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## TENDER DOSSIER

**Subject of the public contract:** PURCHASE OF MEDICINAL PRODUCTS FOR VACCINATION

**Public contract award procedure:** Open procedure (in accordance with Article 40, of the Public Procurement Act)

**Public procurement code:** 34K270319

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## 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 medicinal products for vaccination

**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:** Four years (from 1.9.2019 till 31.08.2023)

**INFORMATION ABOUT THE CONTRACTING AUTHORITY:** National Institute of Public Health  
Trubarjeva 2, 1000 Ljubljana  
VAT Identification Number: SI 44724535  
Registration Number: 6462642000  
C.A. No.: IBAN SI56 0110 0600 0043 188

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**BIDDER:** A bidder may be any physical or legal person eligible to have the status of a bidder according to the provisions of the Public Procurement Act (ZJN-3).  
The bidder shall have a valid authorisation to pursue the activity of manufacture of medicinal products 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 13.06.2019**.

### 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 1st July 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](http://www.sigen-ca.si)), POŠTA®CA ([postarca.posta.si](http://postarca.posta.si)), HALCOM-CA ([www.halcom.si](http://www.halcom.si)), AC NLB ([www.nlb.si](http://www.nlb.si)).

### 1.4. OPENING OF BIDS

The opening of tenders will be carried out automatically in the e-JN information system on **July 1st 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 ZVPVPJN stipulate otherwise. The request for legal protection may be made by an actively identified person, as defined in Article 14 of the ZVPVPJN.

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 ZVPVPJN, 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 medicinal products for vaccination

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

<b>IMMUNOGLOBULINS</b>		
<i>Lot</i>	<i>ATC</i>	<i>MEDICINAL PRODUCT</i>
1	J06BB02	Human tetanus immunoglobulin
2	J06BB04	Human hepatitis B immunoglobulin
3	J06BB05	Human rabies immunoglobulin

<b>BACTERIAL VACCINES</b>		
<i>Lot</i>	<i>ATC</i>	<i>MEDICINAL PRODUCT</i>
4	J07AE01	Cholera vaccine, inactivated
5	J07AG01	Haemophilus influenzae type B conjugate vaccine
6	J07AH08	Tetravalent Meningococcal polysaccharide conjugate vaccine (serogroups A, C, W135 and Y)
7	J07AH09	Meningococcus B, multicomponent vaccine
8	J07AJ52	Vaccine against diphtheria, tetanus and pertussis (acellular), adsorbed
9	J07AL01	Pneumococcal polysaccharide vaccine – 23 valent
10	J07AL52	Pneumococcal polysaccharide conjugate vaccine, adsorbed – 10 valent
11	J07AM01	Tetanus vaccines, adsorbed
12	J07AM51	Diphtheria and tetanus vaccine, adsorbed



13	J07AP03	Typhoid polysaccharide vaccine
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<b>VIRAL VACCINES</b>		
<i>Lot</i>	<i>ATC</i>	<i>MEDICINAL PRODUCT</i>
14	J07BA02	Japanese encephalitis vaccine, inactivated
15	J07BC01	Hepatitis B vaccine, recombinant – for children
16	J07BC01	Hepatitis B vaccine, recombinant – for adults
17	J07BC01	Hepatitis B vaccine, recombinant, without adjuvant – for dialysis patients
18	J07BC01	Hepatitis B vaccine, recombinant, with adjuvant – for dialysis patients
19	J07BC02	Hepatitis A vaccine, inactivated, adsorbed – for children
20	J07BC02	Hepatitis A vaccine, inactivated, adsorbed – for adults
21	J07BC20	Hepatitis A (inactivated) and hepatitis B (recombinant), adsorbed - for children
22	J07BC20	Hepatitis A (inactivated) and hepatitis B (recombinant), adsorbed - for adults
23	J07BD01	Measles vaccine, live attenuated
24	J07BD52	Measles, mumps and rubella vaccine, live attenuated
25	J07BD54	Measles, mumps, rubella and varicella vaccine, live attenuated
26	J07BF03	Trivalent poliomyelitis vaccine, inactivated
27	J07BG01	Rabies vaccine, inactivated
28	J07BH01	Rotavirus vaccine, live attenuated
29	J07BH02	Rotavirus vaccine, pentavalent, live attenuated
30	J07BK01	Varicella vaccine, live attenuated
31	J07BK02	Zoster vaccine, live attenuated, without adjuvant
32	J07BK02	Zoster vaccine, live attenuated, with adjuvant
33	J07BL01	Yellow fever vaccine, live attenuated
34	J07BM02	Vaccine against human papilloma virus (types 16, 18)
35	J07BM03	Vaccine against human papilloma virus (9-valent)

<b>COMBINATIONS OF BACTERIAL AND VIRAL VACCINES</b>		
<i>Lot</i>	<i>ATC</i>	<i>MEDICINAL PRODUCT</i>
36	J07CA06	Vaccine against diphtheria, tetanus, pertussis (acellular), poliomyelitis (inactivated) and Haemophilus type B (conjugate), adsorbed
37	J07CA09	Vaccine against diphtheria, tetanus, pertussis (acellular), poliomyelitis (inactivated), hepatitis B (recombinant) and Haemophilus type B (conjugate), adsorbed

The Bidder may submit a bid for one, two or more lots.

Each lot will be submitted separately, in accordance with the conditions and criteria for the selection, as indicated in invitation.

## 2.6. CONTENTS OF BID DOCUMENTS

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

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

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

1. **INFORMATION ON THE BIDDER – Form 1** (in the case of joint bidding, each of the partners must complete Form 1);
2. **INFORMATION ON THE HOLDER OF THE AUTHORISATION TO PURSUE THE ACTIVITY OF MANUFACTURING MEDICINAL PRODUCTS OR AUTHORISATION TO PURSUE THE ACTIVITY OF THE WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS – Form 2** (in the case of joint bidding, each of the partners holding the authorisation must complete Form 2);
3. **GOOD MANUFACTURING PRACTICES (GMP) certificate – copy** ;
4. **AUTHORISATION TO PURSUE THE ACTIVITY OF WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS ISSUED BY A COMPETENT AUTHORITY REGULATING MEDICINAL PRODUCTS – copy** (if the Bidder, their partner or subcontractor is a holder of the wholesale marketing authorisation for medicinal products);
5. **BID – Form 3** (completed Form 3);
6. **“PREDRAČUN” - PRICE SPECIFICATION – Form 4** (completed Form 4);
7. **SPECIFICATION – Form 5** (completed Form 5);
8. **BIDDER'S STATEMENT ON THE MEETING OF CONDITIONS – Form 6** (in the case of joint bidding, each of the partners must complete Form 6);
9. **STATEMENT ON GOOD MANUFACTURING PRACTICES – Form 7** (completed and signed Form 7; the form must be signed by the person responsible for quality at the company of the holder of the authorisation to pursue the activity of manufacturing medicinal products or wholesale marketing authorisation for medicinal products);
10. **STATEMENT ON GOOD DISTRIBUTION PRACTICES – Form 8** (filled in and signed Form 8, the form shall be signed by the person responsible for quality at the company of the holder of the authorisation to pursue the activity of manufacture of medicinal products or wholesale marketing authorisation for medicinal products);
11. **FOR LEGAL PERSONS – AUTHORISATION TO ACQUIRE AN EXTRACT FROM THE JUDICIAL RECORDS – Form 9.1** (in the case of joint bidding, each of the partners must complete and sign Form 9.1; 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 9.1. 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 9.2** (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 9.2. 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 10** (if the Bidder is bidding with subcontractors);
15. **STATEMENT ON MEETING CONDITIONS AND CONSENT OF THE SUBCONTRACTOR FOR DIRECT PAYMENTS – Form 11**;
16. **FRAMEWORK AGREEMENT – MODEL – Form 12**;

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).

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

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

The tenderer confirms conformity with the conditions of Chapter 2.7.:

- with an ESPD form as preliminary evidence,

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 and signing Form 11 'Statement or Information on Participating Interests of Natural Persons or Legal Entities in the Bidder's Assets',

- by way of filling in and signing Form 2 'Information on the holder of the authorisation to pursue the activity of manufacture of medicinal products or wholesale marketing authorisation for medicinal products' 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 Contracting 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-10: Subcontractor Information),
- state the contact information and legal representatives of the proposed subcontractors (Form P-10: 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**

Bid should suit the criteria stated in Framework Agreement and requirements from this invitation. From the bids, which meet the above requests, the following additional criteria will be applied in rank as stated below:

- 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
- only if no medicinal product, which met above criteria, for separate lot or article was offered, the medicinal product, which is not registered would be selected.

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

### **2.14. AWARD CRITERIA**

The only award criteria is the lowest offered price for each individual lot.



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

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

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

### **2.15. 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.

### **2.16. FRAMEWORK AGREEMENT**

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

### **2.17. FINANCIAL SECURITY**

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

The Framework agreement becomes valid, when the selected Bidder submits financial security for the performance of contractual obligations.

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

performance bond (bank guarantee) within the required deadline shall represent a reason for the drawing on the performance bond.



*Nina Pirnat*  
Nina Pirnat, dr. med. spec.  
Director

**PO POBLASTILU DIREKTORICE**  
**prim. prof. dr. Ivan Eržen**

## II. BIDDING DOCUMENTATION

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## 1. INFORMATION ON THE BIDDER – Form 1

**Subject of contract:**

**Purchase of medicinal products for vaccination**

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**Company name:**

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**Address:**

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**Legal representatives:**

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**Registration court and number:**

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**Reg. ID No.:**

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**ID No.:**

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**Transaction account number with bank:**

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

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**Bidder's contact person:**

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**Telephone number:** \_\_\_\_\_

**GSM :** \_\_\_\_\_

**Fax number:** \_\_\_\_\_

**Email:** \_\_\_\_\_

**Person responsible for signing the contract:**

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We vouch for the correctness of the above particulars.

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**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 medicinal products for vaccination

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

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**Address:**

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

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**Authorisation number and date of issue:**

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**Person responsible for quality:**

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**Telephone number::** \_\_\_\_\_ **GSM :** \_\_\_\_\_

**E-mail:** \_\_\_\_\_

**Person responsible for pharmacovigilance:**

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**Telephone number::** \_\_\_\_\_ **GSM :** \_\_\_\_\_

**E-mail:** \_\_\_\_\_

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**Contact person for logistics:**

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**Telephone number:** \_\_\_\_\_ **GSM :** \_\_\_\_\_

**E-mail:** \_\_\_\_\_

**Contact person for medical questions:**

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**Telephone number::** \_\_\_\_\_ **GSM :** \_\_\_\_\_

**E-mail:** \_\_\_\_\_

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

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**Telephone number::** \_\_\_\_\_ **GSM :** \_\_\_\_\_

**E-mail:** \_\_\_\_\_

**Contact person to deal with complaints:**

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**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.

## 3. BID – Form 3

Bidder:

LOT	ATC	MEDICINAL PRODUCT
1	J06BB02	<b>Human tetanus immunoglobulin</b> It is intended to use for: <ul style="list-style-type: none"> <li>prophylaxis in persons with recent injuries who have no immunity, incomplete or unknown immunity against tetanus,</li> <li>therapy of clinically manifest tetanus.</li> </ul>
<b>REQUESTED:</b>		
Qualitative and quantitative composition		<b>Each dose of the immunoglobulin contains not less than 250 I.U. of tetanus antitoxin.</b>
Pharmaceutical form		Solution for injection.
Type of container		Prefilled syringe.
Packaging		Sc with 1 prefilled syringe with 1 ml of solution.
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		<p><b>MAX. QUANTITY: 45.000 doses</b>            Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement.            The Contracting Authority is not obliged to purchase the whole indicated quantity 45.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b>  <b>10.000 doses ± 20%</b>            For the year 2020, the Contractor must provide at least 12.000 doses of the medicinal product for the Contracting Authority.            The Contracting Authority is not obliged to purchase the whole indicated quantity 12.000 doses in 2020.            For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b>            For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>

<b>Delivery date</b>	<p><b>YEAR 2020</b> For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		
<b>Competent authority who issued the marketing authorization</b>		
<b>Medicinal product's number</b>		
<b>GTIN (Global trade number)</b>		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>		
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>		
<b>Minimum stability period at a temperature below 0°C (hours)</b>		



LOT	ATC	MEDICINAL PRODUCT
2	J06BB04	<b>Human hepatitis B immunoglobulin</b> It is intended to use for passive immunisation of children and adults against hepatitis B infection.
<b>REQUESTED:</b>		
Qualitative and quantitative composition	Each dose of the immunoglobulin contains not less than 50 I.U. antibodies against hepatitis B surface antigen.	
Pharmaceutical form	Solution for injection.	
Type of container	Vial - 2 ml.	
Packaging	Sc with 1 vial with 2 ml of solution.	
Labeling	In accordance with Slovenian legislation.	
Shelf life	At least 6 months from delivery.	
Quantity	<p><b>MAX. QUANTITY: 400 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 400 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> For the year 2020, the Contractor must provide at least 60 doses of the medicinal product for the Contracting Authority. First delivery: expected on JANUARY 2020. The Contracting Authority is not obliged to purchase the whole indicated quantity 60 doses in 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 30.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
Delivery date	<p><b>SKUCCESSIVE DELIVERY</b>, The Contracting Authority confirms the delivery at least three days before delivery. The Contractor will supply the products successively on the basis of the order forms issued by The Contracting Authority. First delivery: expected on JANUARY 2020.</p>	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
Proprietary name of the product		
Name and address of the manufacturer		

<b>Name and address of the marketing authorisation holder</b>	
<b>Marketing authorisation number</b>	
<b>Date of issued of marketing authorization</b>	
<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

LOT	ATC	MEDICINAL PRODUCT
3	J06BB05	<b>Human rabies immunoglobulin</b> It is intended to use for passive immunisation of children and adults against rabies.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>It contains not less than 150 I.U. of rabies antibodies / ml.</b>	
Pharmaceutical form	Solution for injection.	
Type of container	Vial – 2 ml.	
Packaging	Sc with 1 vial with 2 ml of solution.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 800 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 800 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>150 doses ± 20%</b> For the year 2020, the Contractor must provide at least 180 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 180 doses in 2020. For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b> For the delivery of the medicinal product in 2021, 2022 and 2023, the contracting authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract. First delivery: expected on MARCH 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>	
Documentation	In accordance with Slovenian legislation.	

Payment conditions	At least 60 days
<b>OFFERED:</b>	
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)	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
Minimum stability period at a temperature from 8°C to 25°C (hours)	
Minimum stability period at a temperature from 0°C to 2°C (hours)	
Minimum stability period at a temperature below 0°C (hours)	

LOT	ATC	MEDICINAL PRODUCT
4	J07AE01	<b>Cholera vaccine, inactivated</b> It is intended to use for active immunisation of children over 2 years of age against <i>Vibrio Cholerae</i> infections.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Vaccine contains strains of <i>Vibrio Cholerae</i>.</b>	
Pharmaceutical form	Suspension OR effervescent granules for oral suspension.	
Type of container	-	
Number of doses per container	1	
Packaging	Sc with 1 dose.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 1.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 1.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 200 doses</b> For the year 2020, the Contractor must provide at least 200 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 200 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> <b>SUCCESSIVE DELIVERY.</b></p>	

	For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
<b>Proprietary name of the product</b>	
<b>Name and address of the manufacturer</b>	
<b>Name and address of the marketing authorisation holder</b>	
<b>Marketing authorisation number</b>	
<b>Date of issued of marketing authorization</b>	
<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

LOT	ATC	MEDICINAL PRODUCT
5	J07AG01	<b>Haemophilus influenzae type B conjugate vaccine</b> It is intended to use for active immunisation of children over 2 months of age against <i>Haemophilus influenzae type B</i> infections.
<b>REQUESTED:</b>		
Qualitative and quantitative composition	<b>Vaccine contains polysaccharides derived from a suitable strain of <i>Haemophilus influenzae type b</i>, covalently bound to a carrier protein.</b>	
Pharmaceutical form	Powder and solvent for solution for injection	
Type of container	Vial with powder and prefilled syringe with solvent.	
Number of doses per container	1	
Packaging	Sc with 1 vial with powder, 1 prefilled syringe with solvent and two enclosed needles.	
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	<p><b>MAX. QUANTITY: 2.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 2.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 350 doses</b> For the year 2020, the Contractor must provide at least 350 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 350 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
Delivery date	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		
<b>Competent authority who issued the marketing authorization</b>		
<b>Medicinal product's number</b>		
<b>GTIN (Global trade number)</b>		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>		
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>		
<b>Minimum stability period at a temperature below 0°C (hours)</b>		



LOT	ATC	MEDICINAL PRODUCT
6	J07AH08	<p><b>Tetravalent Meningococcal polysaccharide conjugate vaccine (serogroups A, C, W<sub>135</sub> and Y)</b></p> <p>It is intended to use for active immunisation of children, adolescents and adults against <i>Neisseria meningitidis</i> infections (groups A, C, W<sub>135</sub> and Y).</p>
<b>REQUESTED:</b>		
Qualitative and quantitative composition	Each dose of the vaccine contains meningococcal polysaccharides serogroups A, C, W <sub>135</sub> and Y, covalently bound to a carrier protein.	
Pharmaceutical form	Powder and solvent for solution for injection	
Type of container	Vial with powder and prefilled syringe with solvent.	
Number of doses per container	1	
Packaging	Sc with 1 vial with powder and 1 prefilled syringe with solvent.	
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	<p><b>MAX. QUANTITY: 12.000 doses</b></p> <p>Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement.</p> <p>The Contracting Authority is not obliged to purchase the whole indicated quantity 12.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b></p> <p><b>Estimated quantity: 2.000 doses</b></p> <p>For the year 2020, the Contractor must provide at least 2.000 doses of the medicinal product for the Contracting Authority.</p> <p>The Contracting Authority is not obliged to purchase the whole indicated quantity 2.000 doses in 2020.</p> <p>The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b></p> <p>The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
Delivery date	<p><b>YEAR 2020</b></p> <p><b>SUCCESSIVE DELIVERY.</b></p> <p>The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least three days before delivery.</p> <p>First delivery: expected on SEPTEMBER 2019.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least three days before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		
<b>Competent authority who issued the marketing authorization</b>		
<b>Medicinal product's number</b>		
<b>GTIN (Global trade number)</b>		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>		
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>		
<b>Minimum stability period at a temperature below 0°C (hours)</b>		

LOT	ATC	MEDICINAL PRODUCT
7	J07AH09	<b>Meningococcus B, multicomponent vaccine</b> It is intended to use for active immunisation of children, adolescents and adults against <i>Neisseria meningitidis</i> infections (group B).
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Each dose of the vaccine contains meningococcal polysaccharides serogroup B.</b>	
Pharmaceutical form	Suspension for injection.	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 20.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 20.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 5.000 doses</b> For the year 2020, the Contractor must provide at least 5.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 5.000 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least three days before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> <b>SUCCESSIVE DELIVERY.</b></p>	

	For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least three days before delivery.
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
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)	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
Minimum stability period at a temperature from 8°C to 25°C (hours)	
Minimum stability period at a temperature from 0°C to 2°C (hours)	
Minimum stability period at a temperature below 0°C (hours)	

LOT	ATC	MEDICINAL PRODUCT
8	J07AJ52	<b>Vaccine against diphtheria, tetanus and pertussis (acellular), adsorbed</b> It is intended to use for active immunisation of children, adolescents and adults against diphtheria, tetanus and pertussis.
<b>REQUESTED:</b>		
Qualitative and quantitative composition	<b>A combined vaccine composed of diphtheria toxoid, tetanus toxoid and individually purified antigenic components of <i>Bordetella pertussis</i>.</b>	
Pharmaceutical form	Suspension for injection.	
Type of container	Prefilled syringe with 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	<p><b>MAX. QUANTITY: 140.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 140.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>25.000 doses ± 20%</b> For the year 2020, the Contractor must provide at least 30.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 30.000 doses in 2020. For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>	
Delivery date	<p><b>YEAR 2020</b> For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for</p>	

	next year.
Documentation	In accordance with Slovenian legislation. The contractor has to supply two labels for documentation about vaccination with the data of vaccine.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
<b>Proprietary name of the product</b>	
<b>Name and address of the manufacturer</b>	
<b>Name and address of the marketing authorisation holder</b>	
<b>Marketing authorisation number</b>	
<b>Date of issued of marketing authorization</b>	
<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

LOT	ATC	MEDICINAL PRODUCT
9	J07AL01	<b>Pneumococcal polysaccharide vaccine</b> It is intended to use for active immunisation of children over two years of age, adolescents and adults against infection with the types of Streptococcus pneumoniae contained in the vaccine (23 valent vaccine).
<b>REQUESTED:</b>		
Qualitative and quantitative composition	Each dose contains 25 micrograms of each of the 23 polysaccharide types.	
Pharmaceutical form	Solution for injection	
Type of container	Prefilled syringe or vial.	
Number of doses per container	1	
Packaging	Sc with 1 prefilled syringe or vial.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 30.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 30.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2019:</b> <b>SEPTEMBER 3.000 doses</b></p> <p><b>YEAR 2020</b> <b>Estimated quantity: 6.000 doses</b> For the year 2020, the Contractor must provide at least 6.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 6.000 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery.</p>	

	<p>First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b></p> <p>For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.</p>
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
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)	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
Minimum stability period at a temperature from 8°C to 25°C (hours)	
Minimum stability period at a temperature from 0°C to 2°C (hours)	
Minimum stability period at a temperature below 0°C (hours)	



LOT	ATC	MEDICINAL PRODUCT
10	J07AL52	<b>Pneumococcal polysaccharide conjugate vaccine, adsorbed</b> It is intended to use for active immunisation of children over six weeks of age, adolescents and adults, against infection with the types of Streptococcus pneumoniae contained in the vaccine (1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F).).
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Each dose of the vaccine contains suitable quantity of each of polysaccharide types (tenth), covalently bound to a carrier protein.</b>	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<b>MAX. QUANTITY: 1.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 1.000 of the medicinal product as at this moment needs can not be estimated.	
<b>Delivery date</b>	<b>SKUCCESSIVE DELIVERY</b> , The Contracting Authority confirms the delivery at least three days before delivery. The Contractor will supply the products successively on the basis of the order forms issued by The Contracting Authority. First delivery: expected on SPETEMBER 2019.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		

<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

LOT	ATC	MEDICINAL PRODUCT
11	J07AM01	<p><b>Tetanus vaccine, adsorbed</b></p> <p>It is intended to use for:</p> <ul style="list-style-type: none"> <li>• active immunisation of children, adolescents and adults against tetanus,</li> <li>• prophylaxis against tetanus in the case of wounds.</li> </ul>
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<p><b>Each dose of the vaccine contains not less than 40 I.U. of tetanus toxoid.</b></p> <p>The vaccine should not contain thiomersal ("thiomersal free vaccines").</p>	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe.	
Number of doses per container	1	
Packaging	Sc with 1 prefilled syringe.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 200.000 doses</b></p> <p>Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement.</p> <p>The Contracting Authority is not obliged to purchase the whole indicated quantity 200.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b></p> <p><b>Estimated quantity: 40.000 doses</b></p> <p>For the year 2020, the Contractor must provide at least 40.000 doses of the medicinal product for the Contracting Authority.</p> <p>The Contracting Authority is not obliged to purchase the whole indicated quantity 40.000 doses in 2020.</p> <p>For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b></p> <p>For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b></p> <p><b>SUCCESSIVE DELIVERY.</b></p> <p>For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p>First delivery: expected on JANUARY 2020.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		
<b>Competent authority who issued the marketing authorization</b>		
<b>Medicinal product's number</b>		
<b>GTIN (Global trade number)</b>		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>		
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>		
<b>Minimum stability period at a temperature below 0°C (hours)</b>		

LOT	ATC	MEDICINAL PRODUCT
12	J07AM51	<p><b>Diphtheria and tetanus vaccine, adsorbed</b></p> <p>It is intended to use for:</p> <ul style="list-style-type: none"> <li>• active immunisation of children, adolescents and adults against diphtheria and tetanus</li> <li>• prophylaxis of children, adolescents and adults against tetanus in the case of wounds and booster dose against diphtheria.</li> </ul>
<b>REQUESTED:</b>		
Qualitative and quantitative composition	Each dose of the vaccine contains not less than 2 I.U. of diphtheria toxoid and not less than 20 I.U. of tetanus toxoid. The vaccine should not contain thiomersal ("thiomersal free vaccines").	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with needle.	
Number of doses per container	1	
Packaging	Sc with 1 prefilled syringe with neele or Sc with 10 prefilled syringes with needles.	
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	<p><b>MAX. QUANTITY: 180.000 doses</b></p> <p>Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement.</p> <p>The Contracting Authority is not obliged to purchase the whole indicated quantity 180.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b></p> <p><b>Estimated quantity: 40.000 doses</b></p> <p>For the year 2020, the Contractor must provide at least 40.000 doses of the medicinal product for the Contracting Authority.</p> <p>The Contracting Authority is not obliged to purchase the whole indicated quantity 40.000 doses in 2020.</p> <p>For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b></p> <p>For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>	
Delivery date	<p><b>YEAR 2020</b></p> <p><b>SUCCESSIVE DELIVERY.</b></p> <p>For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p>	

	<p>First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b></p> <p>For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
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)	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
Minimum stability period at a temperature from 8°C to 25°C (hours)	
Minimum stability period at a temperature from 0°C to 2°C (hours)	
Minimum stability period at a temperature below 0°C (hours)	

LOT	ATC	MEDICINAL PRODUCT
13	J07AP03	<b>Typhiod polysaccharide vaccine</b> It is intended to use for active immunisation of children and adults against typhoid fever.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Each dose of the vaccine contains 25 micrograms of polysaccharide of Sallmonella Typhi (Ty2 strain).</b>	
Pharmaceutical form	Solution for injection	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 20.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 20.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 4.000 doses</b> For the year 2020, the Contractor must provide at least 4.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 4.000 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> <b>SUCCESSIVE DELIVERY.</b></p>	

	For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
<b>Proprietary name of the product</b>	
<b>Name and address of the manufacturer</b>	
<b>Name and address of the marketing authorisation holder</b>	
<b>Marketing authorisation number</b>	
<b>Date of issued of marketing authorization</b>	
<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	



LOT	ATC	MEDICINAL PRODUCT
14	JO7BA02	<b>Japanese encephalitis vaccine, inactivated</b> It is intended to use for active immunisation of adults against japanese encephalitis.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Vaccine contains suitable strain of virus japanese encephalitis inactivated by a suitable method.</b>	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe.	
Number of doses per container	1	
Packaging	Sc with 1 prefilled syringe.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 500 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 500 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 50 doses</b> For the year 2020, the Contractor must provide at least 50 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 50 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> <b>SUCCESSIVE DELIVERY.</b></p>	

	For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		
<b>Competent authority who issued the marketing authorization</b>		
<b>Medicinal product's number</b>		
<b>GTIN (Global trade number)</b>		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>		
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>		
<b>Minimum stability period at a temperature below 0°C (hours)</b>		

LOT	ATC	MEDICINAL PRODUCT
15	J07BC01	<b>Hepatitis B vaccine, recombinant</b> It is intended to use for active immunisation of <b>children</b> against hepatitis B infection.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>A preparation of hepatitis B surface antigen, that is obtained by recombinant DNA technology.</b>	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with needle.	
Number of doses per container	1	
Packaging	<ul style="list-style-type: none"> <li>• Sc with 1 prefilled syringe with needle or</li> <li>• sc 10 prefilled syringes with 10 needles.</li> </ul>	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 280.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 280.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>60.000 doses ± 20%</b> For the year 2020, the Contractor must provide at least 72.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 72.000 doses in 2020. For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of</p>	

	the medicinal product for fixed delivery no later than 31.08. for next year.
Documentation	In accordance with Slovenian legislation. The contractor has to supply two labels for documentation about vaccination with the data of vaccine.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
<b>Proprietary name of the product</b>	
<b>Name and address of the manufacturer</b>	
<b>Name and address of the marketing authorisation holder</b>	
<b>Marketing authorisation number</b>	
<b>Date of issued of marketing authorization</b>	
<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

LOT	ATC	MEDICINAL PRODUCT
16	J07BC01	<b>Hepatitis B vaccine, recombinant</b> It is intended to use for active immunisation of <b>adults</b> against hepatitis B infection.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>A preparation of hepatitis B surface antigen, that is obtained by recombinant DNA technology.</b>	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 55.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 55.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 12.000 doses</b> For the year 2020, the Contractor must provide at least 12.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 12.000 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> <b>SUCCESSIVE DELIVERY.</b></p>	

	For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.
Documentation	In accordance with Slovenian legislation. The contractor has to supply two labels for documentation about vaccination with the data of vaccine.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
<b>Proprietary name of the product</b>	
<b>Name and address of the manufacturer</b>	
<b>Name and address of the marketing authorisation holder</b>	
<b>Marketing authorisation number</b>	
<b>Date of issued of marketing authorization</b>	
<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

LOT	ATC	MEDICINAL PRODUCT
17	J07BC01	<p><b>Hepatitis B vaccine, recombinant, without adjuvant</b></p> <p>It is intended to use for active immunisation of <b>adults patients with renal insufficiency or in predialysis and dialysis adult patients</b> against hepatitis B infection (therapeutic indication stated in SmpC).</p>
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<p><b>A preparation of hepatitis B surface antigen, that is obtained by recombinant DNA technology.</b></p> <p>The vaccine does not contain an adjuvant.</p>	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 8.000 doses</b></p> <p>Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement.</p> <p>The Contracting Authority is not obliged to purchase the whole indicated quantity 8.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b></p> <p><b>Estimated quantity: 2.000 doses</b></p> <p>For the year 2020, the Contractor must provide at least 2.000 doses of the medicinal product for the Contracting Authority.</p> <p>The Contracting Authority is not obliged to purchase the whole indicated quantity 2.000 doses in 2020.</p> <p>The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b></p> <p>The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b></p> <p><b>SUCCESSIVE DELIVERY.</b></p> <p>The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery.</p> <p>First delivery: expected on JANUARY 2020.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
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)		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
Minimum stability period at a temperature from 8°C to 25°C (hours)		
Minimum stability period at a temperature from 0°C to 2°C (hours)		
Minimum stability period at a temperature below 0°C (hours)		



LOT	ATC	MEDICINAL PRODUCT
18	J07BC01	<b>Hepatitis B vaccine, recombinant, with adjuvant</b> It is intended to use for active immunisation of <b>adults patients with renal insufficiency or in predialysis and dialysis adult patients</b> against hepatitis B infection (therapeutic indication stated in SmpC).
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>A preparation of hepatitis B surface antigen, that is obtained by recombinant DNA technology.</b> The vaccine contains an adjuvant.	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 14.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 14.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 2.500 doses</b> For the year 2020, 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 in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2019 and YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2019 and 2020. The order will be confirmed at least three days before delivery. First delivery: expected on SEPTEMBER 2019.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least three days before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
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)		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
Minimum stability period at a temperature from 8°C to 25°C (hours)		
Minimum stability period at a temperature from 0°C to 2°C (hours)		
Minimum stability period at a temperature below 0°C (hours)		

LOT	ATC	MEDICINAL PRODUCT
19	J07BC02	<b>Hepatitis A vaccine, inactivated, adsorbed</b> It is intended to use for active immunisation of <b>children</b> against hepatitis A infection.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>A preparation of a suitable strain of hepatitis A virus inactivated by a suitable method.</b>	
<b>Marketing authorisation</b>	The medicinal product has marketing authorisation in accordance with the legislation applicable in the Republic of Slovenia.	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 5.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 5.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 1.000 doses</b> For the year 2020, the Contractor must provide at least 1.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 1.000 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2019 and YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2019 and 2020. The order will be confirmed at least three days before delivery. First delivery: expected on SPTEMBER 2019.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least three days before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		
<b>Competent authority who issued the marketing authorization</b>		
<b>Medicinal product's number</b>		
<b>GTIN (Global trade number)</b>		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>		
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>		
<b>Minimum stability period at a temperature below 0°C (hours)</b>		

LOT	ATC	MEDICINAL PRODUCT
20	J07BC02	<b>Hepatitis A vaccine, inactivated, adsorbed</b> It is intended to use for active immunisation of <b>adults</b> against hepatitis A infection.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>A preparation of a suitable strain of hepatitis A virus inactivated by a suitable method.</b>	
<b>Marketing authorisation</b>	The medicinal product has marketing authorisation in accordance with the legislation applicable in the Republic of Slovenia.	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 30.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 30.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 5.500 doses</b> For the year 2020, the Contractor must provide at least 5.500 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 5.500 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2019 and YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2019 and 2020. The order will be confirmed at least three days before delivery. First delivery: expected on SPTEMBER 2019.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least three days before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
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)		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
Minimum stability period at a temperature from 8°C to 25°C (hours)		
Minimum stability period at a temperature from 0°C to 2°C (hours)		
Minimum stability period at a temperature below 0°C (hours)		

LOT	ATC	MEDICINAL PRODUCT
21	J07BC20	<b>Hepatitis A (inactivated) and hepatitis B (recombinat) vaccine, adsorbed</b> It is intended to use for active immunisation of <b>children</b> against hepatitis A and B infections
<b>REQUESTED:</b>		
Qualitative and quantitative composition	<b>A preparation of a suitable strain of hepatitis A virus inactivated and of hepatitis B surface antigen obtained by recombinant DNA technology; the antigens are adsorbed on a mineral carrier.</b>	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with 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	<p><b>MAX. QUANTITY: 500 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 500 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 100 doses</b> For the year 2020, 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 in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
Delivery date	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least three days before delivery. First delivery: expected on JANUARY 2020.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least three days before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
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)		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
Minimum stability period at a temperature from 8°C to 25°C (hours)		
Minimum stability period at a temperature from 0°C to 2°C (hours)		
Minimum stability period at a temperature below 0°C (hours)		



LOT	ATC	MEDICINAL PRODUCT
22	J07BC20	<b>Hepatitis A (inactivated) and hepatitis B (recombinat) vaccine, adsorbed</b> It is intended to use for active immunisation of <b>adults</b> against hepatitis A and B infections
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>A preparation of a suitable strain of hepatitis A virus inactivated and of hepatitis B surface antigen obtained by recombinant DNA technology; the antigens are adsorbed on a mineral carrier.</b>	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 30.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 30.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 5.000 doses</b> For the year 2020, the Contractor must provide at least 5.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 5.000 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2019 and YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2019 and 2020. The order will be confirmed at least three days before delivery. First delivery: expected on SPTEMBER 2019.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least three days before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		
<b>Competent authority who issued the marketing authorization</b>		
<b>Medicinal product's number</b>		
<b>GTIN (Global trade number)</b>		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>		
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>		
<b>Minimum stability period at a temperature below 0°C (hours)</b>		

LOT	ATC	MEDICINAL PRODUCT
23	J07BD01	<b>Measles vaccine, live attenuated</b> It is intended to use for active immunisation of children nine months of age and older against measles.
<b>REQUESTED:</b>		
Qualitative and quantitative composition	Each dose contains not less than: <b>1 x 10<sup>3</sup> CCID50 of live attenuated measles virus.</b>	
Pharmaceutical form	Powder and solvent for suspension for injection.	
Type of container	Vial with powder and prefilled syringe or ampoule with solvent.	
Number of doses per container	1	
Packaging	<ul style="list-style-type: none"> <li>• Sc with 1 vial with powder and sc with 1 ampoule or 1 prefilled syringe with solvent or</li> <li>• Sc with 10 vial with powder and sc with 10 ampoule or 10 prefilled syringe with solvent.</li> </ul>	
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	<p><b>MAX. QUANTITY: 2.000 doses</b>            Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement.            The Contracting Authority is not obliged to purchase the whole indicated quantity 2.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b>  <b>Estimated quantity: 500 doses</b>            For the year 2020, the Contractor must provide at least 500 doses of the medicinal product for the Contracting Authority.            The Contracting Authority is not obliged to purchase the whole indicated quantity 500 doses in 2020.            For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b>            For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>	
Delivery date	<p><b>YEAR 2020</b>  <b>SUCCESSIVE DELIVERY.</b>            For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.            First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b></p>	

	<b>SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
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)	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
Minimum stability period at a temperature from 8°C to 25°C (hours)	
Minimum stability period at a temperature from 0°C to 2°C (hours)	
Minimum stability period at a temperature below 0°C (hours)	

LOT	ATC	MEDICINAL PRODUCT
24	J07BD52	<b>Measles, mumps and rubella vaccine, live attenuated</b> It is intended to use for active immunisation against measles, mumps and rubella.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Each dose contains suitable strains of attenuated measles, mumps, and rubella viruses.</b>	
Pharmaceutical form	<ul style="list-style-type: none"> <li>• Powder and solvent for solution for injection or</li> <li>• Powder and solvent for suspension for injection.</li> </ul>	
Type of container	Vial with powder and prefilled syringe with two needles with solvent.	
Number of doses per container	1	
Packaging	<ul style="list-style-type: none"> <li>• Sc with 1 vial with powder, 1 prefilled syringe with solvent and 2 needles or</li> <li>• Sc with 10 vial with powder, 10 prefilled syringe with solvent and 20 needles.</li> </ul>	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 280.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 280.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>55.000 doses ± 20%</b> For the year 2020, the Contractor must provide at least 66.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 66.000 doses in 2020. For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract. First delivery: expected on JANUARY 2020.</p>	

	<b>YEAR 2021, 2022, 2023</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.
Documentation	In accordance with Slovenian legislation. The contractor has to supply two labels for documentation about vaccination with the data of vaccine.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
<b>Proprietary name of the product</b>	
<b>Name and address of the manufacturer</b>	
<b>Name and address of the marketing authorisation holder</b>	
<b>Marketing authorisation number</b>	
<b>Date of issued of marketing authorization</b>	
<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

LOT	ATC	MEDICINAL PRODUCT
25	J07BD54	<b>Measles, mumps, rubella and varicella vaccine, live attenuated</b> It is intended to use for active immunisation against measles, mumps, rubella and varicella.
<b>REQUESTED:</b>		
Qualitative and quantitative composition	<b>Each dose contains suitable strains of attenuated measles, mumps, rubella and varicella viruses.</b>	
Pharmaceutical form	Powder and solvent for solution for injection	
Type of container	Vial with powder and prefilled syringe with two needles with solvent.	
Number of doses per container	1	
Packaging	Sc with 1 vial with powder and 1 prefilled syringe with two needles with solvent.	
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	<p><b>MAX. QUANTITY: 3.500 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 3.500 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 500 doses</b> For the year 2020, the Contractor must provide at least 500 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 500 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
Delivery date	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		
<b>Competent authority who issued the marketing authorization</b>		
<b>Medicinal product's number</b>		
<b>GTIN (Global trade number)</b>		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>		
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>		
<b>Minimum stability period at a temperature below 0°C (hours)</b>		



LOT	ATC	MEDICINAL PRODUCT
26	J07BF03	<b>Trivalent poliomyelitis vaccine, inactivated</b> It is intended to use for active immunisation against poliomyelitis of children over two months of age, adolescents and adults.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>A preparation of suitable strains of poliomyelitis virus, types 1, 2, and 3, inactivated by a suitable method.</b>	
Pharmaceutical form	Solution for injection.	
Type of container	Vial or prefilled syringe.	
Number of doses per container	1	
Packaging	Sc with 1 vial or 1 prefilled syringe.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 4.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 4.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 650 doses</b> For the year 2020, the Contractor must provide at least 650 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 650 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> <b>SUCCESSIVE DELIVERY.</b></p>	

	For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		
<b>Competent authority who issued the marketing authorization</b>		
<b>Medicinal product's number</b>		
<b>GTIN (Global trade number)</b>		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>		
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>		
<b>Minimum stability period at a temperature below 0°C (hours)</b>		

LOT	ATC	MEDICINAL PRODUCT
27	J07BG01	<b>Rabies vaccine, inactivated</b> It is intended to use for active immunisation of children and adults against rabies. A suitable strain is grown in an approved cell culture.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Each dose contains not less than 2,5 I.U. of inactivated rabies virus grown in an approved cell culture.</b>	
Pharmaceutical form	Powder and solvent for suspension for injection.	
Type of container	Vial with powder and prefilled syringe with solvent.	
Number of doses per container	1	
Packaging	Sc with 1 vial with powder and prefilled syringe with solvent or sc. with 5 vials with powder, 5 ampules with solvent nad 5 syringes.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 8.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 8.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 1.500 doses</b> For the year 2020, the Contractor must provide at least 1.500 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 1.500 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p>	

	<b>YEAR 2021, 2022, 2023 SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
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)		
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>		
Minimum stability period at a temperature from 8°C to 25°C (hours)		
Minimum stability period at a temperature from 0°C to 2°C (hours)		
Minimum stability period at a temperature below 0°C (hours)		

LOT	ATC	MEDICINAL PRODUCT
28	J07BH01	<b>Rotavirus vaccine, live attenuated</b> It is intended to use for active immunisation against rota virus.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Each dose of the vaccine contains not less than <math>10^{6.0}</math> CCID<sub>50</sub> lived, attenuated human rotavirus (strain RIX 4414).</b>	
Pharmaceutical form	Powder and solvent for peroral suspension.	
Type of container	Peroral applicator	
Number of doses per container	1	
Packaging	Sc with 1 prefilled peroral applicator with 1,5 ml peroral suspension.	
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.	
<b>Quantity</b>	<b>MAX. QUANTITY: 80.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 80.000 of the medicinal product as at this moment needs can not be estimated.	
<b>Delivery date</b>	<b>SKUCCESSIVE DELIVERY</b> , The Contracting Authority confirms the delivery at least three days before delivery. The Contractor will supply the products successively on the basis of the order forms issued by The Contracting Authority. First delivery: expected on SPETEMBER 2019.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		

<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

LOT	ATC	MEDICINAL PRODUCT
29	J07BH02	<b>Rotavirus vaccine, live attenuated</b> It is intended to use for active immunisation against rota virus.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	Each dose of the vaccine contains not less than - 2,2 x 10 <sup>6</sup> i.e. <sup>1,2</sup> rotavirusa serotype G1 - 2,8 x 10 <sup>6</sup> i.e. <sup>1,2</sup> rotavirusa serotype G2 - 2,2 x 10 <sup>6</sup> i.e. <sup>1,2</sup> rotavirusa serotype G3 - 2,0 x 10 <sup>6</sup> i.e. <sup>1,2</sup> rotavirusa serotype G4 - 2,3 x 10 <sup>6</sup> i.e. <sup>1,2</sup> rotavirus serotype P1 (8).	
Pharmaceutical form	Peroral solution.	
Type of container	Tube.	
Number of doses per container	1	
Packaging	Sc with tube (2 ml).	
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.	
<b>Quantity</b>	<b>MAX. QUANTITY: 20.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 20.000 of the medicinal product as at this moment needs can not be estimated.	
<b>Delivery date</b>	<b>SKUCCESSIVE DELIVERY</b> , 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. First delivery: expected on SPETEMBER 2019.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		

<b>Date of issued of marketing authorization</b>	
<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	



LOT	ATC	MEDICINAL PRODUCT
30	J07BK01	<b>Varicella vaccine, live attenuated</b> It is intended to use for active immunisation against varicella in healthy adults, adolescents and children.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Each dose contains a suitable strain of live attenuated varicella virus.</b>	
Pharmaceutical form	Powder and solvent for solution for injection or for suspension for injection	
Type of container	Vial with powder and prefilled syringe with solvent.	
Number of doses per container	1	
Packaging	1 vial with powder and 1 prefilled syringe with solvent.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 10.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 10.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 2.000 doses</b> For the year 2020, the Contractor must provide at least 2.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 2.000 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b></p>	

	<b>SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
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)	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
Minimum stability period at a temperature from 8°C to 25°C (hours)	
Minimum stability period at a temperature from 0°C to 2°C (hours)	
Minimum stability period at a temperature below 0°C (hours)	

LOT	ATC	MEDICINAL PRODUCT
31	J07BK02	<b>Zoster vaccine, live attenuated, without adjuvant</b> It is intended to use for active immunisation against varicella zoster virus.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Each dose contains a suitable strain of live attenuated varicella zoster virus.</b> The vaccine does not contain an adjuvant.	
Pharmaceutical form	Powder and solvent for suspension for injection	
Type of container	Vial with powder and prefilled syringe with solvent.	
Number of doses per container	1	
Packaging	1 vial with powder and 1 prefilled syringe with solvent.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 500 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 500 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 50 doses</b> For the year 2020, the Contractor must provide at least 50 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 50 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b></p>	

	<b>SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
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)	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
Minimum stability period at a temperature from 8°C to 25°C (hours)	
Minimum stability period at a temperature from 0°C to 2°C (hours)	
Minimum stability period at a temperature below 0°C (hours)	

LOT	ATC	MEDICINAL PRODUCT
32	J07BK02	<b>Zoster vaccine, live attenuated, with adjuvant</b> It is intended to use for active immunisation against varicella zoster virus.
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>Each dose contains a suitable strain of live attenuated varicella zoster virus.</b> The vaccine contains an adjuvant.	
Pharmaceutical form	Powder and solvent for suspension for injection	
Type of container	Vial with powder and prefilled syringe with solvent.	
Number of doses per container	1	
Packaging	1 vial with powder and 1 prefilled syringe with solvent.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 1.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 1.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 150 doses</b> For the year 2020, the Contractor must provide at least 150 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 150 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b></p>	

	<b>SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
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)	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
Minimum stability period at a temperature from 8°C to 25°C (hours)	
Minimum stability period at a temperature from 0°C to 2°C (hours)	
Minimum stability period at a temperature below 0°C (hours)	

LOT	ATC	MEDICINAL PRODUCT
33	J07BL01	<b>Yellow fever vaccine, live attenuated</b> It is intended to use for active immunisation against yellow fever of children and adults.
<b>Qualitative and quantitative composition</b>		
<b>Qualitative and quantitative composition</b>	<b>Each dose contains not less than 1.000 U. (mouse LD<sub>50</sub>) of attenuated yellow fever virus, 17D strain.</b>	
Pharmaceutical form	Powder and solvent for suspension for injection.	
Type of container	Vial with powder and prefilled syringe with solvent.	
Number of doses per container	1	
Packaging	Sc with 1 vial with powder and 1 prefilled syringe with solvent.	
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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 12.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 12.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 2.500 doses</b> For the year 2020, 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 in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> <b>SUCCESSIVE DELIVERY.</b> For the delivery of the medicinal product in 2021, 2022 and</p>	

	2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
<b>Proprietary name of the product</b>	
<b>Name and address of the manufacturer</b>	
<b>Name and address of the marketing authorisation holder</b>	
<b>Marketing authorisation number</b>	
<b>Date of issued of marketing authorization</b>	
<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	



LOT	ATC	MEDICINAL PRODUCT
34	J07BM03	<b>Vaccine against human papilloma virus (types 16 and 18).</b> It is intended to use for active immunisation of adolescents and adults against human papilloma virus (types 16 and 18).
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>A preparation of suitable strains of papilomavirus, obtained by recombinant DNA technology.</b>	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<b>MAX. QUANTITY: 20.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 20.000 of the medicinal product as at this moment needs can not be estimated.	
<b>Delivery date</b>	<b>SKUCCESSIVE DELIVERY,</b> 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. First delivery: expected on SPETEMBER 2019.	
Documentation	In accordance with Slovenian legislation.	
Payment conditions	At least 60 days	
<b>OFFERED:</b>		
<b>Proprietary name of the product</b>		
<b>Name and address of the manufacturer</b>		
<b>Name and address of the marketing authorisation holder</b>		
<b>Marketing authorisation number</b>		
<b>Date of issued of marketing authorization</b>		
<b>The validity of the marketing authorization</b>		

<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

LOT	ATC	MEDICINAL PRODUCT
35	J07BM03	<b>Vaccine against human papilloma virus (9-valent).</b> 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).
<b>REQUESTED:</b>		
<b>Qualitative and quantitative composition</b>	<b>A preparation of suitable strains of papilomavirus, obtained by recombinant DNA technology.</b>	
Pharmaceutical form	Suspension for injection	
Type of container	Prefilled syringe with 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.	
<b>Quantity</b>	<p><b>MAX. QUANTITY: 120.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 120.000 of the medicinal product as at this moment needs can not be estimated.</p> <p><b>YEAR 2020</b> <b>Estimated quantity: 20.000 doses</b> For the year 2020, the Contractor must provide at least 20.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 20.000 doses in 2020. The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or 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.</p> <p><b>YEAR 2021, 2022, 2023</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08 of the estimated quantity it intends to buy in next year. The contracting authority does not undertake to purchase the entire estimated quantity.</p>	
<b>Delivery date</b>	<p><b>YEAR 2020</b> <b>SUCCESSIVE DELIVERY.</b> The Contracting Authority will inform the Contractor in writing, no later than 31.08.2019 (or at the latest 10 days after the conclusion of the contract) of the estimated quantity it intends to buy in 2020. The order will be confirmed at least one month before delivery. First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b> <b>SUCCESSIVE DELIVERY.</b></p>	

	For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will inform the Contractor in writing no later than 31.08. of the estimated quantity it intends to buy for next year. The order will be confirmed at least one month before delivery.
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
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)	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
Minimum stability period at a temperature from 8°C to 25°C (hours)	
Minimum stability period at a temperature from 0°C to 2°C (hours)	
Minimum stability period at a temperature below 0°C (hours)	

LOT	ATC	MEDICINAL PRODUCT
36	J07CA06	<b>Vaccine against diphtheria, tetanus, pertussis (acellular), poliomyelitis (inactivated) and Haemophilus type B (conjugate), adsorbed</b> It is intended to use for active immunisation of children over two months of age against diphtheria, tetanus, pertussis, poliomyelitis and Haemophilus influenzae type B.
<b>REQUESTED:</b>		
Therapeutic indication	Active immunisation of children over two months of age against diphtheria, tetanus, pertussis, poliomyelitis, and Haemophilus influenzae type B.	
Qualitative and quantitative composition:	<b>A combined vaccine composed of</b> <ul style="list-style-type: none"> <li>• diphtheria toxoid,</li> <li>• tetanus toxoid,</li> <li>• purified antigenic components of Bordetella pertussis,</li> <li>• suitable strains of human polioviruses type 1, 2, and 3 inactivated by a validated method,</li> <li>• polysaccharid of a suitable strain of Haemophilus influenzae type, covalently bound to a carrier protein.</li> </ul>	
Pharmaceutical form:	<ul style="list-style-type: none"> <li>• Powder (Hib) and suspension (DTPa-IPV) for suspension for injection or</li> <li>• suspension for injection (DTPa-IPV+Hib).</li> </ul>	
Type of container:	<ul style="list-style-type: none"> <li>• Vial with powder (Hib) and prefilled syringe with suspension (DTPa-IPV) with enclosed needle or</li> <li>• prefilled syringe (DTPa-IPV+Hib) with enclosed needle.</li> </ul>	
Number of doses in the container	1	
Packaging	<ul style="list-style-type: none"> <li>• Sc with 1 vial with powder (Hib) and 1 prefilled syringe with suspension (DTPa-IPV) with 2 enclosed needles or</li> <li>• sc with 10 vials with powder (Hib) and 10 prefilled syringes with suspension (DTPa-IPV) with 20 enclosed needles or</li> <li>• sc with 1 prefilled syringe (DTPa-IPV+Hib) with 2 enclosed needles or</li> <li>• sc with 10 prefilled syringes (DTPa-IPV+Hib) with 2 enclosed needles.</li> </ul>	
Labelling	In accordance with the legislation applicable in the Republic of Slovenia.	
Shelf-life of the medicinal product	At least 18 months from delivery.	
Quantity	<b>MAX. QUANTITY: 50.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 50.000 of the medicinal product as at this moment needs can not be estimated.  <b>YEAR 2020</b> For the year 2020, the Contractor must provide at least	

	<p>50.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 50.000 doses in 2020.</p> <p>For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b></p> <p>For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>
<b>Delivery deadline</b>	<p><b>YEAR 2020</b></p> <p><b>SUCCESSIVE DELIVERY.</b></p> <p>For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p>First delivery: expected on JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b></p> <p><b>SUCCESSIVE DELIVERY.</b></p> <p>For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>
Documentation	<p>In accordance with the legislation applicable in the Republic of Slovenia.</p> <p>The contractor has to supply two labels for documentation about vaccination with the data of vaccine.</p>
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
<b>Proprietary name of the product</b>	
<b>Name and address of the manufacturer</b>	
<b>Name and address of the marketing authorisation holder</b>	

<b>Marketing authorisation number</b>	
<b>Date of issued of marketing authorization</b>	
<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

LOT	ATC	MEDICINAL PRODUCT
37	J07CA09	<b>Vaccine against diphtheria, tetanus, pertussis (acellular), poliomyelitis (inactivated), hepatitis B (recombinant) and Haemophilus type B (conjugate), adsorbed</b> It is intended to use for active immunisation of children over two months of age against diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and Haemophilus influenzae type B.
<b>REQUESTED:</b>		
Qualitative and quantitative composition		<b>A combined vaccine composed of</b> - diphtheria toxoid, - tetanus toxoid, - individually purified antigenic components of Bordetella pertussis, - suitable strains of human polioviruses type 1, 2, and 3 inactivated by a validated method, - hepatitis B surface antigen obtained by recombinant DNA technology, - polysaccharid of a suitable strain of Haemophilus influenzae type, covalently bound to a carrier protein.
Pharmaceutical form		<ul style="list-style-type: none"> <li>• Powder (Hib) and suspension (DTPa-HBV-IPV) for suspension for injection or</li> <li>• suspension for injection (DTPa-HBV-IPV+Hib).</li> </ul>
Type of container		<ul style="list-style-type: none"> <li>• Vial with powder (Hib) and prefilled syringe with suspension (DTPa-HBV-IPV) with enclosed needle or</li> <li>• prefilled syringe (DTPa-HBV-IPV+Hib) with enclosed needle.</li> </ul>
Number of doses per container		1
Packaging		<ul style="list-style-type: none"> <li>• sc with 1 vial with powder (Hib) and 1 prefilled syringes with suspension (DTPa-HBV-IPV) with 2 enclosed needles or</li> <li>• sc with 10 vial with powder (Hib) and 10 prefilled syringes with suspension (DTPa-HBV-IPV) with 20 enclosed needles or</li> <li>• sc with 1 prefilled syringe (DTPa—HBV-IPV+Hib) with 2 enclosed needles or</li> <li>• sc with 10 prefilled syringe (DTPa—HBV-IPV+Hib) with 20 enclosed needles.</li> </ul>
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		<b>MAX. QUANTITY: 300.000 doses</b> Indicated quantity is merely estimates of the quantity the Contracting Authority intends to purchase during the period of validity of this Framework agreement. The Contracting Authority is not obliged to purchase the whole indicated quantity 300.000 of the medicinal product as at this moment needs can not be estimated.  <b>YEAR 2019</b> <b>5.000 doses</b>



	<p><b>YEAR 2020</b>  <b>60.000 doses ± 20%</b>  For the year 2020, the Contractor must provide at least 72.000 doses of the medicinal product for the Contracting Authority. The Contracting Authority is not obliged to purchase the whole indicated quantity 72.000 doses in 2020.  For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.</p> <p><b>YEAR 2021, 2022, 2023</b>  For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>
<b>Delivery date</b>	<p><b>YEAR 2019</b>  <b>No later than 10.12.2019</b></p> <p><b>YEAR 2020</b>  For the delivery of the medicinal product in 2020, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.8.2019, or at the latest 10 days after the conclusion of the contract.  First delivery: till 10th JANUARY 2020.</p> <p><b>YEAR 2021, 2022, 2023</b>  For the delivery of the medicinal product in 2021, 2022 and 2023, The Contracting Authority will confirm the quantity of the medicinal product for fixed delivery no later than 31.08. for next year.</p>
Documentation	In accordance with Slovenian legislation.
Payment conditions	At least 60 days
<b>OFFERED:</b>	
<b>Proprietary name of the product</b>	
<b>Name and address of the manufacturer</b>	
<b>Name and address of the marketing authorisation holder</b>	
<b>Marketing authorisation number</b>	
<b>Date of issued of marketing authorization</b>	

<b>The validity of the marketing authorization</b>	
<b>Competent authority who issued the marketing authorization</b>	
<b>Medicinal product's number</b>	
<b>GTIN (Global trade number)</b>	
<b>DATA ON STABILITY OF THE MEDICINAL PRODUCT</b>	
<b>Minimum stability period at a temperature from 8°C to 25°C (hours)</b>	
<b>Minimum stability period at a temperature from 0°C to 2°C (hours)</b>	
<b>Minimum stability period at a temperature below 0°C (hours)</b>	

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 90 days after the date set out as the deadline for the submission of bids.

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

Bidder:

<b>REQUESTED:</b>	
<b>MEDICINAL PRODUCT</b>	<b>MEDICINAL PRODUCTS FOR VACCINATION</b>
<b>Public procurement code:</b>	<b>34K270319</b>
<b>Incoterms 2010</b>	<b>DAP Contracting Authority – lot 1, 2, 4, 6, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 28, 29, 30, 31, 32, 34, 35, 36, 37</b> <b>CIP Contracting Authority – lot 3, 5, 13, 26, 27, 33</b>
<b>PRICE SPECIFICATION - PRICE IN EUR without tax</b>	

<b>IMMUNOGLOBULINS</b>		<b>UNIT</b>	<b>Number of ml in container</b>	<b>Unit price with discount</b>	<b>Quantity (Number of units)</b>	<b>Value</b>
<b>Lot</b>	<b>ATC</b>	<b>Packaging</b>	<b>A</b>	<b>B</b>	<b>C</b>	<b>D=B*C</b>
1	J06BB02	Human tetanus immunoglobulin – 250 i.e./1 ml	1 ml		45.000	
2	J06BB04	Human hepatitis B immunoglobulin – 50 i.e./1 ml	2 ml		400	
3	J06BB05	Human rabies immunoglobulin – 250 i.e./1 ml	2 ml		800	

<b>BACTERIAL VACCINES</b>								
Lot	ATC	MEDICINAL PRODUCT	UNIT	Number of doses in packaging	Unit price with discount	Dose price with discount	Quantity (Number of doses)	Value
4	J07AE01	Cholera vaccine, inactivated	Packaging	A	B	C =B/A	D	E= B*D/A
			SC				1.000	
5	J07AG01	Haemophilus influenzae type B conjugate vaccine	SC				2.000	
6	J07AH08	Tetavalent Meningococcal polysaccharide conjugate vaccine (serogroups A, C, W135 and Y)	SC				12.000	
7	J07AH09	Meningococcus B, multicomponent vaccine	SC				20.000	
8	J07AJ52	Vaccine against diphtheria, tetanus and pertussis (acellular), adsorbed	SC				140.000	
9	J07AL01	Pneumococcal polysaccharide vaccine – 23 valent	SC				30.000	
10	J07AL52	Pneumococcal polysaccharide conjugate vaccine, adsorbed – 10 valent	SC				1.000	
11	J07AM01	Tetanus vaccines, adsorbed	SC				200.000	
12	J07AM51	Diphtheria and tetanus vaccine, adsorbed	SC				180.000	
13	J07AP03	Typhoid polysaccharide vaccine	SC				20.000	

<b>VIRAL VACCINES</b>								
Lot	ATC	MEDICINAL PRODUCT	UNIT	Number of doses in packaging	Unit price with discount	Dose price with discount	Quantity (Number of doses)	Value
14	J07BA02	Japanese encephalitis vaccine, inactivated	Packaging	A	B	C =B/A	D	E= B*D/A
			SC				500	

15	J07BC01	Hepatitis B vaccine, recombinant – for children	sc						280.000
16	J07BC01	Hepatitis B vaccine, recombinant – for adults	sc						55.000
17	J07BC01	Hepatitis B vaccine, recombinant, without adjuvant – for dialysis patients	sc						8.000
18	J07BC01	Hepatitis B vaccine, recombinant, with adjuvant – for dialysis patients	sc						14.000
19	J07BC02	Hepatitis A vaccine, inactivated, adsorbed – for children	sc						5.000
20	J07BC02	Hepatitis A vaccine, inactivated, adsorbed – for adults	sc						30.000
21	J07BC20	Hepatitis A (inactivated) and hepatitis B (recombinant), adsorbed - for children	sc						500
22	J07BC20	Hepatitis A (inactivated) and hepatitis B (recombinant), adsorbed - for adults	sc						30.000
23	J07BD01	Measles vaccine, live attenuated	sc						2.000
24	J07BD52	Measles, mumps and rubella vaccine, live attenuated	sc						280.000
25	J07BD54	Measles, mumps, rubella and varicella vaccine, live attenuated	sc						3.500
26	J07BF03	Trivalent poliomyelitis vaccine, inactivated	sc						4.000
27	J07BG01	Rabies vaccine, inactivated	sc						8.000
28	J07BH01	Rotavirus vaccine, live attenuated	sc						80.000
29	J07BH02	Rotavirus vaccine, pentavalent, live attenuated	sc						20.000
30	J07BK01	Varicella vaccine, live attenuated	sc						10.000

31	J07BK02	Zoster vaccine, live attenuated, without adjuvant	sc				500	
32	J07BK02	Zoster vaccine, live attenuated, with adjuvant	sc				1.000	
33	J07BL01	Yellow fever vaccine, live attenuated	sc				12.000	
34	J07BM02	Vaccine against human papilloma virus (types 16, 18)	sc				20.000	
35	J07BM03	Vaccine against human papilloma virus (9-valent)	sc				120.000	

**COMBINATIONS OF BACTERIAL AND VIRAL VACCINES**

Lot	ATC	MEDICINAL PRODUCT	UNIT	Number of doses in packaging	Unit price with discount	Dose price with discount	Quantity (Number of doses)	Value
36	J07CA06	Vaccine against diphtheria, tetanus, pertussis (acellular), poliomyelitis (inactivated) and Haemophilus type B (conjugate), adsorbed	sc	A	B	C = B/A	D	E = B * D/A
37	J07CA09	Vaccine against diphtheria, tetanus, pertussis (acellular), poliomyelitis (inactivated), hepatitis B (recombinant) and Haemophilus type B (conjugate), adsorbed	sc				300.000	

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

**Method of realisation:** The final total price shall be indicated by the Bidder in EUR, excluding VAT, as indicated by the individual items on the pro forma invoice. By 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.



## 5. 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) or holds conformation of an authority responsible for the medicinal product stating that the holder of the marketing authorization submitted to the administration an application for the extension of the marketing authorization in accordance with the applicable law;
- unregistered medicinal products - holding a valid decision - a marketing authorization in one or more Member States of the EU, EEA, Switzerland, USA or Canada or holds conformation of an authority responsible for the medicinal product stating that the holder of the marketing authorization submitted to the administration an application for the extension of the marketing authorization in accordance with the applicable law.

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

The medicinal product shall 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.

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

Bidder:

Full name of the  
company:

Registered office and  
municipality:

No. of entry in the register  
of companies:

Reg. insert  
No.:

Company's reg. ID no.:

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

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

1. there are no reasons for exclusion as stipulated in the first, second and fourth paragraph of Article 75 of ZJN-3;
  2. the following reasons for exclusion do not exist:
    - a) breach of obligations regarding the fulfilment of liabilities regarding environmental, social or labor law as per the European Union, regulations applicable in the Republic of Slovenia, collective contracts or the rules of international environmental, social and labor law.
    - b) if proceedings have been brought against an economic operator due to insolvency or compulsory winding up in accordance with the law governing companies, if its assets or operations are governed by a liquidator or court, or if their business activities have been temporarily halted, or if in accordance with the regulations of another country proceedings have begun against it or a situation with the same legal effects has arisen.
    - c) if the economic operator is guilty of grave professional misconduct which has undermined its integrity;
    - d) if the Contracting Authority may 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 as per 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 it will initiate infringement proceedings;
    - e) if the conflict of interest as per the third paragraph of Article 91 ZJN-3 cannot be efficiently remedied with other, less stringent measures;
-

- f) if due to the previous participation of economic operators in the drafting of the public Procurement Procedure in Accordance with Article 65 ZJN-3 cannot be efficiently remedied with other, less stringent measures;
- g) if major or persistent deficiencies in the fulfilment of a key obligation were 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;
- h) if the economic operator is guilty of serious misrepresentation in providing 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 as per Article 79 ZJN-3;
- i) if the economic operator attempted to unjustifiably influence the Contracting Authority's decision making or acquire confidential information that would give them unjustified advantage in the Public Procurement procedure, or due to negligence stated misleading information that could significantly influence a decision on exclusion, selection, or the awarding of the public contract.

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

**Subject of contract:**

**Purchase of medicinal products for vaccination**

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**Company name:**

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**Address:**

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

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

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

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

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

Place and date:

Signature of the person responsible for quality:

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

**Subject of contract:**

**Purchase of medicinal products for vaccination**

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**Company name:**

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**Address:**

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

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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 9.1**

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**

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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 medicinal products for vaccination'** 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 9.2.**

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 medicinal products for vaccination**' 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 10**

Name Registered office Telephone Telefax 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 11**

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:**

<b>Name of bidder:</b>	
<b>Registered office of bidder:</b>	
<b>Registration ID no.:</b>	
<b>Tax ID no.:</b>	

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:

<b>No.</b>	<b>Name:</b>	<b>Registered office:</b>
<b>1</b>		
<b>2</b>		
<b>3</b>		
<b>...</b>		

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

<b>No.</b>	<b>Name and surname</b>	<b>Permanent residence address</b>	<b>Participating interest in %</b>
<b>1</b>			
<b>2</b>			
<b>3</b>			
<b>...</b>			

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.

### 13. Model Framework agreement – Form 12

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

#### CONTRACT ON THE PURCHASE OF MEDICINAL PRODUCTS FOR VACCINATION

##### Introductory Provision

##### Article 1

The Contracting Authority has carried out the public contract award procedure for the Purchase of medicinal products for vaccination, in accordance with Article 39(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 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.

## Quality

### Article 3

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

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

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

The medicinal product shall comply with the:

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

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

Each medicine series must be accompanied by documents that ensure the traceability of the medicine, confirm the quality of the medicinal product and is required for the entry 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 4

The prices of medicinal products 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 5**

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

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

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

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

If the Contractor introduces (enters) or imports the vaccine into the Republic of Slovenia, they shall also hand over to the Contracting Authority a 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 6**

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

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

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

## **Contractor's Guarantees and Obligations**

### **Article 7**

The Contractor shall perform its activity in accordance with:

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

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

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

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

The Contractor shall regularly notify the Contracting Authority of eventual changes in the marketing authorisation or other procedures relating to the medicinal product and conducted by the authority competent for medicinal products. The 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 8**

In the event of delay in the supply of the medicinal product, the Contracting Parties agree on a contractual penalty equivalent to 0.5% of the order value of the consignment in delay for each calendar day of delay, whereby the penalty may in no event exceed 5% of the value of the order which is supplied with a delay.

The supply of the medicinal product shall be deemed the delivery of the medicinal product and the entire documentation on the medicinal product required pursuant to the contractual provisions.

In the event of a delay which is not attributable to the Contracting Authority, the Contractor shall be obliged to pay a contractual penalty to the Contracting Authority. The contractual penalty shall be calculated accounted and charged upon the payment of the contract price.

If the Contractor is late with the supply and the Contracting Authority thereby incurs damage higher than 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 Contractor is no longer able to accomplish their intended purpose due to delays or faults in delivery.

## **Payment Method**

### **Article 9**

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

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

In the event of a delay in payment, the Contractor may charge interest on the arrears at the statutory rate. In the event of a well-founded complaint by the Contracting Authority with respect to the quality of the medicinal product or adequacy of documentation, the Contractor is not entitled to interest on arrears.

### **Authorised Representatives**

#### **Article 10**

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

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

The authorised representative of the Contractor is \_\_\_\_\_.

### **Duration of the Framework agreement**

#### **Article 11**

This contract is concluded with the signature date of the last of the two contractual partner.

The Framework Agreement shall be valid for a period of four (4 )years from 1.9.2019 till 31.8.2023.

### **Termination of the Framework agreement**

#### **Article 12**

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

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

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

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

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

### **Confidentiality**

### **Article 13**

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

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

The Contractor shall be obliged to notify their employees that they could come into contact with confidential or personal information in their work and that in their work they must handle such information with the maximum care.

At least the same strict data protection regime as the regime that applies to the Contracting Authority shall also apply to the Contractor that performs contractual obligations for the Contracting Authority.

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

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

### **Anti-Corruption Clause**

#### **Article 14**

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

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

shall be null and void.

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

This Framework agreement is concluded under a resolutive 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 resolutive 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 resolutive on the thirtieth day since the familiarisation with the violation.

## **Subcontractors**

### **Article 15**

The Contractor shall execute the works without subcontractors.

  OR  

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

[name and full address],

Legal representative of the subcontractor:

Registration ID no.:

Tax ID no.:

C.A. no.:

Subject of works:

Place and deadline of execution:

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

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

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

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

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

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

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

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

## **Final Provisions**

### **Article 16**

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

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

No.:  
In Ljubljana, \_\_\_\_\_

No.:  
In \_\_\_\_\_, \_\_\_\_\_

CONTRACTING AUTHORITY:

CONTRACTOR:

National Institute of Public Health

Nina Pirnat, dr. med. spec.  
Director

**Annexes:**

Annex 1: Specification

Annex 2: Bid

Annex 3: Price specification

Annex 4: Information on Subcontractors

Annex 5: Partnership Contract