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Number: 4300-100/2019-2 (172)
Date: 02.10.2019

# TENDER DOSSIER

| | |
|---|---|
| **Subject of the public contract:** | **PURCHASE OF VACCINE AGAINST HUMAN PAPILLOMA VIRUS** |
| **Public contract award procedure:** | **Open procedure** (in accordance with Article 40, of the Public Procurement Act) |
| **Public procurement code:** | **78K160919** |

# 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.: 801-13/2014-2 of 19.3.2014).
Authorisation No. 801-13/2014-2 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 vaccine against human papilloma virus** |
| **TYPE OF PUBLIC CONTRACT:** | **Open procedure** (in accordance with Article 40, of ZJN3) |
| **A PUBLIC TENDER DIVIDED INTO LOTS:** | **YES** |
| **AN ORDER IS DIVIDED:** | **The Bidder may submit a bid for one or more lots** |
| **VALIDITY OF CONTRACT:** | Till 31.08.2023 |
| **INFORMATION ABOUT THE CONTRACTING AUTHORITY:** | **National Institute of Public Health**<br>**Trubarjeva 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>Nina Pirnat, dr. med. spec.<br>Director<br><br>**Contact person:**<br>Suzana Rodela<br>Tel.: +386 5 6630 802<br>Email: suzana.rodela@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).<br>The bidder shall have a valid authorisation to pursue the activity of manufacture of medicinal products or a valid wholesale marketing authorisation for medicinal |

products 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, hereafter ZZdr-2).

# 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 FOR DOWNLOADING THE TENDER DOSSIER

The tender documentation is available for download on the Institute's website. It is published at **http://www.nijz.si/** under the heading **Public Contracts**.

## 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.

The final deadline for sending additional questions is **10 am on 28.10.2019.**

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

The tender is submitted in good time if the customer receives it via the e-JN system https://ejn.gov.si/eJN2 by **10 am on 14.11.2019**. A submitted tender is a tender that has the status "SUBMITTED" in the e-JN information system.

Bidders must submit their tenders in the e-JN information system at https://ejn.gov.si/eJN2 in accordance with point 3 of the document *Usage instructions of the information system to submit e-JN offers electronically*: BIDDERS (hereinafter: e-JN Usage instructions). These instructions are part of the tender specifications published on the web page https://ejn.gov.si/eJN2 .

The bidder must be registered before submitting the offer at https://ejn.gov.si/eJN2 in accordance with e-JN Usage instructions. If the bidder is already registered in the e-JN information system, the same address can be used to log in to the application.

A digital certificate, issued by a qualified certification authority, is required to submit an offer: SIGEN-CA (www.sigen-ca.si), POŠTA®CA (postarca.posta.si), HALCOM-CA (www.halcom.si), AC NLB (www.nlb.si).

## 1.4. OPENING OF BIDS

The opening of tenders will be carried out automatically in the e-JN information system on **14.11.2019 at 10:15 am** at https://ejn.gov.si/eJN2 .

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

Bidders can change or withdraw their tenders according to e-JN Usage instructions, published at https://ejn.gov.si/eJN2 .

## 1.6. LEGAL NOTE

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.

The request for review shall be filed in duplicate in writing directly at the Contracting Authority by registered mail or registered mail with return receipt. At the same time, the applicant shall provide a copy of the application to the ministry responsible for public procurement.

# 2. INSTRUCTIONS ON COMPILING THE BID

## 2.1. LEGAL BASIS

The Tender Dossier was drawn up pursuant to the Public Procurement Act (Official Gazette of the Republic of Slovenia, No. 91/2016, hereinafter: 'ZJN-3'), implementing regulations adopted pursuant to the Auditing of Public Procurement Procedures Act – ZRPJN (Official Gazette of the Republic of Slovenia, No. 78/1999, 90/1999 – corr., 110/2002, 2/2004 – ZPNNVSM, 42/2004, 61/2005, 78/2006, 53/2007, 32/2009 – dec. of the Const. Court), the Code of Obligations (Official Gazette of the Republic of Slovenia, No. 83/2001, 32/2004, 28/2006 – dec. of the Const. Court, 40/2007) and other regulations governing public contracts or the subject of the public contract award.

## 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 vaccine against human papilloma virus**

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

| **VIRAL VACCINES** | | |
|---|---|---|
| *Lot* | *ATC* | *MEDICINAL PRODUCT* |
| 1 | J07BM02 | Vaccine against human papilloma virus (types 16, 18) |
| 2 | J07BM03 | Vaccine against human papilloma virus (9-valent) |

The Bidder may submit a bid for one or two 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 (if the Bidder, their partner or subcontractor is a holder of the wholesale marketing authorisation for medicinal products);
5. **BID, Framework agreement – Forum 3.1.** (completed Form 3.1.);
6. **BID, supply in 2019 and 2020 – Forum 3.2.** (completed Form 3.2.);
7. **"PREDRAČUN" - PRICE SPECIFICATION, supply in years 2019 and 2020 – Form 4** (completed Form 4);
8. **SPECIFICATION – Form 5** (completed Form 5);
9. **STATEMENT ON GOOD MANUFACTURING PRACTICES – Form 6** (completed and signed Form 6; 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);
10. **STATEMENT ON GOOD DISTRIBUTION PRACTICES – Form 7** (filled in and signed Form 7, 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);
11. **FOR LEGAL PERSONS – AUTHORISATION TO ACQUIRE AN EXTRACT FROM THE JUDICIAL RECORDS – Form 8.1** (in the case of joint bidding, each of the partners must complete and sign Form 8.1; applies to companies with registered offices in the Republic of Slovenia)
    The tenderer can present a copy from the relevant register such as the court register instead of Form 8.1. If there is no such register, an equivalent document issued by the appropriate judicial or administrative body of the Republic of Slovenia, another member country or home member state or a country where the business entity has its headquarters, which clearly shows that there are no grounds for exclusion;
12. **FOR NATURAL PERSONS – authorisation to acquire an EXTRACT FROM THE JUDICIAL RECORDS – Form 8.2** (for legal representatives, members of administrative, management and supervisory boards of Slovenian nationality. In the case of joint bidding, the foregoing provision applies to all partners)
    The tenderer can present a copy from the relevant register such as the court register instead of Form 8.2. If there is no such register, an equivalent document issued by the appropriate judicial or administrative body of the Republic of Slovenia, another member country or home member state or a country where the business entity has its headquarters, which clearly shows that there are no grounds for exclusion;
13. **ESPD Form** (if the Bidder bids jointly with partners or subcontractors, they must also submit the ESPD Form for partners or subcontractors)
    If the contracting entity acquires the supporting evidence directly from the database, an ESPD needs to include information required for that purpose especially the web address of the database, identification data as well as consent (Form 9.1 and Form 9.2) for the contracting entity to gain supporting evidence if needed;
14. **INFORMATION ON SUBCONTRACTORS – Form 9** (if the Bidder is bidding with subcontractors);
15. **STATEMENT ON MEETING CONDITIONS AND CONSENT OF THE SUBCONTRACTOR FOR DIRECT PAYMENTS – Form 10;**
16. **FRAMEWORK AGREEMNET – MODEL – Form 11;**

17. **PARTNERSHIP CONTRACT** (this applies if the Bidder participates in the bidding procedure with subcontractors);
18. **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.

**A. Exclusion of Bidders:**

1. The Contracting Authority shall exclude a bidder from the Public Procurement procedure if it is established in the verification procedure in accordance with Articles 77, 79, and 80 of ZJN-3 or is otherwise be informed that the bidder or a person that was a member of an administrative, management or supervisory board of this economic operator or that is authorised for representation or decision-making or supervisory purposes was subject to a final judgement that has elements of the following criminal offences as defined in the Criminal Code (Official Gazette of the Republic of Slovenia, No. 50/12 – official consolidated text and 54/15; hereinafter: 'KZ-1'):
   - terrorism (Article 108 KZ-1),
   - financing of terrorism (Article 109 KZ-1),
   - incitement and acclamation of terrorist acts (Article 110 KZ-1),
   - recruitment and training for terrorism (Article 111 KZ-1),
   - enslavement (Article 112 KZ-1),
   - trafficking in human beings (Article 113, KZ-1),
   - acceptance of bribes during an election or ballot (Article 157 KZ-1),
   - violation of fundamental rights of employees (Article 196 KZ-1),
   - fraud (Article 211 KZ-1),
   - abuse of a position of monopoly (Article 225 KZ-1),
   - false bankruptcy (Article 226 KZ-1),
   - defrauding creditors (Article 227 KZ-1),
   - business fraud (Article 228 KZ-1),
   - fraud to the detriment of European communities (Article 229 KZ-1),
   - fraud in obtaining loans or benefits (Article 230 KZ-1),
   - fraud in securities trading (Article 231 KZ-1),
   - deception of purchasers (Article 232 KZ-1),
   - unauthorised use of another's mark or model (Article 233 KZ-1),
   - unauthorised use of another's patent or topography (Article 234 KZ-1),
   - forgery or destruction of business documents (Article 235 KZ-1),
   - disclosure and unauthorised acquisition of trade secrets (Article 236 KZ-1),
   - breaking into business information systems (Article 237 KZ-1),
   - abuse of insider information (Article 238 KZ-1),

- abuse of financial instruments market (Article 239 KZ-1),
- abuse of position or trust in business activity (Article 240 KZ-1),
- unauthorised acceptance of gifts (Article 241 KZ-1),
- unauthorised giving of gifts (Article 242 KZ-1),
- counterfeiting money (Article 243 KZ-1),
- fabrication and use of counterfeit stamps of value or securities (Article 244 KZ-1),
- money laundering (Article 245 KZ-1),
- presentation of bad cheques and abuse of bank or credit cards (Article 246 KZ-1),
- use of a counterfeit bank, credit, or other cards (Article 247 KZ-1),
- fabrication, acquisition and disposal of instruments of forgery (Article 248 KZ-1),
- tax evasion (Article 249 KZ-1),
- smuggling (Article 250 KZ-1),
- abuse of office or official duties (Article 257 KZ-1),
- causing damage to public funds (Article 257a KZ-1),
- disclosure of classified information (Article 260 KZ-1),
- acceptance of bribes (Article 261 KZ-1),
- giving bribes (Article 262 KZ-1),
- accepting benefits for illegal remediation (Article 263 KZ-1),
- giving of gifts for illegal intervention (Article 264 KZ-1),
- criminal association (Article 294 KZ-1),

2. The Contracting Authority shall exclude a bidder from the public procurement procedure if it is established in the verification procedure in accordance with Articles 77, 79, and 80 of ZJN-3 that the Bidder does not pay the compulsory charges and other non-tax cash liabilities in accordance with the law governing financial administration collected by the tax authority in accordance with the regulations of the country in which the bidder is established, or regulations of the country of the Contracting Authority if the value of unpaid liabilities at the date of the award of tenders or requests amounts to 50 euros or more. It shall be considered that the Bidder has not met its liabilities as per the preceding sentence even if, on the date of submission of the bid, they had submitted all the statements of tax withholdings on work-related income for the last five years to the date of submission of the bid.

3. The Contracting Authority shall exclude a bidder from the Public Procurement procedure if, as of the bid submission expiry date, the bidder is excluded from public procurement procedures due to its inclusion in the register of economic operators with negative references.

4.The contracting entity will exclude a tenderer from the public procurement process if the competent authority of the Republic of Slovenia or another member state or third country established at least two infringements concerning remuneration, working time, breaks and 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 in the last three years before the tendering or submission deadline expiry.

5. The Contracting Authority shall exclude a Bidder from the Public Procurement procedure if proceedings have been brought against them due to insolvency or compulsory winding up in accordance with the law governing companies, if their assets or operations are controlled by a liquidator or court, or if their business activities have been temporarily halted, or if, as per the regulations of other countries', proceedings have begun against them or a situation with the same legal effects has arisen.

6. The Contractor may also exclude bidders from participation for the following reasons:
a) if the Contracting Authority can in any way prove a breach with respect to the fulfilment of existing obligations regarding environmental, social or labour law of the European Union, the regulations

applicable in the Republic of Slovenia under collective contracts, or the rules of international environmental, social and labour law.
b) if proceedings have been brought against them due to insolvency or compulsory winding up in accordance with the law governing companies; if their assets or operations are controlled by a liquidator or court, or if their business activities have been temporarily halted, or if in accordance with the regulations of other countries, proceedings have begun against them or a situation with the same legal effects has arisen.
c) if the Contracting Authority can prove by appropriate means that the economic operator is guilty of grave professional misconduct which has undermined its integrity;
c) If the Contracting Authority can reasonably conclude that the economic operator has made an arrangement with other operators the object or effect of which is the prevention, restriction or distortion of competition. It shall be considered that the conclusion of the Contracting Authority in the preceding sentence is justified if the authority responsible for the protection of competition, on the basis of the Contracting Authority's application, notifies the Contracting Authority within 15 days that they will initiate infringement proceedings;
d) if the conflict of interest as per the third paragraph of Article 91 ZJN-3 cannot be efficiently remedied with other, less stringent measures;
e) if, due to the previous participation of economic operators in the preparation of the public Procurement Procedure in accordance with Article 65 ZJN-3, the distortions of competition cannot be efficiently remedied with other, less stringent measures;
f) if major or persistent deficiencies in the fulfilment of a key obligation have been established with respect to the economic operator in a previous public procurement contract or a previous concession contract, due to which the Contracting Authority withdrew early from the previous order, i.e. contract, or claimed compensation or other comparable sanctions were implemented;
g) if the economic operator is guilty of serious misrepresentation in giving the information requested to verify the existence of reasons for exclusion or participation conditions, or if they failed to disclose this information, or if they cannot provide the evidence required under Article 79 ZJN-3;
h) if the economic operator attempted to unjustifiably influence the Contracting Authority's decision-making or acquire confidential information that would give them an unjustified advantage in the Public Procurement procedure, or, due to negligence, deliver misleading information that could significantly influence the decision on exclusion, selection, or the awarding of the public contract.

**B. 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).

The Bidder must offer a medicinal product that has 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.

When a Bidder intends to perform the public contract with partners or subcontractors, the exclusion criteria referred to in Point A shall also apply toe 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,

As sufficient evidence that there are no grounds for exclusion from Article 75 of this act, the contracting entity accepts the following supporting evidence:
A) an extract from the relevant Register such as the judicial record regarding the first section of Article 75 of this act; if there is no such register, an equivalent document issued by a competent judicial or administrative authority in the Republic of Slovenia, other member state or state of origin or a state in which the economic operator is established which clearly demonstrates there are no grounds for exclusion;
b) relating to the second section of Article 75 of this act and b) an item of section six of Article 75 of this act a certificate, issued by a competent authority in the Republic of Slovenia, another member state or third country;
c) relating to b) an item of section four of Article 75 of this act an extract from the Record of final decisions on offences, managed by a competent authority in the Republic of Slovenia, another member state or third country.
If a member state or a third country does not issue the documents and certificates from the previous section or if they do not include all cases from sections one and two and b) an item from section four b) and section six of Article 75 of this act, they can be substituted with a sworn statement and if the latter is not intended in a member state or a third country, a statement from a certain person, given before a competent judicial or administrative authority, notary or a competent professional or trade organisation in the state of origin or a state in which the economic operator is established.
- by completing Form 10 'Statement or Information on Participating Interests of Natural Persons or Legal Entities in the Bidder's Assets',
- by way of filling in 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' and a certificate of good manufacturing practices or wholesale marketing authorisation for medicinal products issued by a competent authority regulating medicinal products.

## 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 at https://ejn.gov.si/eJN2. 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.

The Contracting Authority shall treat as confidential those pages of the bidding documents bearing the wording CONFIDENTIAL ('Zaupno') in capital letters in the upper right-hand corner, as well as the signature of the person who signed the bid below the above wording. If only certain data in the document is to be confidential, the confidential part must be underlined in red, and the word CONFIDENTIAL ('Zaupno') must be written in the same line next to the right border.
The Contracting Authority shall not be responsible for the confidentiality of information that is not marked as indicated above. However, the price and information relating to the meeting of conditions and criteria may not be marked as confidential.

## 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 stamped and 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;
- the subcontractor's authorization to acquire an extract from the judicial records for legal and natural persons.

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

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.

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

## 2.14. CRITERIA FOR SUBMISSION - CONCLUSION OF FRAMEWORK AGREEMENTS

The Contracting Authority shall conclude framework agreements for each individual lot with all Bidders who shall submit complete bids or fulfil the conditions under point 2.7. CONDITIONS FOR THE ASSESSMENT OF CAPABILITY.

## 2.15. PROCUREMENT METHOD IN THE CONTRACTUAL PHASE

The framework agreement shall not bind The Contracting Authority to order a defined quantity of products, considering that at the time of conclusion of the framework agreement the quantity is objectively impossible to establish.

**Supply of vaccine against papilloma virus in years 2019 and 2020**
The Bidder shall submit the Bid on Form 3.2 as defined in Section 1.3. Method, place and date for bid reception.

**Supply of vaccine against papilloma virus in years 2021, 2022 and 2023**
On the basis of the concluded framework agreement The Contracting Authority shall, in the contractual phase of the purchase of medicinal products, simultaneously send a demand to all contractors with which it concluded a framework agreement for a medicinal product (lot) which The Contracting Authority requests. In the invitation to submit bids The Contracting Authority shall define the subject of the bid (specification of the medicinal product) and conditions for the award of contract.
The Contracting Authority shall inform the contractors about the selection. For each individual procurement an annex to the framework agreement shall be concluded with the selected contractor.

## 2.16. AWARD CRITERIA IN THE CONTRACTUAL PHASE

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 for individual lot, award shall be made by a drawing. The draw shall be made among the most advantageous bids with the same price for individual lot, in the presence of for that purpose appointed commission that provide credibility of the draw.

## 2.17. CONTRACT AWARD NOTICE

After the ranking of timely bids in terms of the criteria and verifying whether a bid has been assessed as the most advantageous is complete, the Contracting Authority shall decide on the award of the public contract within a period not longer than 90 days. The Contracting Authority shall justify its decision and indicate the findings and reasons for the decision. In its decision, the Contracting Authority shall notify Bidders of the available legal protection and indicate where and within which time limit they may lodge a claim to apply for legal protection within the public procurement procedure, the transaction account number to which the fee is to be paid and the reference number that is to be used to effect the payment.

In accordance with Article 90, paragraph 10 of ZJN-3, The Contracting Authority shall notify Bidders of its decision by posting it on the Public Procurement Portal.

The decision shall be considered served on the day it is published on the Public Procurement Portal.

## 2.18. 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 Framework agreement. The Contracting Authority shall conclude the Framework agreement on the purchase of vaccine against papilloma virus. The Framework agreement shall be awarded by being signed by all contractual parties (in joint bidding, also all partners).

## 2.19. FINANCIAL SECURITY

The selected Budder shall be obliged to deliver to the Contracting Authority bank guarantee for the good performance of the contractual obligations in the amount and in the manner defined in the contractual phase of the framework agreement.

The selected Bidder for the suppy of the vaccine against human papillomavirus vaccine in 2019 and 2020 shall be obliged to deliver to the Contracting Authority a bank guarantee of 10% of the tender value as a performance bond, i.e. no later than within 8 days of the signing of the Framework agreement. The guarantee must be valid until 05/01/2021.
Article 2a of the Framework Agreement becomes valid, when the selected Bidder submits financial security for the performance of contractual obligations.


Nina Pirnat, dr. med. spec.
Director

# II. BIDDING DOCUMENTATION

**TABLE OF CONTENTS**

## 1. INFORMATION ON THE BIDDER – Form 1

**Subject of contract:**
**Purchase of vaccine against human papilloma virus**

**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 : _____

**Fax number**: _____ Email: _____

**Person responsible for signing the contract:**

We vouch for the correctness of the above particulars.

Place and date:

## 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 vaccine against human papilloma virus**

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

**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 (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:

## 3. BID, framework agreement – Form 3.1

Bidder:

| LOT | ATC | MEDICINAL PRODUCT |
|---|---|---|
| 1 | J07BM03 | **Vaccine against human papilloma virus (types 16 and 18).**<br>It is intended to use for active immunisation of adolescents and adults against human papiloma virus (types 16 and 18). |
| **REQUESTED:** | | |
| **Qualitative and quantitative composition** | | **A preparation of suitable strains of papilomavirus, obtained by recombinant DNA technology.** |
| **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)** | | |
| | | |

| LOT | ATC | MEDICINAL PRODUCT |
|---|---|---|
| 2 | J07BM03 | **Vaccine against human papilloma virus (9-valent).**<br>It is intended to use for active immunisation of adolescents and adults against human papiloma virus (types 6, 11, 16, 18, 31, 33, 45, 52, 58). |
| **REQUESTED:** | | |
| **Qualitative and quantitative composition** | | **A preparation of suitable strains of papilomavirus, obtained by recombinant DNA technology.** |
| **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)** | | |
| | | |

The indicated quantities shall be estimated quantities that the Contracting Authority intends to purchase during the term of this Framework Contract. Estimated quantities may change during this period due to changes in actual needs for the medicinal products. The Contracting Authority does not undertake to purchase the indicated quantity of medicinal products. The supplier shall supply medicinal products successively, based on the orders placed by the Contracting Authority.

**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,
- by 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.

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.

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

Place and date:

## 4. BID, supply in 2019 and 2020 – Form 3.2

Bidder:

| LOT | ATC | MEDICINAL PRODUCT |
|---|---|---|
| 1 | J07BM03 | **Vaccine against human papilloma virus (types 16 and 18).**<br>It is intended to use for active immunisation of adolescents and adults against human papiloma virus (types 16 and 18). |
| **REQUESTED:** | | |
| **Qualitative and quantitative composition** | | **A preparation of suitable strains of papilomavirus, obtained by recombinant DNA technology.** |
| Pharmaceutical form | | Suspension for injection |
| Type of container | | Prefilled syringe wiht needle. |
| Number of doses per container | | 1 |
| Packaging | | Sc with 1 prefilled syringe with needle. |
| Labeling | | In accordance with Slovenian legislation. |
| Parcels | | Height - not more than 57 cm, width - not more than 75 cm, delivery on EU pallet. |
| Shelf life | | At least 18 months from delivery. |
| **Quantity** | | **YEARS 2019 and 2020**<br>**ESTIMATED QUANTITY: 5.000 doses**<br>For the year 2019, the Contractor must provide at least 100 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 100 doses.<br>For the year 2020, the Contractor must provide at least 4.900 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 4.900 doses.<br><br>The Contracting Authority will inform the Contractor in writing, at the latest 10 days after the conclusion of the contract, of the estimated quantity it intends to buy in 2020. The contracting authority does not undertake to purchase the entire estimated quantity. |
| **Delivery date** | | **SKUCCESSIVE DELIVERY,** The Contracting Authority confirms the delivery at least fourteen days before delivery. The Contractor will supply the products successively on the basis of the order forms issued by The Contracting Authority.<br>First delivery: expected on DECEMBER 2019. |
| Documentation | | In accordance with Slovenian legislation. |
| Payment conditions | | At least 60 days |
| **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)** | |

| LOT | ATC | MEDICINAL PRODUCT |
|---|---|---|
| 2 | J07BM03 | **Vaccine against human papilloma virus (9-valent).**<br>It is intended to use for active immunisation of adolescents and adults against human papiloma virus (types 6, 11, 16, 18, 31, 33, 45, 52, 58). |

| **REQUESTED:** | |
|---|---|
| **Qualitative and quantitative composition** | **A preparation of suitable strains of papilomavirus, obtained by recombinant DNA technology.** |
| Pharmaceutical form | Suspension for injection |
| Type of container | Prefilled syringe wiht needle. |
| Number of doses per container | 1 |
| Packaging | Sc with 1 prefilled syringe with needle. |
| Labeling | In accordance with Slovenian legislation. |
| Parcels | Height - not more than 57 cm, width - not more than 75 cm, delivery on EU pallet. |
| Shelf life | At least 18 months from delivery. |
| **Quantity** | **YEARS 2019 and 2020**<br>**ESTIMATED QUANTITY: 25.000 doses**<br>For the year 2019, the Contractor must provide at least 2.500 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 2.500 doses.<br>For the year 2020, the Contractor must provide at least 22.500 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 22.500 doses.<br><br>The Contracting Authority will inform the Contractor in writing, at the latest 10 days after the conclusion of the contract, of the estimated quantity it intends to buy in 2020. The contracting authority does not undertake to purchase the entire estimated quantity. |
| **Delivery date** | **SKUCCESSIVE DELIVERY,** The Contracting Authority confirms the delivery at least fourteen days before delivery. The Contractor will supply the products successively on the basis of the order forms issued by The Contracting Authority.<br>First delivery: expected on DECEMBER 2019. |
| Documentation | In accordance with Slovenian legislation. |
| Payment conditions | At least 60 days |
| **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)** | |
| | |

The indicated quantities shall be estimated quantities that the Contracting Authority intends to purchase during the term of this Framework Contract. Estimated quantities may change during this period due to changes in actual needs for the medicinal products. The Contracting Authority does not undertake to purchase the indicated quantity of medicinal products. The supplier shall supply medicinal products successively, based on the orders placed by the Contracting Authority.

**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,
- by 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.

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.

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

Place and date:

## 5. "PREDRAČUN" – PRICE SPECIFICATION, supply in years 2019 and 2020 – Form 4

Bidder:

| **REQUESTED:** | |
|---|---|
| **MEDICINAL PRODUCT** | **VACCINE AGAINST PAPILLOMA VIRUS** |
| **Public procurement code:** | **78K160919** |
| **Incoterms 2010** | **DAP Contracting Authority** |
| **PRICE SPECIFICATION - PRICE IN EUR without tax** | |

| **VIRAL VACCINES** | | | *UNIT* | *Number of doses in packaging* | *Unit price with discount* | *Dose price with discount* | *Quantity (Number of doses)* | *Value* |
|---|---|---|---|---|---|---|---|---|
| *Lot* | ATC | *MEDICINAL PRODUCT* | Packaging | *A* | *B* | *C =B/A* | *D* | *E= B*D/A* |
| 1 | J07BM02 | Vaccine against human papilloma virus (types 16, 18) | sc | | | | 5.000 | |
| 2 | J07BM03 | Vaccine against human papilloma virus (9-valent) | sc | | | | 25.000 | |

**The bid shall be valid** for three mounts 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 submitting and signing the bid, the Bidder undertakes to observe the Rules determining the prices of medicinal products for human use (hereinafter: the 'Rules'), i.e. based on the manufacturer's price element (MPE; Slovenian term: *proizvajalčev element cene*). If the applicable price of the medicinal product decreases in the period from the submission of the bid until the delivery so that the contractual price no longer complies with the Rules, the Bidder shall deliver the medicinal product to the Contracting Authority at a reduced price that is in accordance 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 indicated prices shall remain fixed.

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

## 6. SPECIFICATION – Form 5

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).

The medicinal product shall be manufactured in accordance with principles of good manufacturing practice and the marketing authorisation.
The medicinal product shall conform to the specifications set forth in the marketing authorisation. The medicinal product shall conform to 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 batch of the medicinal product shall be accompanied by 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. The supplied medicinal product shall be labelled and packaged in accordance with the applicable statutory provisions in the Republic of Slovenia.

Each batch of the high-risk medicinal product 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;
- 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 statement of the responsible person declaring that special control of the quality of the high-risk medicinal product has been carried out in accordance with the legislation applicable in the Republic of Slovenia.

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.

Place and date:

## 7. GOOD MANUFACTURING PRACTICE (GMP) STATEMENT – Form 6

**Subject of contract:**
**Purchase of vaccine against human papilloma virus**

**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 7

**Subject of contract:**
**Purchase of vaccine against human papilloma virus**

**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. For medicinal products that must be kept refrigerated, we shall ensure cold chain transportation until the actual delivery of the medicinal product to the Contracting Authority.

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.
Transportation shall be organised in such a manner as to ensure that the medicinal product does not leave the EU en route to Slovenia.

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. AUTHORISATION to acquire an extract from judicial records on legal entities (legal entities with registered office in the Republic of Slovenia) – Form 8.1

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, _____*/name of the constituent/* , hereby authorise the National Institute of Public Health, Trubarjeva cesta 2, 1000 Ljubljana, for the purpose of verifying compliance with the conditions in the public contract award procedure, the subject of which is the '**Purchase of vaccine against human papilloma virus**' to acquire an extract from the judicial records of the Republic of Slovenia/_____ (the constituent cites the records if not the records of the Republic of Slovenia);

Place and date: Bidder's stamp and signature:

## 10. AUTHORISATION to acquire an extract from judicial records on natural persons (legal representatives, members of administrative, management and supervisory boards that are nationals of the Republic of Slovenia) – Form 8.2.

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

I, _____*/name of the constituent/* , hereby authorise the National Institute of Public Health, Trubarjeva cesta 2, 1000 Ljubljana, for the purpose of verifying compliance with the conditions in the public contract award procedure, the subject of which is the '**Purchase of vaccine against human papilloma virus**' to acquire an extract from the judicial records of the Republic of Slovenia/_____ (the constituent cites the records if not the records of the Republic of Slovenia);

My personal details are as follows:

Name and surname: Personal Identification Number:

Place of birth: Municipality of birth:

Permanent/temporary residence address:

- (street and house number):
- (post code and post office):

Nationality:

Previous personal name (if applicable):

Signatory (constituent)

Name and surname:

Signature:

Date:

## 11. 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 photocopied 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 stamp Subcontractor's signature

## 12. INFORMATION ON PARTICIPATING INTERESTS IN ASSOCIATED COMPANIES – Form 10

including the participating interests of dormant partners and economic operators that are deemed to be companies associated with the bidder pursuant to the provision of the act governing companies (sixth paragraph of Article 14 of the Integrity and Prevention of Corruption Act, Official Gazette of the Republic of Slovenia, No. 69/2001).

**INFORMATION ABOUT THE BIDDER:**

| | |
|---|---|
| **Name of bidder:** | |
| **Registered office of bidder:** | |
| **Registration ID no.:** | |
| **Tax ID no.:** | |

I, the undersigned representative, hereby declare that the following legal entities, including dormant partners, hold participating interests in the assets of the above-mentioned bidder:

| No. | Name: | Registered office: |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |
| ... | | |

I, the undersigned representative, hereby declare that the following natural persons hold participating interests in the assets of the above-mentioned bidder:

| No. | Name and surname | Permanent residence address | Participating interest in % |
|---|---|---|---|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| ... | | | |

I, the undersigned representative, hereby declare that the following economic operators are companies deemed to be companies associated with the bidder pursuant to the act governing companies:

| No. | Name | Registered office | Reg. ID No.: |
|---|---|---|---|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| ... | | | |

**The bidder may submit all of the above-required information in electronic format.**

If the bidder submits a false statement or provides false information on the facts stated, the Contract shall be rendered null and void.

Place and date:

## 13. Model Framework agreement – Form 11

National Institute of Public Health, Trubarjeva 2, 1000 Ljubljana, represented by the Director Nina Pirnat, dr. med.spec. 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

**FRAMEWORK AGREEMENT ON THE PURCHASE OF VACCINE AGAINST PAPILLOMA VIRUS**

**Introductory Provision**

**Article 1**

The Contracting Authority has carried out the public contract award procedure for the Purchase of vaccine against papilloma virsu, in accordance with Article39(1)(g) 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 medicinal products for vaccination.

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

| No. | Name of the medicinal products (invented) | National medicinal product code | Packaging |
|---|---|---|---|
| 1. | | | |

## Quantities and delivery dates for years 2019 and 2020

### Article 2a

Quantities and delivery dates for years 2019 and 2020 are listed in Annex 2 (Bid).

The indicated quantities shall be estimated quantities that the Contracting Authority intends to purchase during the term of this Framework agreement. 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.

## Method for the execution of the framework agreement contractual phase

### Article 3

On the basis of the concluded framework agreements for the purchase of medicinal products The Contracting Authority shall, in the contractual phase, simultaneously send a demand to all qualified Contractors for a specific lot.

The invitation to tender shall be forwarded by the Contracting Authority to Contractors normally in electronic form via e-mail specifying the method and deadline for the receipt of tenders. The Contracting Authority shall also specify in the invitation to bid the object of contract, conditions for tender submission and additional information related to each specific contract.
Each lot - medicinal product shall be submitted separately, in accordance with the conditions and criteria for the selection, as indicated in each invitation of the contractual phase.

The criteria for the selection shall be the lowest price of each requested medicinal product.
If two or more the most advantageous bids have the same price for individual lot or medicinal product, award shall be made by a drawing. The draw shall be made among the most advantageous bids with the same price for individual lot or medicinal product, in the presence of for that purpose appointed commission that provide credibility of the draw.

The Contractor shall confirm the receipt of the invitation to tender via e-mail. The Contractor shall immediately inform the Contracting Authority about eventual changes of the e-mail address.

The Contracting Authority shall in accordance with the applicable law inform all contractors, who submitted their bids for each specific lot, about the award of contract. The Contracting Authority shall conclude an annex to the framework agreement with the selected Contractor, on the basis of which the Contractor shall supply the medicinal product under the agreed conditions.

## Quality

### Article 4

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).

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 or import of the medicinal product into the Republic of Slovenia.
The supplied medicinal product shall be labelled and packaged in accordance with the applicable legislative provisions in the Republic of Slovenia.

**Price**

**Article 5**

The prices of medicinal products for 2019 and 2020 shall be indicated in EUR exclusive of VAT:

| Lot | MEDICINAL PRODUCTS | Unit | UNIT PRICE | ESTIMATED QUANTITY | ENVISAGED VALUE |
|---|---|---|---|---|---|
| 1. | | | | | |
| | | | | | |

The price of the medicinal product shall be set in accordance with the Rules determining the 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 6**

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 statement of the responsible person declaring that special control of the quality of the high-risk medicinal product has been carried out in accordance with the legislation applicable in the Republic of Slovenia.

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 7

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 8

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 procedures for modifying the marketing authorization relating to the composition of the vaccine must be carried out in time.

Medicinal products that are financed by public funds must have a valid price in accordance with the Rules from the first delivery. The price must be valid for the duration of the framework agreement.

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 seven 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 9**

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 10**

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 11**

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 12**

This contract is concluded with the signature date of the last of the two contractual partner.
The Framework Agreement shall be valid till 31.8.2023.

## Termination of the Framework agreement

### Article 13

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 14

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 15**

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 16**

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 17**

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.:
In Ljubljana, _____

No.:
In _____, _____

CONTRACTING AUTHORITY:

National Institute of Public Health

Nina Pirnat, dr. med. spec.
Director

CONTRACTOR:

**Annexes:**
Annex 1: Specification
Annex 2: Bid
Annex 3: Price specification
Annex 4: Information on Subcontractors
Annex 5: Partnership Contract