

**by 23th May 2025 until 9:00 am.**

A bid is deemed to have been submitted if it is designated as "SUBMITTED" in the e-JN information system.

## 1.4. OPENING OF BIDS

The opening of tenders will be carried out automatically in the e-JN information system on **23th May 2025 at 12:00 (noon)** at https://ejn.gov.si/ .

The opening of the tenders is carried out automatically by the e-JN information system at the time set for the public opening of tenders. The system shows information about bidders, about variants (if requested or allowed) and enables access to the .pdf document which the bidder uploads to the e-JN system using the "Predračun" (Estimate) tab. For bidders who submit tenders this information is available in the e-JN information system under "Zapisnik o odpiranju ponudb" (Records of opened tenders).

## 1.5. AMENDMENTS AND WITHDRAWAL OF BIDS

A bidder may withdraw or amend its bid up until the bid submission deadline. If a bidder withdraws its bid from the e-JN information system, it shall be deemed that the bid was not submitted and will also not be seen by the contracting authority in the e-JN information system. If a bidder changes its bid in the e-JN information system, the contracting authority has access to the most recently submitted bid in the information system.
Bids may no longer be submitted after the deadline for submissions has passed.

## 1.6. LEGAL PROTECTION

Legal protection for bidders in the public tender procurement procedure is provided in accordance with the provisions of the Legal Protection in Public Procurement Procedures Act (Official Gazette of the Republic of Slovenia, No. 43/11 and 63/11, hereinafter: 'ZVPVPJN', according to the procedures and manner provided by law.

A request for legal protection in public procurement procedures may be made at any stage of the procurement procedure against any action on the part of the Contracting Authority, unless the law governing the award of public contracts or the ZPVPJN stipulate otherwise. The request for legal protection may be made by an actively identified person, as defined in Article 14 of the ZPVPJN.

The request for revision must contain:

1. name and address of applicant and the contact person,
2. name of the Contracting Authority
3. public procurement code,
4. subject of the public contract,
5. contested infringements,
6. facts and evidence proving the infringements,
7. power of attorney in the pre-revision and revision procedure if the applicant acts jointly with the authorised person,

8. an indication of whether the specific public procurement procedure is co-financed from European funds, and from which fund specifically.

In accordance with the third indent of the first paragraph of Article 71 ZPVPJN, with an application of the revision request referring to the content of the notice or tender dossier, the applicant shall supplement the request with proof of payment of a charge in the amount of EUR 4,000.00.

The charge shall be paid to the following subaccount open at the Bank of Slovenia for the purpose of the payment of fees for pre-revision and revision procedures, No. SI56 0110 0100 0358 802- enforcement of the budget of the Republic of Slovenia. In doing so, the applicant is required to complete the order for payment with the following information in the pre-box and the reference box: 11 16110-7111290-XXXXXXLL (the character X denotes the public procurement notice No., whereas the designation L denotes the year. if the public procurement notice number is shorter than six characters, 0 shall be written in the initial spaces.
A bidder may submit a request for a revision in the pre-revision procedure against the content of the notice or tender documentation within ten working days of the publication of the contract notice or notice of additional information, information on incomplete procedure or correction, provided this notice amends or supplements the requirements or selection criteria for the most favourable bidder, but no later than the deadline for the submission of bids.

An application for a review shall be lodged via the eRevizija website. The information that a request for a review has been submitted is immediately and automatically published via the eRevizija portal in the public procurement file on the public procurement portal.

# 2. INSTRUCTIONS ON COMPILING THE BID

## 2.1. LEGAL BASIS

The tender documentation is compiled on the basis of the Public Procurement Act (Official Gazette of the Republic of Slovenia, No. 91/2015, Official Journal of the European Union, Nos 307/2015, 337/2017, Official Gazette of the Republic of Slovenia, No. 14/2018, 69/2019 - Constitutional Court ruling, Official Journal of the European Union, No. 279/2019, Official Gazette of the Republic of Slovenia, No. 49/2020 - ZIUZEOP, 80/2020 - ZIUOOPE, 152/2020 - ZZUOOP, 175/2020 - ZIUOPDVE, 15/2021 - ZDUOP, 112/2021 - ZNUPZ, 206/2021 - ZDUPŠOP, 121/2021, Official Journal of the European Union, No. 398/2021, Official Gazette of the Republic of Slovenia, No. 10/2022, 74/2022 - Constitutional Court Decision, 100/2022 - ZNUZSZS, 141/2022 - ZNUNBZ, 158/2022 - ZNPOVCE, 28/2023, 88/23 – ZOPNN-F; hereinafter: the ZJN-3), secondary legislation adopted on its basis, Legal Protection in Public Procurement Procedures Act (Official Gazette of the Republic of Slovenia, Nos 43/2011, 60/2011 - ZTP-D, 63/2013, 90/2014 - ZDU-1l, 95/2014 - ZIPRS1415-C, 96/2015 - ZIPRS1617, 80/2016 - ZIPRS1718, 60/2017, 72/2019), the Code of Obligations (Official Gazette of the Republic of Slovenia, Nos 83/2001, 32/2004, 28/2006 - Constitutional Court Decision, 40/2007, 64/2016 - Constitutional Court Decision, 20/2018) and other regulations governing public procurement and the subject of the public contract award procedure.

## 2.2. LANGUAGE OF THE BID

The bid shall be submitted entirely in the Slovenian or English languages.

## 2.3. BID VARIANTS

The Contracting Authority shall not consider bid variants.

## 2.4. VALIDITY OF THE BID

The bid shall be valid for no less than three months after the deadline fixed as the final deadline for the reception of bids.

## 2.5. SUBJECT OF THE PUBLIC CONTRACT

### Purchase of palivizumab and Vaccine against tuberculosis

The medicinal products, which are the subject of the public procurement, are divided into following lots:

| *Lot* | *ATC* | *MEDICINAL PRODUCT* |
|---|---|---|
| 1 | J06BB16 | Palivizumab – recombinant humanised monoclonal antibody against respiratory syncytial virus (RSV) - 50 mg / 0,5 ml |
| 2 | J06BB16 | Palivizumab – recombinant humanised monoclonal antibody against respiratory syncytial virus (RSV) – 100 mg / 1 ml |
| 3 | J07AN01 | Tuberculosis vaccine, live attenuated |

The Bidder may submit a bid for one, two or more lots.
Each lot will be submitted separately, in accordance with the conditions and criteria for the selection, as indicated in invitation.

## 2.6. CONTENTS OF BID DOCUMENTS

The Contracting Authority shall consider a bid to be admissible if there are no reasons to exclude it and if the bid meets the participation conditions, the requirements and demands of the Contracting Authority stipulated in technical specifications and the Tender Dossier, is timely, without proven collusion or corruption, is not assessed as unusually low, and the bid price does not exceed the resources provided by the Contracting Authority.

For a tender to be admissible, it must contain all documents that comprise the bidding documents, including all statements, certificates or evidence required in this Tender Dossier.

**The Bid shall comprise all of the forms below, which must be duly completed and signed:**

1. **INFORMATION ON THE BIDDER** – **Form 1** (in the case of joint bidding, each of the partners must complete Form 1);
2. **INFORMATION ON THE HOLDER OF THE AUTHORISATION TO PURSUE THE ACTIVITY OF MANUFACTURING MEDICINAL PRODUCTS OR AUTHORISATION TO PURSUE THE ACTIVITY OF THE WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS** – **Form 2** (in the case of joint bidding, each of the partners holding the authorisation must complete Form 2);
3. **GOOD MANUFACTURING PRACTICES (GMP) certificate –** copy ;
4. **AUTHORISATION TO PURSUE THE ACTIVITY OF WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS ISSUED BY A COMPETENT AUTHORITY REGULATING MEDICINAL PRODUCTS –** copy, **the permit must include risk or immunological medicines (for lot 3), as well as medicines that are stored under special conditions (from 2°C to 8°C) (for lot 1, 2, 3),** (if the Bidder, their partner or subcontractor is a holder of the wholesale marketing authorisation for medicinal products in question);
5. **BID – Forum 3** (completed Form 3),
6. **"PREDRAČUN" - PRICE SPECIFICATION** – **Form 4** (completed Form 4);
7. **SPECIFICATION** – **Form 5** (completed Form 5);
8. **STATEMENT OF THE MARKETING AUTHORIZATION HOLDER** that he is business related with the Bidder and that the Bidder can offer the vaccine in accordance with the specifications (form 5) of the tender documentation No.: 4300-45/2025-1 (382) (if the Bidder is not the marketing authorization holder);
9. **BIDDER'S STATEMENT ON THE MEETING OF CONDITIONS** – **Form 6** (in the case of joint bidding, each of the partners must complete Form 6);
10. **STATEMENT ON GOOD MANUFACTURING PRACTICES** – **Form 7** (completed and signed Form 7; the form must be signed by the person responsible for quality at the company of the holder of the authorisation to pursue the activity of manufacturing medicinal products or wholesale marketing authorisation for medicinal products in question);
11. **STATEMENT ON GOOD DISTRIBUTION PRACTICES** – **Form 8** (filled in and signed Form 8, the form shall be signed by the person responsible for quality at the company of the holder of the authorisation to pursue the activity of manufacture of medicinal products or wholesale marketing authorisation for medicinal products in question);
12. **ESPD Form** for all economic operators; the ESPD form is an official declaration by an economic operator that there are no grounds for its exclusion and that it meets the conditions for participation. It also provides the relevant information required by the contracting authority. The ESPD form also includes an official statement that the economic operator will be able to submit supporting documents upon request and without delay in order to prove that there are no grounds for its exclusion and that it meets the conditions for participation. The statements in the ESPD form and/or the supporting documents submitted by the economic operator must be valid. The economic operator shall download the contracting authority's ESPD form (XML file) from the website of the e-JN portal/ESPD: https://ejn.gov.si/espd/ and enter the required information directly into it. A completed and signed ESPD form must be enclosed with the tender for all economic operators participating in the tender in any manner (bidder, participating tenderers in the case of a joint tender,

economic operators whose capacities are used by the bidder and subcontractors). Bidders that submit tenders in the e-JN system shall upload their own ESPD form to the "ESPD – Bidder" section and the ESPD forms of other participants to the "ESPD – Other Participants" section. Bidders that submit tenders in the e-JN system shall upload an electronically signed ESPD form in XML format or an unsigned ESPD form in XML format, whereby, in the latter case, in line with the General Terms and Conditions of Use of the e-JN Information System, a legally binding document will be deemed to have been submitted with the same validity as a signed document. For other participants, the bidder shall attach in the "ESPD – Other Participants" section the signed ESPD form in PDF format, or in XML format signed electronically; in Section B (Information on the representatives of the economic operator) of Part II of the ESPD form, **the contracting authority requires the EMŠO number of all persons who are: members of the administrative, management or supervisory bodies, or persons having powers of representation or decision-making or control thereof, and who are also citizens of the Republic of Slovenia;**

13. **INFORMATION ON SUBCONTRACTORS** – **Form 9** (if the Bidder is bidding with subcontractors);
14. **STATEMENT ON MEETING CONDITIONS AND CONSENT OF THE SUBCONTRACTOR FOR DIRECT PAYMENTS** – **Form 10** (for all economic entities participating in the offer in any role)**;**
15. **FRAMEWORK AGREEMENT** – **MODEL** – **Form 11;**
16. **PARTNERSHIP CONTRACT** (this applies if the Bidder participates in the bidding procedure with subcontractors);
17. **MARKETING AUTHORIZATION FOR OFFERED MEDICINAL PRODUCTS** (a copy of the decision, a summary of the product characteristics, a package leaflet and template of packaging).

If the country in which the Bidder is headquartered (has its registered office) does not issue such documents, the Bidder may submit a sworn statement of witnesses or a sworn statement by the Bidder instead of the written supporting document to certify the fulfilment of the condition or the ESPD form. The statement must be made before a judicial or administrative body, notary public or competent body of professional or economic institutions in the country in which the Bidder has their registered office. The ESPD form is an official statement of the economic operator that there are no reasons of exclusion and that it meets the conditions for participation, and at the same time provides the relevant information requested by the Contracting Authority. In addition, the ESPD form cites the official body or third party responsible for issuing certificates, and also includes an official statement that the economic operator will be able to present such evidence immediately on request.

## 2.7. CONDITIONS FOR THE ASSESSMENT OF CAPABILITY

The Contracting Authority shall recognise the capability of all Bidders who demonstrate – in the manner laid down in the Tender Dossier – that they meet all of the conditions contained in this Tender Dossier.

**Exclusion of Bidders:**

The contracting authority shall exclude a bidder from participating in the procurement procedure if the following grounds for exclusion exist:

**A: Grounds relating to criminal convictions**

A final judgment containing elements of the criminal offences defined in the first paragraph of Article 75 of the ZJN-3 has not been imposed on the economic operator, or on a person who is a member of an administrative, management or supervisory body of the economic operator or who has powers of representation, decision-making or control therein.
(The condition must be met by any economic operator that participates in the public procurement.)

**B: Grounds relating to the payment of taxes or social security contributions**

An economic operator shall provide assurance that:
by the date of the submission of the tender or application, in accordance with the regulations of the country of establishment or those of the contracting authority's country, it has no outstanding past-due liabilities in the amount of EUR 50 or more in connection with mandatory taxes or other non-tax monetary liabilities in accordance with the law governing financial administration;
by the date of the submission of the tender or application, all withholding tax returns for employment earnings for the period of five years to the date of the submission of the tender or application have been submitted.
(The condition must be met by any economic operator that participates in the public procurement.)

**C: Grounds relating to insolvency, conflicts of interests or professional misconduct**

An economic operator shall provide assurance that:
it has not breached the obligations set out in the second paragraph of Article 3 of the ZJN-3 (obligations in the area of environmental, social security and labour law);
no insolvency or compulsory winding-up proceedings pursuant to the law governing insolvency and compulsory winding-up proceedings or liquidation proceedings pursuant to the law governing companies have been initiated against it, its assets and operations are not under the administration of a liquidator or court, its business activities have not been suspended, no proceedings have been initiated against it in accordance with the regulations of another country and no situation of equivalent legal consequences has arisen;
it has not committed a serious breach of professional rules owing to which its integrity is compromised;
no significant or ongoing deficiencies in the performance of key obligations were evidenced in respect of the economic operator in a previous public contract or previous concession agreement concluded with the contracting authority as a result of which the contracting authority prematurely withdrew from the previous contract or agreement, claimed damages or imposed other comparable sanctions;
(The condition must be met by any economic operator that participates in the public procurement.)

**D: National grounds for exclusion**

1. National provision – the register of economic operators with the ancillary sanction of exclusion from public procurement procedures imposed
On the day the tender or application submission deadline expires, the economic operator must not be entered in the register of economic operators with the ancillary sanction of exclusion from public procurement procedures imposed under Article 110 ZJN-3.
(The condition must be met by any economic operator that participates in the public procurement.)

2. National provision – breach relating to remuneration for work
A fine has not been imposed on the economic operator two or more times during the three years prior to the deadline for the submission of tenders by virtue of a final decision or multiple final decisions issued by a competent authority of the Republic of Slovenia, another Member State or a third country for a breach in connection with remuneration for work, working hours, rest periods, or the performance of contract-based work despite the existence of elements of an employment relationship, or in connection with undeclared work.

Pursuant to Constitutional Court Decision No. U-I-180/19-23, dated 5 May 2022, those parts of this point (i.e. point (b) of the fourth paragraph of Article 75 ZJN-3) relating to breaches in connection with working time and rest periods do not comply with the Slovenian Constitution. The Slovenian National Assembly is required to eliminate the established non-compliance with the Constitution

within one year of the publication of the decision in question in the Uradni list Republike Slovenije (Official Gazette of the Republic of Slovenia). Until the established non-compliance with the Constitution is eliminated, this point shall continue to be applied such that an economic operator may, even in this position, submit evidence to the contracting authority that it has taken measures sufficient to enable it to demonstrate its reliability despite the existence of grounds for its exclusion. Sufficient measures shall be deemed to be the payment of compensation or undertaking to pay compensation in respect of any damage caused by the breaches referred to in point (b) of the fourth paragraph of Article 75 ZJN-3, active collaboration with investigating authorities in order to clarify the facts and circumstances in a comprehensive manner, and taking specific and appropriate technical, organisational and personnel measures to prevent further breaches. When assessing the measures taken by the economic operator, the contracting authority shall take into consideration the severity and particular circumstances of the breach. If the contracting authority assesses that the evidence supplied by the economic operator is sufficient, it shall not exclude it from the public procurement procedure. If the contracting authority assesses that the measures are not sufficient, it shall exclude the economic operator from the public procurement procedure and provide grounds for its decision. (The condition must be met by any economic operator that participates in the public procurement.)

**Requirements for participation:**

**ADEQUACY FOR PURSUING THE PROFESSIONAL ACTIVITY:**

1. The Bidder shall be registered in one of the professional or trade registers of the Member State where they are headquartered.

2. The Bidder shall have an authorisation to pursue their activity if such authorisation is required under the applicable legislation, or shall be a member of a certain organisation if this is required in accordance with the applicable legislation for pursuing the professional activity of the Bidder.

The Bidder shall have a valid authorisation to pursue the activity of manufacturing medicinal products or a valid wholesale marketing authorisation for medicinal products pursuant to the the Republic of Slovenia (in the case of a joint bid or a bid with subcontractors, each of the partners must comply with this condition).
A Bidder who is not a marketing authorization holder of a medicinal product must be a business associated with a holder of marketing authorisation according to the Medicinal Products Law (ZZdr-2).

When a Bidder intends to perform the public contract with partners or subcontractors, the exclusion criteria referred shall also apply to partners and subcontractors participating in the performance of the public contract.

## 2.8. METHOD FOR PROVING THE BIDDER'S CAPABILITY

The tenderer confirms conformity with the conditions of Chapter 2.7.:
- with an ESPD form as preliminary evidence,
- by completing and signing Form 10 ‘Statement or Information on Participating Interests of Natural Persons or Legal Entities in the Bidder's Assets’,
- by way of filling in and signing Form 2 ‘Information on the holder of the authorisation to pursue the activity of manufacture of medicinal products or wholesale marketing authorisation for medicinal products in question’ and a certificate of good manufacturing practices or wholesale marketing authorisation for medicinal products in question issued by a competent authority regulating medicinal products.

**An economic operator with no registered office in the Republic of Slovenia** validates the fulfilment of the requirements by submitting:

- a completed ESPD form;
- an extract from the relevant companies register or, if such a register does not exist, an equivalent document issued by a competent judicial or administrative authority in some other Member State or home country or country in which the economic operator is established.

If a country in which the economic operator is not established does not issue these documents and certificates, or if they do not cover all cases referred to in the first paragraph of Article 75 of the ZJN-3, the economic operator shall present to the contracting authority instead of written evidence a sworn statement, or if this is not provided for in the Member State or third country a statement from a specific person given before a competent judicial or administrative authority, a notary public or a professional or trade organisation in this person's home country or in the country in which the economic operator is established.

The contracting authority shall deem as suitable evidence extracts of supporting documents from the relevant register that are not more than four months old, counting from the tender or application submission deadline, or which are obtained within 90 days of the tender or application submission deadline.

## 2.9. CAPABILITY ASSESSMENT

The Contracting Authority shall recognise the capability of bidders that meet the conditions indicated below.
The Contracting Authority may request documents proving the meeting of conditions later (after the opening of bids and concluded review of bids). In such an event, the Contracting Authority shall invite the bidder concerned to deliver all documents proving that conditions have been met to the Contracting Authority within a particular deadline. If the said bidder fails to deliver the documents, authorisations or evidence in a timely manner or if they deliver documents, authorisations or evidence contrary to the Contracting Authority's requirements, the Contracting Authority shall reject their bid.
The documents shall reflect the actual state of affairs, with the exception of cases when it is expressly required that the document refer to a particular period or that a document be of a specific age. It is possible to submit photocopies of documents proving that conditions have been met, unless specifically indicated otherwise for an individual document. The Contracting Authority may subsequently request the submission of originals if they doubt the authenticity of photocopies.

## 2.10. BID FORMAT

The bidder sends the tender before the deadline for submitting tenders using the online application e-Oddaja, available https://ejn.gov.si/.
Tender documents must all be filled out. The indicated parts of the offer documentation must be signed by a legal representative of the bidder or another person, authorised to sign the foreseen type, value and scope of the contract. It must be submitted electronically in the format of the contracting authority's forms or completed manually and scanned in PDF format.

## 2.11. JOINT BIDDING

A group of several economic operators may submit a bid. In this case, they must deliver a legal act (agreement or contract) on the joint implementation of the public contract if they are selected in the public tender).

The legal act on the joint performance of the public tender shall precisely define the tasks and responsibilities of individual economic operators regarding the implementation of the public contract. The legal act on the joint implementation of the public contract shall also define the managing partner representing the group of economic operators, which, if the public contract is awarded to it, have joint and several liability to the Contracting Authority. The above-cited legal act shall come into force if a group of economic operators is selected as the most favourable bidder.

If a group of economic operators submits a joint bid, the Contracting Authority shall establish the meeting of the basic capability and the ability to perform the professional activity for each bidder individually (each bidder shall individually deliver the appropriate certificates), and the fulfilment of other conditions for all economic operators jointly.

The legal act on the joint implementation of the public contract and the forms shall be signed by each economic operator.

If the public contract is awarded to bidders that have submitted a joint bid, a change in group membership shall not be allowed during the implementation of the contract. If a group member wishes to cease implementation of the public contract, or if proceedings against any of the group members commence the purpose of which is the cessation of operations, the Contraction Authority may terminate the contract on the implementation of the public tender.

## 2.12. SUBCONTRACTORS

A subcontracting relationship is any relationship in which the lead contractor contracts part of public tender to another person, i.e. a subcontractor.

If a bidder plans to implement the public contract with subcontractors, their bid shall:

- cite all the subcontractors and each part of the public contract that they intend to subcontract (Form P-9: Subcontractor Information),
- state the contact information and legal representatives of the proposed subcontractors (Form P-9: Subcontractor Information),
- append the completed ESPD forms of these subcontractors, as per Article 79 of ZJN-3, and
- append the request of the subcontractor for direct payment if the subcontractor so requires.

During the implementation of the public contract the bidder/lead contractor shall notify the Contracting Authority of any possible change of information with respect to the preceding paragraph and send the information on new subcontractors that they intend to subsequently include no later than five days after the change. If new subcontractors are included, the lead contractor shall accompany the notice with the information and documents pursuant to the second, third, and fourth indents of the preceding paragraph.

Direct payment shall be deemed obligatory in accordance with ZJN-3 only if the subcontractor, in accordance with and by the method specified in the second and third paragraphs of Article 94 of ZJN-3, demands direct payment; this obligation is binding on the Contracting Authority and the lead contractor. If the bidder intends to implement the public contract with a subcontractor that requires direct payment in accordance with this article:

- the lead contractor shall authorise the Contracting Authority to pay the subcontractor directly in the Contract on the basis of an invoice or situation confirmed by the lead contractor,
- the subcontractor shall provide the consent pursuant to which the Contracting Authority shall settle the subcontractor's receivable against the bidder instead of the bidder,
- the lead contractor shall append to their invoice or situation a pre-confirmed account or situation.

If direct payment to the subcontractor is not required, the Contracting Authority shall demand from the lead contractor that, no later than 60 days after the payment of the final invoice or situation, they send their written statement and the written statement of the subcontractor confirming that the subcontractor has received the payment in direct relation to the subject of the public contract.

If in the implementation of the contract the bidder does business with subcontractors directly, they shall not change any subcontractor without the consent of the Contracting Authority.

A bidder carrying out the Public Contract with one or more subcontractors shall at the conclusion of the Contract with the Contracting Authority or during its implementation have concluded contracts with subcontractors. The subcontractor shall provide the Contracting Authority with a copy of the contract concluded with their contracting authority (the Bidder in this tender) no later than five days after the conclusion of the contract. The bidder shall notify all of their subcontractors of this requirement.

## 2.13. SELECTION CRITERION

Bid should suit the criteria stated in Framework Agreement and requirements from this invitation.

**For lot 1 and 2**

The the Contracting Authority will choose a registered medicinal products - holding a valid decision - marketing authorization in the Republic of Slovenia issued by the Public Agency for medicinal products and medicinal devices of the Republic of Slovenia (JAZMP) or a marketing authorization in the EU obtained by the centralized authorization procedure (Council Regulation (EC) No 726/2004) or holds conformation of an authority responsible for the medicinal products stating that the holder of the marketing authorization submitted to the administration an application for the extension of the marketing authorization in accordance with the applicable law.

**For lot 3**

The vaccine must hold a valid marketing authorisation in one of the EU countries issued by the competent authority responsible for the medicinal products.

All criteria should be fulfilled in date of submission of the bid.

## 2.14. AWARD CRITERIA

The only award criteria is the lowest offered price for each individual lot.
The tenderee will award the tenderer who will fulfill all requested conditions of the tender documentation and offers the lowest total price in EUR without TAX for an individual lot or article.

If two or more the most advantageous bids have the same total price award shall be made by consideration of stability of medicinal products at the temperature from 8°C to 25°C. The tenderee will award the tenderer who will among the most advantageous bids with the same price offer a medicinal product with the best stability.

If two or more the most advantageous bids have the same price and the same stabilitiy at the temperature from 8°C to 25°C, award shall be made by a drawing. The draw shall be made among the most advantageous bids with the same price and stability in the presence of for that purpose appointed commission that provide credibility of the draw.

The price (with discount) excluding VAT is taken into account when evaluating.

## 2.15. CONTRACT AWARD NOTICE

The contracting authority shall take the award decision by the legal deadline. Within five days of the end of the verification and assessment, the contracting authority shall inform each bidder of the decision taken on the awarding of the public contract by publishing the signed decision on the public procurement portal, in accordance with Article 89 of the Public Procurement Act (ZJN-3).

## 2.16. FRAMEWORK AGREEMENT

The selected Bidder must conclude the Framework agreement within eight (8) days after receiving the request to sign it; otherwise, the Contracting Authority may conclude that the Bidder has withdrawn from the signature of the Frameworka agreement. The Contracting Authority shall conclude the Framework agreement with selected bidder on the purchase of a medicinal product. The Framework agreement shall be awarded by being signed by all contractual parties (in joint bidding, also all partners).

## 2.17. FINANCIAL SECURITY

The selected Bidder shall be obliged to deliver to the Contracting Authority a bank guarantee of 10% of the value of the contracts inclusive of VAT as a performance bond, i.e. no later than within 8 days of the signing of the Framework agreement. The above security shall be valid for at least one day after the expiry of the validity of the Framework agreement.
The Framework agreement becomes valid, when the selected Bidder submits financial security for the performance of contractual obligations.

The Contracting Authority and the selected Bidder may agree for the performance bond of 10% of the annual value inclusive of VAT be renewed annually, whereby the contractor shall no less that 15 days prior to the expiry of the submitted performance bond submit a new performance bond (bank guarantee) in the amount of 10% of the annual value inclusive of VAT. The failure to submit a new performance bond (bank guarantee) within the required deadline shall represent a reason for the drawing on the performance bond.

Assoc. Prof. Branko Gabrovec, PhD
General Director

# II. BIDDING DOCUMENTATION

**TABLE OF CONTENTS**

## 1. INFORMATION ON THE BIDDER – Form 1

**Subject of contract:**
**Purchase of palivizumab and Vaccine against tuberculosis**.

**Company name:**

**Address:**

**Legal representatives:**

**Registration court and number:**

**Reg. ID No.:**

**ID No.:**

**Transaction account number with bank:**

**CONTACT DATA OF BIDDER (Name / Address):**

**Bidder's contact person:**

**Telephone number:** **GSM :**

**E-mail:**

**Person responsible for signing the contract:**

We vouch for the correctness of the above particulars.

Place and date: Signature of the responsible person:

## 2. INFORMATION ON THE HOLDER OF THE AUTHORISATION TO PURSUE THE ACTIVITY OF MANUFACTURING MEDICINAL PRODUCTS OR AUTHORISATION TO PURSUE THE ACTIVITY OF WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS – Form 2

**Subject of contract:**
**Purchase of palivizumab and Vaccine against tuberculosis**.

**Name of the holder of the authorisation to pursue the activity of manufacturing medicinal products or wholesale marketing authorisation for medicinal products in question:**

**Address:**

**Body competent for medicinal products that issued the authorisation:**

**Authorisation number and date of issue:**

**Person responsible for quality:**

**Telephone number**:: _____ **GSM :** _____

**E-mail:** _____ _____

**Person responsible for pharmacovigilance:**

**Telephone number**:: _____ **GSM :** _____

**E-mail:** _____ _____

**Contact person for logistics:**

**Telephone number**: _____ **GSM :** _____

**E-mail:** _____ _____

**Contact person for medical questions:**

**Telephone number**:: _____ **GSM :** _____

**E-mail:** _____ _____

**Contact person for medicinal products stability questions:**

**Telephone number**:: _____ **GSM :** _____

**E-mail:** _____ _____

**Contact person to deal with complaints:**

**Telephone number**:: _____ **GSM :** _____

**E-mail:** _____ _____

We hereby declare that are authorised to pursue the activity of manufacturing medicinal products/wholesale of medicinal products in question (the Bidder shall delete the irrelevant authorisation).
We hereby declare that we are marketing authorization holder of offered medicine products / we are business associated with a holder of marketing authorisation according to the Medicinal Products Law (ZZdr-2).
We vouch for the correctness of the above particulars.

We declare that the Contracting Authority may at any time – for the purposes of the performance of the public contract – request the competent state authorities to provide confirmation of the statements contained in the bidding documents and that the Contracting Authority may on behalf of the Bidder obtain the relevant supporting documents (evidence) from official records that prove the fulfilment of conditions laid down in the Tender Dossier.

Place and date: Signature of the responsible person:

## 3. BID – Form 3

Bidder:

| LOT | ATC | MEDICINAL PRODUCT | |
|---|---|---|---|
| **1** | **J06BB16** | **Palivizumab – recombinant humanised monoclonal antibody against respiratory syncytial virus.**<br>The medicine is indicated for prevention of infants and children against RSV. | |
| **REQUESTED:** | | | |
| **Qualitative and quantitative composition** | | **Each vial contains 50 mg palivizumab.** | |
| Pharmaceutical form | | Solution for injection | |
| Type of container | | Vial with solution for injection. | |
| Number of doses per container | | 1 | |
| Packaging | | Sc with one vial with solution for inejction.<br>1 vial contains 0,5 ml solution, 50 mg palivizumaba | |
| Labeling | | In accordance with Slovenian legislation. | |
| Parcels | | Width - not more than 57 cm, height - not more than 75 cm<br>The parcel must be on EU pallets. | |
| Shelf life | | At least 18 months from delivery. | |
| **Quantity** | | **MAX. QUANTITY: 1.600 doses**<br>Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement.<br>The Contracting Authority is not obliged to purchase the whole indicated quantity 1.600 of the medicinal product as at this moment needs can not be estimated.<br><br>**SEASON 2025/2026**<br>**540 doses**<br><br>**SEASON 2026/2027**<br>For the delivery of the medicinal product in season 2026/2027, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.05.2026. | |
| Delivery date | | **SEASON 2025/2026**<br>**OCTOBER 2025 – 180 doses**<br>**NOVEMBER 2025 - 144 doses**<br>**DECEMBER 2025 – 108 doses**<br>**JANUARY 2026 – 72 doses**<br>**FEBRUARY 2026 – 36 doses**<br><br>**SEASON 2026/2027**<br>For the delivery of the medicinal product in season | |

| | |
|---|---|
| | 2026/2027, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.05.2026. |
| Documentation | In accordance with Slovenian legislation. |
| **OFFERED:** | |
| **Proprietary name of the product** | |
| **Name and address of the manufacturer** | |
| **Name and address of the marketing authorisation holder** | |
| **Marketing authorisation number** | |
| **Date of issued of marketing authorization** | |
| **The validity of the marketing authorization** | |
| **Competent authority who issued the marketing authorization** | |
| **Medicinal product's number** | |
| **GTIN (Global trade number)** | |
| **DATA ON STABILITY OF THE MEDICINAL PRODUCT** | |
| **Minimum stability period at a temperature from 8°C to 25°C (hours)** | |
| **Minimum stability period at a temperature from 0°C to 2°C (hours)** | |
| **Minimum stability period at a temperature below 0°C (hours)** | |
| | |
| **PAYMENT CONDITIONS IN DAYS (beginning on the day of the receipt of the correct invoice)**<br>The contracting authority shall pay the contractor after the service in accordance to specification, within the period indicated in the tender documentation and in accordance with regulatory provisions. | |
| **Payment conditions in days** | |

| LOT | ATC | MEDICINAL PRODUCT | |
|---|---|---|---|
| **2** | **J06BB16** | **Palivizumab – recombinant humanised monoclonal antibody against respiratory syncytial virus.**<br>The medicine is indicated for prevention of infants and children against RSV. | |
| **REQUESTED:** | | | |
| **Qualitative and quantitative composition** | | **Each vial contains 100 mg palivizumab.** | |
| Pharmaceutical form | | Solution for injection | |
| Type of container | | Vial with solution for injection. | |
| Number of doses per container | | 1 | |
| Packaging | | Sc with one vial with solution for inejction.<br>1 vial contains 1 ml solution, 100 mg palivizumaba | |
| Labeling | | In accordance with Slovenian legislation. | |
| Parcels | | Width - not more than 57 cm, height - not more than 75 cm<br>The parcel must be on EU pallets. | |
| Shelf life | | At least 18 months from delivery. | |
| **Quantity** | | **MAX. QUANTITY: 2.500 doses**<br>Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement.<br>The Contracting Authority is not obliged to purchase the whole indicated quantity 2.500 of the medicinal product as at this moment needs can not be estimated.<br><br>**SEASON 2025/2026**<br>**864 doses**<br><br>**SEASON 2026/2027**<br>For the delivery of the medicinal product in season 2026/2027, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.05.2026. | |
| Delivery date | | **SEASON 2025/2026**<br>**OCTOBER 2025 – 216 doses**<br>**NOVEMBER 2025 - 180 doses**<br>**DECEMBER 2025 – 180 doses**<br>**JANUARY 2026 – 180 doses**<br>**FEBRUARY 2026 – 108 doses**<br><br>**SEASON 2026/2027**<br>For the delivery of the medicinal product in season 2026/2027, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.05.2026. | |
| Documentation | | In accordance with Slovenian legislation. | |
| **OFFERED:** | | | |

| | |
|---|---|
| **Proprietary name of the product** | |
| **Name and address of the manufacturer** | |
| **Name and address of the marketing authorisation holder** | |
| **Marketing authorisation number** | |
| **Date of issued of marketing authorization** | |
| **The validity of the marketing authorization** | |
| **Competent authority who issued the marketing authorization** | |
| **Medicinal product's number** | |
| **GTIN (Global trade number)** | |

| | |
|---|---|
| **DATA ON STABILITY OF THE MEDICINAL PRODUCT** | |
| **Minimum stability period at a temperature from 8°C to 25°C (hours)** | |
| **Minimum stability period at a temperature from 0°C to 2°C (hours)** | |
| **Minimum stability period at a temperature below 0°C (hours)** | |
| | |
| **PAYMENT CONDITIONS IN DAYS (beginning on the day of the receipt of the correct invoice)**<br>**The contracting authority shall pay the contractor after the service in accordance to specification, within the period indicated in the tender documentation and in accordance with regulatory provisions.** | |
| **Payment conditions in days** | |

| LOT | ATC | MEDICINAL PRODUCT |
|---|---|---|
| **3** | **J07AN01** | **Tuberculosis vaccine, live attenuated**<br>It is intended to use for active immunisation against tuberculosis of children and adults. |

| **REQUESTED:** | |
|---|---|
| **Qualitative and quantitative composition** | **Each dose contains a suitable strain of live attenuated Mycobacterium bovis BCG.** |
| Pharmaceutical form | Powder and solvent for suspension for injection. |
| Type of container | Ampoules or vials with powder and ampoules or vials with solvent. |
| Number of doses per container | 10 |
| Packaging | Sc with 1 ampoules / vials with powder and 1 ampoules / vials with solvent or<br>Sc with 5 ampoules / vials with powder and 5 ampoules / vials with solvent . |
| Labeling | In accordance with Slovenian legislation. |
| Parcels | Width - not more than 57 cm, height - not more than 75 cm<br>The parcel must be on EU pallets. |
| Shelf life | At least 18 months from delivery. |
| **Quantity** | **QUANTITY: 24.000 doses**<br><br>**<u>YEAR 2025</u>**<br>**12.000 doses**<br><br>**<u>YEAR 2026</u>**<br>**12.000 doses** |
| Delivery date | **<u>YEAR 2025</u>**<br>**NOVEMBER 2025 – 12.000 doses**<br><br>**<u>YEAR 2026</u>**<br>**NOVEMBER 2026 – 12.000 doses** |
| Documentation | In accordance with Slovenian legislation. |

| **OFFERED:** | |
|---|---|
| **Proprietary name of the product** | |
| **Name and address of the manufacturer** | |
| **Name and address of the marketing authorisation holder** | |
| **Marketing authorisation number** | |

| | |
|---|---|
| **Date of issued of marketing authorization** | |
| **The validity of the marketing authorization** | |
| **Competent authority who issued the marketing authorization** | |
| **Medicinal product's number** | |
| **GTIN (Global trade number)** | |

| | |
|---|---|
| **DATA ON STABILITY OF THE MEDICINAL PRODUCT** | |
| **Minimum stability period at a temperature from 8°C to 25°C (hours)** | |
| **Minimum stability period at a temperature from 0°C to 2°C (hours)** | |
| **Minimum stability period at a temperature below 0°C (hours)** | |
| | |
| **PAYMENT CONDITIONS IN DAYS (beginning on the day of the receipt of the correct invoice)**<br>**The contracting authority shall pay the contractor after the service in accordance to specification, within the period indicated in the tender documentation and in accordance with regulatory provisions.** | |
| **Payment conditions in days** | |

**Documentation:**
Each batch of medicinal product shall be accompanied by:

- correctly filled in documents that accompany the consignment (for example the consignment note, delivery note), documentation shall demonstrate the traceability of the medicinal product,
- documentation that confirms the quality of the medicinal product and is required for the import or entry of the medicinal product into the Republic of Slovenia,
- documentation required for specific quality control.

The tenderer by signing an offer undertakes, to supply the following documentation on the request of the tenderee at the latest before the first delivery:

- Package Leaflet and Summary of Product Characteristics and a in Slovenian language,
- valid good manufacturing practices (GMP) certificate,
- CCDS (Company Core Data Sheet).

The tenderer by signing an offer undertakes, to promptly inform the tenderee of any changes to the above-mentioned documentation.

The tenderer undertakes that the marketing authorization holder will perform all pharmacovigilance obligations in accordance with the rules governing medicinal products in the EU. The Contractor shall provide the pharmacovigilance documentation requested by the Contracting Authority or by the competent authorities in the field of medicinal products.

Place and date: Signature of the responsible person:

## 4. "PREDRAČUN" – PRICE SPECIFICATION – Form 4

Bidder:

| **REQUESTED:** | | | | | |
|---|---|---|---|---|---|
| **Public tender** | **Purchase of palivizumab and Vaccine against tuberculosis**. | | | | |
| **Oznaka JN** | **56L150425** | | | | |
| **Incoterms 2020** | **DAP Contracting Authority** | | | | |
| **PRICE SPECIFICATION - PRICE IN EUR without tax** | | | | | |
| **LOT** | **UNIT** | **MEDICINAL PRODUCT UNIT PRICE WITH DISCOUNT** | **UNIT (doses) PRICE WITH DISCOUNT** | **ESTIMATED QUANTITY (doses)** | **TOTAL PRICE** |
| | | | A | B | C = A*B |
| 1 | Dose | Palivizumab – recombinant humanised monoclonal antibody against respiratory syncytial virus (RSV) - 50 mg / 0,5 ml | | 1,600 | |
| 2 | Dose | Palivizumab – recombinant humanised monoclonal antibody against respiratory syncytial virus (RSV) – 100 mg / 1 ml | | 2,500 | |
| 3 | Dose | Tuberculosis vaccine, live attenuated | | 24,000 | |

**The bid shall be valid** for three months after the date set out as the deadline for the submission of bids.

**Method of realisation:** The final total price shall be indicated by the Bidder in EUR, excluding VAT, as indicated by the individual items on the pro forma invoice.
By signing the offer the Contractor undertakes that in the event that in the period after the submission of the offer and during the contract period the price for the medicinal products will be formed at the level of the manufacturer's element of price (PEC) in accordance with the Rules on Pricing of Medicinal Products for Human Use (hereinafter Rules) and it will be lower than the offered price, the Contractor shall supply the medicinal product to the Contracting Authority at a lower price, as set out in the Rules. The Contractor is obliged to inform the Contracting Authority about any promotional prices and to take them into account when supplying the goods if such promotional prices are lower than the contractual ones. Otherwise, the offered prices remain fixed.

The quantity indicated is the estimated quantity that the contracting authority intends to purchase during the term of this framework agreement. The contracting authority does not undertake to purchase the entire quantity of the medicinal product, as at this time it is unable to assess its needs in an objective manner.
The Contractor shall supply medicinal products successively based on the orders placed by the Contracting Authority

**Payment deadline:** The Contracting Authority shall pay the contractor after the service has been completed in its entirety in accordance with the specifications, within the deadline indicated in the bidding documents and in accordance with the legislative provisions.

Place and date:

First name and surname of the responsible person:

Signature

# 5. SPECIFICATION – Form 5

## 1. MARKETING AUTHORIZATION

LOT 1 and 2

Medicinal products must have a marketing authorisation issued by a body competent for medicinal products:

- registered medicinal products - holding a valid decision - marketing authorization in the Republic of Slovenia issued by the Public Agency for medicinal products and medicinal devices of the Republic of Slovenia (JAZMP) or a marketing authorization in the EU obtained by the centralized authorization procedure (Council Regulation (EC) No 726/2004) or holds conformation of an authority responsible for the medicinal product stating that the holder of the marketing authorization submitted to the administration an application for the extension of the marketing authorization in accordance with the applicable law.

LOT 3

The vaccine must hold a valid marketing authorisation in one of the EU countries issued by the competent authority responsible for the medicinal products.

The Contractor must inform the Contracting Authority in good time of the procedures for the medicinal product conducted by the competent authority for medicinal products and of any changes to the marketing authorization.

## 2. QUALITY

The medicinal product must be manufactured packaged and labelled in accordance with the principles of good manufacturing practice, marketing authorization and in accordance with the applicable legal rules in the Republic of Slovenia. The transport of the medicinal product to the Contracting Authority must be organized in accordance with good distribution practice.
The medicinal product must comply with the specifications in the marketing authorization.
The medicinal product must correspond to the quality description and characteristics given in the tender documentation.

The Contracting Authority may at any time without prior notice carry out the assessment of the Contractor's compliance with provisions of good manufacturing and good distribution practice. In case of such assessment and supervision the Contractor must, within the set deadline, provide the assessor with all required information or provide the access to documentation.

## 3. DOCUMENTATION

Each batch of the medicinal product shall be accompanied by documentation that confirms the quality of the medicinal product and is required for entry of the medicinal product into the Republic of Slovenia and for the implementation of a special quality control of the vaccine.

Each batch of the vaccine shall be accompanied by:

- valid good manufacturing practices (GMP) certificate;
- the manufacturer's certificate of analysis;
- Official Control Authority Batch Release (*OCABR*) in accordance with EU guidelines issued by a competent authority in the territory of the EU, EEA or Switzerland (lot 3);
- marketing information in the territory of the Republic of Slovenia (form MIF - Marketing Information Form, annex IV to guideline EC Administrative Procedure For Official Control Authority Batch Release) (lot 3);
- copy or photography of the outer packaging with the serial number of the medicinal product;

- when the information on the packaging of the medicinal product does not match the certificate on account of product repackaging, different sub-batches or different designation of the medicinal product, a clarification of such discrepancy, which is signed by a responsible person, shall be provided.

If the contractor introduces (enters) the vaccine into the Republic of Slovenia, they shall also hand over to the Contracting Authority a statement of NLZOH declaring that special control of the quality has been carried out (lot 3).

The entire documentation shall be submitted as original documents, as certified copies or copies of documents with a statement of a responsible person on the authenticity of information.

For medicinal products that must be kept refrigerated, the Contractor shall be responsible for ensuring cold chain transportation until the delivery of the medicinal product to the Contracting Authority. The Contractor undertakes to submit a certificate to the Contracting Authority certifying that the delivery of the medicinal product is proceeding according to the rules for cold chain transport and that they shall submit evidence on the temperature conditions during transport from the manufacturer to the Contracting Authority for each individual consignment.

The Contractor shall upon the announcement of the delivery also communicate to the Contracting Authority the information on the method for the monitoring of temperature during transport. Locations in the consignment where temperature indicators or temperature gauges are located shall be marked.

When the contractor announces the delivery, the information about the type and material of the transport package and vaccine packaging (primary and secondary packaging) must also be included.

In the event of a disruption in the cold chain, the Contractor shall immediately or no later than within three business days obtain data on the stability of the medicinal product and an opinion from the marketing authorisation holder or manufacturer of the medicinal product as to whether the medicinal product is still safe, effective and usable.

**4. PACKAGING AND LABELLING**

The supplied medicinal product must be equipped and packaged in accordance with the applicable regulations in the Republic of Slovenia.
If necessary, the Contractor may obtain a permission from the competent authority for medicinal products for different equipment or labelling. The Contractor shall provide sufficient patients leaflets in the Slovenian language for each package delivered.

**5. SAFETY FEATURES**

Safety features must be affixed to the outer packaging of the medicinal product in accordance with the applicable rules in the Republic of Slovenia.
If necessary, the Contractor may obtain a permission from the competent authority for medicinal products for other equipment of the outer packaging with safety features.
A unique identifier must be placed on the packaging of medicinal products in accordance with the delegated EU Commission Regulation 2016/161. The information must be uploaded in the EMVS and / or SiMVS as set out in the Delegated Regulation 2016/161.

**6. SUPPLY**

The Contracting Authority orders the medicine successively. Successive delivery, the contractor delivers the vaccine no later than fourteen days after receiving the Contracting Authority 's order form.

The Contractor must immediately inform the Contracting Authority in case of problems or delays in the production of the medicinal product which would affect the supply of the market in the Republic of Slovenia.

The Contractor must notify the Contracting Authority in writing of the intended delivery at least three working days before delivery. The notification must state the method of delivery, the estimated day and time of delivery.
Delivery shall be made to the Contracting Authority's warehouse in Ljubljana. The Contractor shall supply the medicinal products in accordance with Incoterms 2020 DAP Contracting Authority's warehouse.
Acceptance of the medicinal products shall be done with an acceptance document signed by an authorized person of the Contracting Authority. The acceptance of the medicinal products shall be deemed completed on the day of signing of the acceptance document.

**7. PRICE AND PAYMENT**

By signing the offer the Contractor undertakes that in the event that in the period after the submission of the offer and during the contract period the price for the medicinal products will be formed at the level of the manufacturer's element of price (PEC) in accordance with the Rules on Pricing of Medicinal Products for Human Use (hereinafter Rules) and it will be lower than the offered price, the Contractor shall supply the medicinal product to the Contracting Authority at a lower price, as set out in the Rules. The Contractor is obliged to inform the Contracting Authority about any promotional prices and to take them into account when supplying the goods if such promotional prices are lower than the contractual ones. Otherwise, the offered prices remain fixed.

The Contractor shall issue an invoice within eight (8) days from the delivery of the medicinal product to the Contracting Authority on the basis of a duly completed acceptance document signed by the Contracting Authority. The Contracting Authority undertakes to inspect the invoice and attachments within 8 days of receiving them and to notify the Contractor of any irregularities and deficiencies. The Contracting Authority has the right to reasonably reject the invoice with the attached documentation within 8 days of receipt.

**8. COMPLAINTS**

The Contracting Authority reserves the right to complain within thirty (30) days of the receipt of the medicinal product if:

- the medicinal product is not manufactured in accordance with good manufacturing practice and the marketing authorisation;
- the quality, description and characteristics of the medicinal product do not comply with the indications in the bidding documents;
- the medicinal product does not conform to the specifications in the marketing authorisation;
- the Contracting Authority does not receive the required documentation on the medicinal product;
- inadequacy or non-compliance of any document on the medicinal product or of a document accompanying the consignment is established;
- transport of the medicinal product to the Contracting Authority is inadequate.

The Contracting Authority may reject the medicinal product that is the subject of a complaint.

**9. PHARMACOVIGILANCE**

The Contracting Authority and the Contractor must comply with pharmacovigilance obligations in accordance with the applicable legislation (Rules on pharmacovigilance of medicinal products for human use (Official Gazette RS, no. 57/2014 and 27/2017).

The Contactor must provide to the Contracting Authority all information relevant to the safety and quality of the medicinal product in a timely manner. The Contracting Authority may request information relevant to the efficacy, safety and quality of the medicinal product from the Contactor,

and the Contactor must provide the requested information to the Contracting Authority as soon as possible. In case of information on serious adverse drug reactions, the Contractor must provide the available information to the Contracting Authority immediately, no later than within 1 business day of receiving the inquiry, all other questions must be answered by the Contactor no later than within ten days after receipt.

The Contactor undertakes that as the marketing authorization holder will perform all pharmacovigilance obligations in accordance with the regulations governing medicinal products in the EU. The Contactor is obliged to submit pharmacovigilance documentation at the request of the Contracting Authority or the body responsible for medicinal products.

## 10. RECALL

The Contracting Authority and the Contractor must have a system in place to recall medicinal products in accordance with applicable law (Rules on recall of medicinal products (Official Gazette RS, no. 105/2008 in 17/2014 – ZZdr-2).
The Contractor shall bear all costs that would arise due to the recall of the Product due to a defect committed by the Contractor or manufacturer of the medicinal product offered by the Contractor.
The Contractor undertakes that the marketing authorization holder, the manufacturer of the medicinal product and the Contractor will act in accordance with the regulations governing medicinal products in the EU and in the Republic of Slovenia in the event of recall of medicinal products. The Contracting Authority will cooperate in the recall in accordance with its powers and capabilities.

## 11. CONTACT PERSONS

The Contractor must immediately inform the Contracting Authority in the event of changes in the contact persons for logistics, quality, pharmacovigilance and medical related questions.

## 12. LIST OF TASKS AND RESPONSIBILITIES

X- designates the responsible contracting party

| **GENERAL LIABILITY** | **Contracting authority NIJZ** | **Contractor** |
|---|---|---|
| Fulfilment of contractual provisions | **X** | **X** |
| Compliance with the Medicinal Products Act (ZZdr-2) with secondary legislation and other sectoral legislation | **X** | **X** |
| Compliance with the Guidelines on Good Manufacturing Practice (GMP) for Medicinal Products for Human Use | | **X** |
| Compliance with the Guidelines on Good Distribution Practice (GDP) for Medicinal Products for Human Use | **X** | **X** |
| Valid authorisation to engage in the manufacturing of medicinal products or valid authorisation to engage in the wholesale of medicinal products in accordance with the legislation in force in the Republic of Slovenia. | **X** | **X** |
| **QUALITY** | **Contracting authority NIJZ** | **Contractor** |
| The quality system of the manufacturer, marketing authorisation holder and contractor | **-** | **X** |

| | | |
|---|---|---|
| The standard operating procedures (SOPs) or work instructions of the contractor related to the procedures for the distribution of medicinal products | - | X |
| The contracting authority's instructions for work related to the procedures for the distribution of medicinal products | X | - |
| Risk assessment and management | X | X |
| Internal control of the contractor | - | X |
| Review of the contractor | X | - |
| The medicinal product must be manufactured, packed and labelled in accordance with the principles of good manufacturing practice, the marketing authorisation and the applicable statutory regulations in the Republic of Slovenia.<br>The medicinal product must comply with the specifications in the marketing authorisation.<br>The medicinal product must comply with the quality, description and characteristics given in the context of the tender documentation. | - | X |
| **PLANNING AND ORDERING MEDICINAL PRODUCTS** | **Contracting authority NIJZ** | **Contractor** |
| Planning and review of current inventories of medicinal products | X | X |
| Ordering medicinal products | X | - |
| Acceptance and approval of orders | - | X |
| Notification in case of issues or delays in the manufacture of the medicinal products that could impact the market supply in the Republic of Slovenia. | - | X |
| **DELIVERY AND ACCEPTANCE OF MEDICINAL PRODUCTS** | **Contracting authority NIJZ** | **Contractor** |
| Notification of the contracting authority of the supply of medicinal products | - | X |
| Delivery of medicinal products to the contracting authority's warehouse (under DDP warehouse terms) | - | X |
| Documentation accompanying the shipment and ensuring the traceability of the medicinal products (e.g. bill of lading, delivery note). | - | X |
| Documentation certifying the quality of medicinal products, which is necessary for the entry of medicinal products into the Republic of Slovenia and for the implementation of the specific quality control of a vaccine. | - | X |
| Documentation confirming the adequacy of the temperature conditions during transport from the manufacturer to the contracting authority | - | X |
| Receipt of shipments of medicinal products | X | - |
| Inspection of shipments:<br>• verifying the correctness of the shipments (the quantity and identity of the medicinal product – name, strength, serial number, expiry date of a vaccine),<br>• quality control (recording visible damage),<br>• checking temperature indicators, stopping temperature meters and the temperature records, checking temperature records during transport, | X | - |

| | | |
|---|---|---|
| • checking protective elements (if there is a unique mark on the outer packaging of the vaccine, only one pack is checked for whether the data have been uploaded into the SiMVS system) | | |
| Moving the shipment to a suitable temperature environment in accordance with the manufacturer's instructions at the contracting authority's warehouse. | **X** | **-** |
| Acknowledgement of receipt on the supplier's acceptance documents (date, time, signature, stamp or electronic approval) and completion of the supplier's acceptance documents linked to the acceptance (e.g. Transport Data Logger Tracking Form) | **X** | **-** |
| **MEDICINAL PRODUCT ON THE MARKET** | **Contracting authority NIJZ** | **Contractor** |
| A marketing authorisation for a medicinal product or authorisation for the entry of an unregistered medicinal product. | **-** | **X** |
| Special quality control of medicinal products. | **-** | **X** |
| Notification of the price of a medicinal product. | **-** | **X** |
| Notification of the procedures being carried out by the authority responsible for medicinal products and of any changes to the marketing authorisation. | **-** | **X** |
| Timely notification of the authority competent for medicinal products of supply disruptions | **-** | **X** |
| **WASTE** | **Contracting authority NIJZ** | **Contractor** |
| The collection of waste medicinal products from vaccination providers | **X** | **-** |
| The deactivation of waste medicinal products in case of regulatory requirements | **X** | **-** |
| Coverage of the cost of the professional destruction of waste medicinal products (e.g. a medicine that has reached the end of its shelf life). | **-** | **X** |
| **COMPLAINTS** | **Contracting authority NIJZ** | **Contractor** |
| Acceptance of complaints related to the quality of medicinal products from vaccination providers | **X** | **-** |
| Acceptance of medicinal products subject to complaints at vaccination providers | **X** | **-** |
| Handling and resolving complaints related to the quality of medicinal products | **-** | **X** |
| Handling and resolving complaints related to the distribution of medicinal products due to the contractor's error (e.g. undelivered medicinal product, shortages) | **-** | **X** |
| **RECALL** | **Contracting authority NIJZ** | **Contractor** |
| System in place for the recall of medicinal products in accordance with applicable | **X** | **X** |

| | | |
|---|---|---|
| legislation | | |
| Communication with the marketing authorisation holder and the authority responsible for medicinal products | - | X |
| Recall in accordance with the instructions of the authority responsible for medicinal products from the vaccination sites that received the medicinal product from the contracting authority | X | - |
| Destruction of recalled medicinal products | - | X |
| Coverage of recall costs | - | X |
| **PHARMACOVIGILANCE** | **Contracting authority NIJZ** | **Contractor** |
| Compliance with the pharmacovigilance obligations of the manufacturer, marketing authorisation holder and contractor in accordance with applicable legislation | - | X |
| Compliance with the pharmacovigilance obligations of the contracting authority in accordance with applicable legislation | X | - |
| **AVAILABILITY** | **Contracting authority NIJZ** | **Contractor** |
| Notification in case of changes to contact persons in logistics, quality and pharmacovigilance | X | X |

Place and date: Signature of the responsible person:

## 6. BIDDER'S STATEMENT on compliance with conditions – Form 6

Bidder: _____

Full name of the company: _____

Registered office and municipality: _____

No. of entry in the register of companies: _____

Reg. insert No.: _____

Company's reg. ID no.: _____

Contracting Authority: **National Institute of Public Health**

I, the undersigned representative/agent of the Bidder applying for the concerned public procurement tender hereby declare that we have been informed of the conditions, criteria and other content of the tender dossier for the cited public procurement and that we fully accept them.

Place and date: Signature of the responsible person:

## 7. GOOD MANUFACTURING PRACTICE (GMP) STATEMENT – Form 7

**Subject of contract:**
**Purchase of palivizumab and Vaccine against tuberculosis.**

**Company name:**

**Address:**

**Body competent for medicinal products that exercises supervision of good manufacturing practice:**

By signing this statement under criminal and material liability, we declare and confirm that the medicinal products were manufactured in accordance with good manufacturing practice and the marketing authorisation.

We hereby confirm that each batch of the medicinal product will be accompanied by documentation which confirms the quality of the medicinal product and which is required for the entry of the medicinal product into the Republic of Slovenia.

We hereby declare that copies of the documentation on the medicinal product shall be consistent with the original documents.

We hereby declare that we grant permission to the Contracting Authority, the National Institute of the Public Health, to verify the good manufacturing practice system at any time.

Place and date: Signature of the person responsible for quality:

## 8. GOOD DISTRIBUTION PRACTICE (GMP) STATEMENT – Form 8

**Subject of contract:**
**Purchase of palivizumab and Vaccine against tuberculosis.**

**Company name:**

**Address:**

**Body competent for medicinal products that exercises supervision of good distribution practice:**

By signing this statement under criminal and material liability, we declare and confirm that the transport of medicinal products shall be organised and carried out in accordance with good distribution practice.

During transportation, medicinal products shall be appropriately packaged, and a certificate of temperature conditions during transportation shall be provided for each delivery of a refrigerated medicinal product.

The transportation of medicinal products shall be qualified.

We hereby declare that we grant permission to the Contracting Authority, the National Institute of the Public Health, to verify the good distribution practice system at any time.

Place and date: Signature of the person responsible for quality:

## 9. INFORMATION ON SUBCONTRACTORS – Form 9

| | |
|---|---|
| Name<br>Registered office<br>Telephone<br>Telefax<br>Notification email | |
| Reg. ID no.: | |
| Tax ID no.: | |
| C.A. and bank | |
| Type of service/goods delivered by the subcontractor | |
| Quantity | |
| Value excl. VAT | |
| Subject, quantity, value, place, deadline for service/goods delivery | |

*The form must be copied for the required number of subcontractors

The bidder must provide the ESPD form for all subcontractors.

In accordance with Article 5, paragraph 94 of ZJN-3, we request direct payment by the Contracting Authority (circle as appropriate):

YES NO

Subcontractors submitting a written request for direct payment, and only circling 'YES' grant permission to the Contracting Authority to settle the subcontractor's receivables against the lead contractor in the manner stipulated in the model Contract.

Date: Subcontractor's signature

## 10. DECLARATION/INFORMATION ON THE PARTICIPATION OF NATURAL PERSONS AND LEGAL ENTITIES IN THE BIDDER'S OWNERSHIP STRUCTURE - Form 10

and regarding economic operators that are considered to be the bidder's affiliates according to the Act governing companies

**Information about the bidder**

| | |
|---|---|
| **Name of the bidder:** | |
| **Registration number:** | |
| **Tax/VAT ID No.:** | |
| **The bidder's statutory representative:** | |

For the purposes set out under the sixth paragraph of Article 14 of the Integrity and Prevention of Corruption Act (Official Gazette of the Republic of Slovenia, Nos 69/11 –official consolidated version – and 158/20), i.e. to ensure the transparency of the transaction and to prevent corruption risks in the conclusion of legal transactions, I, the undersigned statutory representative of the bidder, hereby declare:

1. that the following natural persons participate in the ownership of the aforementioned bidder:

| No. | First name and surname | Permanent residence | Percentage of ownership (%) |
|---|---|---|---|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| … | | | |

2. that the following legal entities participate in the ownership of the aforementioned bidder:

| No. | Company name and registered office of the legal entity | Registration number | Percentage of ownership (%) |
|---|---|---|---|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| … | | | |

3. that in accordance with the provisions of the Act governing companies, the following economic operators are companies associated with the aforementioned bidder:

| Item no. | Name and registered office of the economic operator | Registration number |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |
| … | | |

I hereby declare that I have listed the following natural persons as participants in the bidder's ownership structure:

- any natural persons who directly or indirectly hold more than a 5% stake in shares or participate with more than a 5% stake in the founder's rights, management or equity of the legal entity or have a controlling position in the management of the legal entity's assets;
- any natural person who indirectly provides assets to the legal entity, on the basis of which he or she may exercise control, guide or otherwise significantly influence the decisions of the management board or any other management body of the legal entity regarding financing and operations.

By signing this declaration, I guarantee that the entire ownership structure contains no other natural persons or legal entities or economic operators regarded as affiliates in accordance with the Companies Act.

By signing this declaration, I guarantee that the information is accurate and true, and I am aware that the contract/order/framework agreement shall be null and void if a false declaration or false information is submitted. I hereby undertake to inform the contracting authority of any changes to the information submitted.

**A bidder may submit all the above required information in electronic form**

** The Act Amending the Companies Act (the ZGD-1G; Official Gazette of the Republic of Slovenia, No. 57/2012 of 27 July 2012) abolishes silent partnerships, which shall cease to exist by law as of the entry into force of the aforementioned law (28 July 2012). The part of the provisions of the sixth paragraph of Article 14 of the Integrity and Prevention of Corruption Act (ZIntPK) setting out the mandatory content of the declaration of the ownership structure and an indication of silent partners no longer applies to undertakings established in Slovenia. The provisions still apply unchanged to foreign undertakings, if a silent partnership exists as an entity under the relevant foreign law.*

Statutory representative: In/at , date

First name and surname:

Signature:

## 11. FRAMEWORK AGREEMENT – MODEL – Form 11

National Institute of Public Health, Trubarjeva cesta 2, 1000 Ljubljana, represented by the General Director Assoc. Prof. Branko Gabrovec, PhD as the Contracting Authority
VAT Identification Number: SI44724535
Registration ID No.: 6462642000
Business account No.: SI56 01100 6000043188 opened with the Bank of Slovenia

And

_____,
represented by _____ as the Contractor
VAT Identification Number: _____
Registration ID no.: _____
Business account no.: _____, opened with _____

hereby conclude the following

**CONTRACT ON THE PURCHASE OF PALIVIZUMAB AND VACCINE AGAINST TUBERCULOSIS**

**Introductory Provision**

**Article 1**

The Contracting Authority has carried out the public contract award procedure for the Purchase of medicinal products for vaccination, in accordance with Article 40 of ZJN-3 (Official Gazette of the Republic of Slovenia, No. 91/2015), published on the Public Procurement Portal, No. _____ of _____, for the purpose of concluding a contract.

The Specification of the Tender Dossier for the public contract referred to in the preceding paragraph, the Contractor's bid and Price Specification of _____ shall form an integral part hereof.

**Subject of the Contract**

**Article 2**

The Contracting Authority and the Contractor hereby conclude the Framework agreement for the Purchase of PALIVIZUMAB (ATC: J06BB16) AND VACCINE AGAINST TUBERCULOSIS (ATC: J07AN01).

The Contractor undertakes to supply the following medicinal products to the Contracting Authority:

| **Lot** | **Name of the medicinal products (invented)** Packaging | **National medicinal product code** | **QUANTITY (number of doses)** | **DELIVERY DEADLINES** |
|---|---|---|---|---|
| 1 | | | 1,600 | SUCCESSIVE SUPPLIES |
| 2 | | | 2,500 | SUCCESSIVE SUPPLIES |

| | | | | |
|---|---|---|---|---|
| 3 | | | 24,000 | 12,000 – 11/2025<br>12,000 – 11/2026 |

The indicated quantities shall be estimated quantities. Estimated quantities may change during this period due to changes in the actual needs for the medicinal products. The Contracting Authority does not undertake to purchase the indicated quantity of medicinal products.

According to the unified vocabulary of public procurement, the CPV code of the contract is: 33600000.

**Quality**

**Article 3**

Medicinal products must have a marketing authorisation issued by a body competent for medicinal products:

- registered medicinal products - holding a valid decision - marketing authorization in the Republic of Slovenia issued by the Public Agency for medicinal products and medicinal devices of the Republic of Slovenia (JAZMP) or a marketing authorization in the EU obtained by the centralized authorization procedure (Council Regulation (EC) No 726/2004) or holds conformation of an authority responsible for the medicinal product stating that the holder of the marketing authorization submitted to the administration an application for the extension of the marketing authorization in accordance with the applicable law.

The medicinal product shall be manufactured in accordance with principles of good manufacturing practice and the marketing authorisation.
The medicinal product shall comply with the:

- specifications stipulated in the marketing authorisation;
- the quality, description and characteristics defined in the bidding documents.

A unique identifier must be placed on the packaging of medicinal products in accordance with the delegated EU Commission Regulation 2016/161. The information must be uploaded in the EMVS and / or SiMVS as set out in the Delegated Regulation 2016/161.

Each medicine series must be accompanied by documents that ensure the traceability of the medicine, confirm the quality of the medicinal product and is required for the entry of the medicinal product into the Republic of Slovenia and for the implementation of a special quality control of the vaccine.
The supplied medicinal product shall be labelled and packaged in accordance with the applicable legislative provisions in the Republic of Slovenia.

**Price**

**Article 4**

The price of a medicinal product shall be indicated in EUR exclusive of VAT according to the DAP parity (Incoterms 2020):

| **Lot** | **MEDICINAL PRODUCT** | Unit | UNIT PRICE | ESTIMATED QUANTITY | ENVISAGED VALUE |
|---|---|---|---|---|---|
| 1 | Palivizumab – recombinant humanised monoclonal antibody against respiratory | dose | | 1,600 | |

| | | | | | |
|---|---|---|---|---|---|
| | syncytial virus (RSV) - 50 mg / 0,5 ml | | | | |
| 2 | Palivizumab – recombinant humanised monoclonal antibody against respiratory syncytial virus (RSV) – 100 mg / 1 ml | dose | | 2,500 | |
| 3 | Tuberculosis vaccine, live attenuated | dose | | 24,000 | |

The price of the medicinal product shall be set in accordance with the Rules on nomination of prices of medicinal products for human use (hereinafter: the "Rules"). If the applicable price of the medicinal product decreases in the period from the conclusion of the Framework agreement until the delivery so that the contractual price no longer complies with the Rules, the Contractor shall deliver the medicinal product to the Contracting Authority at a reduced price that has been harmonised with the Rules. The bidder – contractor must notify the contracting authority about reduced prices and abide by them when supplying goods if the reduced prices are lower than the contractual ones. Otherwise, the prices shall remain fixed throughout the term hereof.

**Ordering and Delivery**

**Article 5**

The Contractor shall supply medicinal products successively based on the orders placed by the Contracting Authority.

The Contractor shall prior to executing the supply hand over to the Contracting Authority the following documents relating to the medicinal product:

- valid good manufacturing practices (GMP) certificate;
- the manufacturer's certificate of analysis;
- Official Control Authority Batch Release (OCABR) in accordance with EU guidelines issued by a competent authority in the territory of the EU, EEA or Switzerland;
- marketing information in the territory of the Republic of Slovenia (form MIF - Marketing Information Form, annex IV to guideline EC Administrative Procedure For Official Control Authority Batch Release);
- copy or photography of the outer packaging with the serial number of the medicinal product;
- when the information on the packaging of the medicinal product does not match the certificate on account of product repackaging, different sub-batches or different designation of the medicinal product, a clarification of such discrepancy, which is signed by a responsible person, shall be provided.

The Contractor shall communicate information on marketing in the territory of the Republic of Slovenia (Form MIF) for the entire quantity of an individual batch on a single MIF form irrespective of the fact that the contract envisages successive supply.

If the Contractor introduces (enters) or imports the vaccine into the Republic of Slovenia, they shall also hand over to the Contracting Authority a certificate of special quality control issued by NLZOH.

The entire documentation shall be submitted as original documents, as certified copies or copies of documents with a statement of a responsible person on the authenticity of information.

The Contractor shall ensure that transport of medicinal products is carried out in accordance with good distribution practice.

For medicinal products that must be kept refrigerated, the Contractor shall be responsible for ensuring cold chain transportation until the delivery of the medicinal product to the Contracting Authority. The Contractor undertakes to submit a certificate to the Contracting Authority certifying

that the delivery of the medicinal product is proceeding according to the rules for cold chain transport and that they shall submit evidence on the temperature conditions during transport from the manufacturer to the Contracting Authority for each individual consignment.
The Contractor shall upon the announcement of the delivery also communicate to the Contracting Authority the information on the method for the monitoring of temperature during transport. Locations in the consignment where temperature indicators or temperature gauges are located shall be marked.
When the contractor announces the delivery, the information about the type and material of the transport package must also be included.

The Contractor shall notify the Contracting Authority of the envisaged delivery in writing no less than three business days prior to the delivery. The notification shall state the method of delivery and the envisaged date and time of the delivery.

The Contracting Authority shall confirm acceptance within the shortest time possible, however, no later than within one business day. The Contracting Authority ordering the goods shall not be obliged to accept goods that have not been announced or the delivery of which proceeds in contravention of the agreed upon delivery method.

Together with the supply of the medicinal product to the Contracting Authority, the Contractor shall also produce correctly filled in documents that accompany the consignment (for example the consignment note, delivery note). The documentation shall demonstrate the traceability of the medicinal product.

Acceptance of the medicinal product shall be performed by way of an acceptance protocol that shall be signed by the Contracting Authority's authorised person. The acceptance of the medicinal product shall be deemed to have been completed on the day the acceptance protocol is signed.

**Complaints**

**Article 6**

The Contracting Authority reserves the right to complain within thirty (30) days of the receipt of the medicinal product in the event:

- the medicinal product is not manufactured in accordance with the good manufacturing practice and the marketing authorisation.
- the quality, description and characteristics of the medicinal product do not comply with the indications in the bidding documents;
- the medicinal product does not conform to the specifications set forth in the marketing authorisation;
- the Contracting Authority does not receive the required documentation on the medicinal product;
- inadequacy or non-compliance of any document on the medicinal product or of a document accompanying the consignment is established;
- of inadequate transport of the medicinal product to the Contracting Authority.

The Contracting Authority may reject the medicinal product that is the subject of a complaint and the Contractor shall be considered in delay as of the day the medicinal product is rejected. In the event of a delay by the Contractor due to a complaint, the contractual penalty is specified in Article 9 of this Framework agreement.

**Contractor's Guarantees and Obligations**

**Article 7**

The Contractor shall perform its activity in accordance with:

- the principles and guidelines of good manufacturing and distribution practices,
- the regulations governing medicinal products in countries in which they are headquartered and hold manufacturing authorisation or the wholesale marketing authorisation for medicinal products,
- the regulations governing the area of medicinal products in the Republic of Slovenia.

The Contractor shall inform the Contracting Authority immediately if the contact person, the person responsible for the quality or person responsible for pharmacovigilance changes.

The Contractor undertakes to deliver – in accordance with the Contracting Authority's instructions – a high-quality medicinal product, together with documentation that complies fully with all the descriptions, characteristics and specifications presented in the bidding documents.

The Contractor shall immediately inform the Contracting Authority of any problems or delay in the manufacture of the medicinal product which could affect supply to the market in the Republic of Slovenia.

The Contractor shall regularly notify the Contracting Authority of eventual changes in the marketing authorisation or other procedures relating to the medicinal product and conducted by the authority competent for medicinal products.
The Contractor shall in a timely manner provide the Contracting Authority with all information that is important for the safety and quality of medicinal products.
The Contracting Authority may request the Contractor to provide data important for the effectiveness, safety and quality of the medicinal product, and the Contractor shall provide the Contracting Authority with the requested data within the shortest time possible. If the data relate to serious adverse reactions, the Contractor shall communicate the data to the Contracting Authority immediately, and no later than within 24 hours of receiving a query, while they shall answer all other questions no later than within seven days of receiving the respective question.

The Contractor shall ensure that the marketing authorisation holder meets all pharmacovigilance obligations in accordance with the rules governing medicinal products in the EU. The Contractor shall provide pharmacovigilance documentation requested by the Contracting Authority or by the competent authorities in the field of medicinal products.

In the event of a disruption in the cold chain, the Contractor shall immediately or no later than within three working days obtain data on the stability of the medicinal product and an opinion from the marketing authorisation holder or manufacturer of the medicinal product as to whether the medicinal product is still safe, effective and usable.

The Contractor shall cover all costs and expenses incurred due to a recall of the medicinal product as a result of an error made by the Contractor or by the manufacturer of the medicinal product supplied by the Contractor. The Contractor shall ensure that in the event of a recall of medicinal products, the marketing authorisation holder, the manufacturer of the product and the Contractor proceed with comply with the rules on medicinal products in the EU and the Republic of Slovenia.
Liability for damage arising from the unsuitable quality of the medicinal product or the results of the use of the medicinal product is set, or shall be assessed, in accordance with the Medicinal Products Act applicable in the Republic of Slovenia.

If laboratory testing is required, the Contractor shall provide the necessary reference substances in a timely manner.

The Contractor shall cover the costs of the professional destruction of waste medicinal products (e.g. a medicinal product with an expired shelf life).

An unjustified rejection of an order by the Contractor or deviations from the ordered method of performance shall constitute a breach of the contractual obligation, due to which the Contracting Authority may carry out a covering purchase, rescind the Framework agreement, call on the performance bond, and also claim damages if they incur damage or loss.

The Contracting Authority may at any time and without prior notice carry out an audit of the Contractor with respect to the implementation of the provisions of good manufacturing and distribution practices. In the event of an audit and supervision, the Contractor shall within the required time forward to the auditor all of the requested data or provide the auditor with access to documentation.

**Contractual Penalty**

**Article 8**

In the event of delay in the supply of the medicinal product, the Contracting Parties agree on a contractual penalty equivalent to 0.5% of the order value of the consignment in delay for each calendar day of delay, whereby the penalty may in no event exceed 5% of the value of the order which is supplied with a delay.
The supply of the medicinal product shall be deemed the delivery of the medicinal product and the entire documentation on the medicinal product required pursuant to the contractual provisions.
In the event of a delay which is not attributable to the Contracting Authority, the Contractor shall be obliged to pay a contractual penalty to the Contracting Authority. The contractual penalty shall be calculated accounted and charged upon the payment of the contract price.

If the Contractor is late with the supply and the Contracting Authority thereby incurs damage higher that the contractual penalty, the Contracting Authority may demand that the Contractor compensate them for the entire damage caused by the delay.
The Contracting Authority may rescind the Framework agreement if the Contracting Authority is no longer able to accomplish their intended purpose due to delays or faults in delivery.

**Payment Method**

**Article 9**

The Contractor shall issue an invoice to the Contracting Authority within eight (8) days of the delivery of the medicinal product, i.e. on the basis of a completed acceptance document protocol signed by the Contracting Authority. The Contracting Authority undertakes to review the invoice and the annexes within 8 days and inform the Contractor of any errors or deficiencies. The Contracting Authority may with a reasoned justification reject the invoice and the accompanying documentation within 8 days of the delivery.

If the Contracting Authority does not partially or fully reject an invoice within 8 days of delivery, it shall settle each invoice on the _____ day beginning on the day of the receipt of the correct invoice. In the event of a partial rejection, the Contracting Authority shall settle the undisputed part of the invoice within the same deadline.

In the event of a delay in payment, the Contractor may charge interest on the arrears at the statutory rate. In the event of a well-founded complaint by the Contracting Authority with respect to the

quality of the medicinal product or adequacy of documentation, the Contractor is not entitled to interest on arrears.

**Authorised Representatives**

**Article 10**

In the performance of the Contract, the Contracting Parties shall be represented by their respective authorised representatives, who shall also be the custodians of the Contract.

The authorised representative of the Contracting Authority is Mrs Staša Javornik.
The authorised representative of the Contractor is _____.

**Duration of the Framework agreement**

**Article 11**

This contract is concluded with the signature date of the last of the two contractual partners and it goes into effect on 1.10.2025. The Contract shall apply until 30.09.2027.

**Termination of the Framework agreement**

**Article 12**

The Framework agreement may be terminated in the event of a material breach of the provisions of this Contract by any or both of the Contracting Parties. In the event of a withdrawal from the Framework agreement, the Contracting Parties shall be obliged to settle mutual obligations arising from this Framework agreement and the damage incurred.

The period of notice shall commence on the day the counter-Contracting Party receives a written notification on termination.

In the event of an early expiry of the validity of this Framework agreement, the Contracting Parties shall be obliged to settle any mutual obligations and which arose up to the moment of the termination of this Framework agreement.

This Framework agreement states all the rights and obligations of the Contracting Parties unless expressly provided otherwise in the Framework agreement. Supplements and amendments of the contractual provisions shall be valid only if concluded by both Contracting Parties in the form of an annex hereto concluded in writing. An eventual waiver of the request for their written form shall also be concluded in such a manner.

If any of the provisions herein is or becomes null, this shall not affect the validity of other contractual provisions. An invalid provision shall be replaced by a valid one that conforms as closely as possible to the purpose of the invalid provision.

**Confidentiality**

**Article 13**

The Contracting Parties agree that all data and information they obtain in the performance hereof or hereunder shall be deemed business secrets, with the exception of those which the law expressly states may not be deemed a business secret, whereby the Contracting Parties further undertake to diligently safeguard all data and information and use them exclusively in relation to the performance hereof.

The Contractor undertakes especially to use all documents which they receive or to which access is provided to the Contractor's employees by the Contracting Authority, as well as all information which is provided verbally or otherwise to the Contractor's employees within the scope of the performance hereof exclusively for the performance of activities hereunder, and not to provide access thereto to third parties under any circumstances. They further undertake that the Contractor and their employees shall not copy or otherwise distribute (verbally or otherwise) the information or documents.

The Contractor shall be obliged to notify their employees that they could come into contact with confidential or personal information in their work and that in their work they must handle such information with the maximum care.
At least the same strict data protection regime as the regime that applies to the Contracting Authority shall also apply to the Contractor that performs contractual obligations for the Contracting Authority.

The obligation to safeguard data and information or business secrets relates both to the time of the performance hereof and the time after that. In the event of a violation of the provisions on safeguarding business secrets or the confidentiality of data and information, the Contractor shall be liable for all direct and indirect damage vis-à-vis the Contracting Authority.

The Contractor may publish its contractual links to the Contracting Authority only with the express written permission of the latter.

**Anti-Corruption Clause**

**Article 14**

The contract, under which a person promises, offers or provides – on behalf of or for the account of another contracting party – to a representative or agent of a public sector body or organisation any undue advantage for the following:

- the acquisition of a business deal or
- the conclusion of a business deal under more favourable conditions or
- the omission of due supervision over the performance of contractual obligations or
- other act or omission, which causes damage or loss to a public sector body or organisation or if this enables the acquisition of an undue advantage by a representative of the public authority, agent of a public sector body or organisation, the counter-contracting party or their representative, agent or intermediary;

shall be null and void.

The Contracting Authority shall – in the event that they find an alleged existence of an actual state-of-affairs referred to in the first paragraph of this Article or that they receive a notification from the Anti-Corruption Commission or other authorities regarding its alleged occurrence – commence examining conditions for the nullity of the Contract referred to in the preceding paragraph of this Article or shall take other measures in accordance with the regulations of the Republic of Slovenia.

This Framework agreement is concluded under a resolutory condition which is actualized if one of the following circumstances is fulfilled:

- If the client is informed that the court determined failure to comply with labour, environmental or social legislation by the contractor or the subcontractor; or
- If the client is informed that the appropriate government body found at least two violations by the contractor or the subcontractor during the execution of the framework agreement regarding:
    - Remuneration of work,
    - Working time,
    - Breaks,
    - Performing work based on civil law contracts despite the existence of an employment relationship or related to illegal employment for which a fine was imposed with a final decision or decisions of the court,

And under the condition that there is at least six months' time between being made aware of the violation and until the expiry of the validity of the Framework agreement or if the contractor acts with a subcontractor and also if due to a determined violation the contractor does not replace or change this subcontractor in a way, defined with accordance to Article 94 of the Law on Public Contracts (ZJN-3) and this Contract terms 30 days since the familiarisation with the violation.
If the circumstances and terms from the previous paragraph are fulfilled, it is considered that the Framework agreement is resolutory on the day of settlement of the new contract on the public contract execution for the relevant contract. The client will inform the contractor of the date of settlement of the new contract.
If the client does not begin a new public contract procedure within 30 days since being familiarised with the violation, it is considered that the Framework agreement is resolutory on the thirtieth day since the familiarisation with the violation.

**Subcontractors**

**Article 15**

The Contractor shall execute the works without subcontractors.

_ OR _

In addition to the Contractor, the following subcontractors stated in the 'Information about Subcontractor' form shall participate in the execution of the works.

[name and full address],

Legal representative of the subcontractor:

Registration ID no.:

Tax ID no.:

C.A. no.:

Subject of works:

Place and deadline of execution:

Quantity: in the value of _____ EUR (excl. VAT), which amounts to __ % of the entire bid.

Instead of the lead Contractor, the Contracting Authority shall settle the subcontractor's receivable to the lead contractor, for which the subcontractor shall submit written consent or appropriately complete the form 'Information about the Subcontractor'.

The Contractor shall mandatorily supplement its invoice with invoices or situations of its subcontractor or subcontractors that it has confirmed in advance.

If the subcontractor has not requested direct payment, the Contracting Authority shall request that the lead contractor send its written statement and the written statement of the subcontractor that the subcontractor has received payment for the executed services no later than 60 days after the payment of the final invoice.

During the implementation of the public contract, the contractor shall submit to the Contracting Authority information on new subcontractors that it intends to subsequently include no later than five days after the change. In the event of inclusion of new subcontractors the lead contractor shall supplement the notice with the following information (in addition to the information as per the first paragraph):

- contact information and the legal representatives of the proposed subcontractors,
- competed ESPD forms of these subcontractors, in accordance with Article 79 of ZJN-3 and
- append the request of the subcontractor for direct payment if the subcontractor so requires.

The Contracting Authority shall reject any subcontractor for which the reasons for exclusion in the first, second or fourth paragraphs of Article 75 of ZJN-3 exist, except in the case of the third paragraph of Article 75, but they may also reject any subcontractor if the reasons as per the sixth paragraph of Article 75 of ZJN-3 exist.

The Contracting Authority may also reject a proposal for a change of a subcontractor or inclusion of a new subcontractor if this could affect the smooth implementation or conclusion of works or if the new subcontractor does not meet the conditions laid down by the Contracting Authority in the documentation related to awarding the public contract. The Contracting Authority shall notify the lead contractor on the potential rejection of a new subcontractor no later than ten days from the receipt of the proposal.

**Final Provisions**

**Article 16**

The Contracting Parties shall resolve disputes by amicably; otherwise, the court with subject matter jurisdiction in Ljubljana shall be competent to resolve disputes in accordance with Slovenian law.

This Framework Agreement is drawn up and signed in two (2) identical copies, of which each Contracting Party shall receive one (1) copy.

| | |
|---|---|
| No.: | No.: |
| In Ljubljana, _____ | In _____, _____ |
| CONTRACTING AUTHORITY: | CONTRACTOR: |
| National Institute of Public Health | |
| Assoc. Prof. Branko Gabrovec, PhD.<br>General Director | |

**Annexes:**
Annex 1: Specification

Annex 2: Bid
Annex 3: Price specification
Annex 4: Information on Subcontractors
Annex 5: Partnership Contract