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**Specification**

**for the purchase of medicine Naloxone.**

**Profile of the service customer.**

IBF "Alliance of Public Health" (hereinafter the Alliance) is a leading professional organization that, in cooperation with key public organizations, the Ministry of Health and other government bodies, fights against a number of epidemics, including HIV/AIDS and TB in Ukraine, manages prevention programs and provides quality technical support and financial resources to organizations on the ground. The mission of the Alliance is to reduce the spread of infections and mortality and to reduce the negative impact of epidemics by supporting public response to them in Ukraine, as well as by spreading effective approaches to prevention and treatment in Eastern Europe and Central Asia.

As an independent legal entity, registered in Ukraine since 2003 and after acquiring management independence since January 2009, the Alliance shares the values and remains a member of the global partnership Frontline AIDS, which was previously known as the IBF "International Alliance for HIV/AIDS" (an international charitable organization, which connects 30 organizations from different countries, with the Secretariat in Hove, Great Britain).

The purchase takes place within the framework of the implementation of the program:

"Acceleration of progress in reducing the burden of tuberculosis and HIV infection in Ukraine" in accordance with the Grant Agreement No. 3644 dated December 19, 2023 (grant name UKR-C-AUA) between the Public Health Alliance and the Global Fund to fight AIDS, tuberculosis and malaria.

Importantly! Payment is made without value added tax on the basis of Clause 26 of Subsection 2 of Chapter XX of the Tax Code of Ukraine.

1. **Requirements for products for purchase.**
   1. **Medicines for purchase:**

|  |  |  |
| --- | --- | --- |
| **№** | **Goods** | **Total number** |
| 1 | Naloxone - solution for injection 0.4 mg/ml ampoule 1 ml box, No. 10 | 134 920 ampoules |

1.2. The number of ampoules can be adjusted according to the multiplicity of packaging.

1.3. The Alliance reserves the right to increase or decrease the quantity of purchased Goods within +/- 20%.

**2. Terms of delivery and payment.**

2.1. The delivery is expected: 50% of the goods by 15.01.2025 and 50% of the goods by 31.03.2025. The buyer allows the delivery of the order in several batches before the specified delivery date. However, participants are invited to provide their own forecasts regarding the terms of delivery of partial and full volume of the order, as well as delivery in several lots in the price offer (see Appendix No. 3 to this Specification).

2.2. Delivery basis:

The consignee of the Goods is the Alliance. To the attention of the participants: the Alliance does not have a license for the right to carry out wholesale trade in medicinal products. The delivery will be made to the pharmacy warehouse, which carries out responsible storage for the Alliance, located at the address: "Pharmasoft" LLC, str. Boryspilska 9, p. Velyka Oleksandrivka, Boryspil district, Kyiv region.

2.3. Terms of payment:

• Advance payment of 50% of the cost of the Goods. Payment terms: 10 banking days after signing the supply contract;

• Final payment of 50% of the cost of the Goods - within 10 banking days after completion of delivery;

• Or balance payment of 100% of the cost of the Goods - within 10 banking days after completion of delivery.

2.4. The supply contract will be concluded and payments will be made in:

• hryvnias of Ukraine for residents of Ukraine, which will be the equivalent in dollars according to the official exchange rate of the National Bank of Ukraine on the day of invoicing.

• US dollars with non-residents of Ukraine.

**3. Registration requirements.**

3.1. Medicinal products proposed for this procurement must be registered for use in Ukraine in accordance with current legislation at the time of submission of tender documents.

3.2. In the event that the medicinal product is not registered on the date of submission of the commercial offer, the winner of the competition undertakes to provide documentation proving its registration for use in Ukraine no later than the date of delivery (March 31, 2025).

3.3. If, at the time of submission of the application for participation in the competition, there are less than 90 days left before the expiration of the certificate of state registration, a letter issued by the authorized state body that takes care of the registration of pharmaceutical preparations must be provided, which will testify to the fact of submitting an application for re-registration.

The supplier must provide a copy of the registration certificate certified by the supplier's seal.

**4. Primary packaging and Marking.**

4.1. The primary packaging must preserve the quality, safety and stability of the drug it contains. All packaging must be properly sealed and protected from tampering. All components of the packaging must meet the standards in force in Ukraine according to the current legislation, and be approved for the packaging of pharmaceutical products by the national regulatory authorities of the country of manufacture. Each package must contain instructions for the medical use of drugs in the Ukrainian language.

4.2. Marking of the primary packaging must be done in accordance with the registration dossier for products in Ukraine.

**5. Expiry date.**

At the time of delivery of products to the logistics warehouse of the Alliance, their remaining shelf life should be **at least 75%.**

**6. Number of series of products in the order.**

6.1. Delivery should be made within the framework of the smallest possible number of product series.

**7. Compliance with Good Manufacturing Practice (GMP) procedures.**

The production process of the proposed drug must meet the requirements of good manufacturing practice (GMP), which must be documented by the following documents:

• a certificate of compliance with the requirements of good manufacturing practice or an opinion on confirmation of compliance with the requirements of good manufacturing practice, issued by the State Service of Ukraine for Medicinal Products. In the event that the validity period of the GMP certificate/conclusion issued by the State Service of Medicines of Ukraine expires before 31.03.2025, a guarantee letter must be provided from the official distributor or authorized representative office of the manufacturer stating that the validity of the certificate/conclusion will be extended without interruption . In the event that at the time of submission of the tender offer, the validity period of the GMP certificate will be less than 30 days, the original number and date of the application submitted to the State Service of Medicines of Ukraine for the purpose of extending the validity period of the conclusion/certificate must be provided.

**8. Composition of the tender documentation.**

As part of its tender application, the tenderer must submit the following documentation:

8.1. A copy of the documentation proving the state registration of the participating company in accordance with the legislation of the relevant country.

8.2. If the participant is an intermediary (does not produce goods, but offers the products of another legal entity) - a warranty letter issued by the manufacturer confirming the status of the participant as a distributor of such products (if possible).

8.3. A copy of a valid registration certificate for the drug, issued by the relevant authorized body in Ukraine and certified by the supplier's seal, in accordance with the requirements of clause 3 of this specification or a letter from the participant in accordance with the requirements of paragraph 2 and 3 of clause 3 of this specification.

8.4. Instructions for medical use, written in Ukrainian.

8.5. A copy of the documentation confirming the compliance of the production with the requirements of item 7 of the specification.

8.6. Completed and duly signed Annexes No. 1-4 (Annex №3 additionally in .doc format).

**9. Requirements for drawing up a tender offer**

Please ensure that your tender is properly structured:

9.1. Documents must be structured according to the list specified in Clause 8 of this Specification;

9.2. The tender offer must contain a table of contents with a list of all submitted documents;

9.3. All documents drawn up in languages other than Ukrainian, English or Russian must necessarily have a translation into one of the specified languages;

9.4. Scanned copies of each document must be certified by signature and seal; additionally, Appendix No. 3 in word format.

9.5. Proposals must be sent in encrypted ZIP archives to a separate e-mail box: tenders@aph.org.ua:

• In the subject of the letter, it is necessary to indicate: Attention: Blaise Olga, proposal for a tender for the purchase of medicine Naloxone.

• Indicate in the letter:

|  |
| --- |
| **PROPOSAL FOR TENDER**  **From LLC "\_\_\_\_\_\_\_\_\_"**  **for the purchase of medicine Naloxone.**  **DO NOT DISCLOSE until 12:00 p.m., November 20, 2024** |

• In parallel with the proposal, send a notification about sending this proposal to the email address: blaise@aph.org.ua:

LLC "\_\_\_\_\_\_\_" sent a price offer for the tender for the purchase of medicine Naloxone in November … 2024 at ..:.. .

• November 20, 2024 until 12:15 p.m. send the password from the offer to the chat, messenger or email address: blaise@aph.org.ua.

**10. Key criteria for evaluating tender offers:**

a) compliance of the participant's application with the conditions of the tender documentation;

b) price;

c) delivery terms in accordance with clause 2.1. Specifications.

**Annex# 1 to the Specification for the purchase of medicine Naloxone.**

Familiarize yourself with the text of the form and submit it in its completed form to the tender organizer.

To ICF "Alliance of Public Health"

Dear ladies and gentlemen,

Our company confirms that it has received the tender documentation from the tender organizer as part of the tender announcement, specifications and annexes to it. After we have carefully and carefully studied these tender documents, we propose to supply (manufacture) the specified goods (list...) in full accordance with the requirements of the specified tender documents at the prices indicated in our tender offer contained in the appendices.

We undertake, in the event that our company's offer is recognized as the winner, to provide the specified goods in accordance with the conditions specified in the tender documentation.

By submitting our tender offer for consideration, we agree to the validity period of our offer specified in the tender announcement and warrant that our company undertakes to carry out our offer at any time until the expiry of the specified tender offer period.

Until the moment when the contract for the provision of the above-mentioned services is concluded and executed by all parties, this tender offer together with the official confirmation of the IBF "Alliance of Public Health" on receipt of our offer and the notification of the selected tender winner(s) are considered binding on both parties to the agreement.

We understand that IBF "Alliance of Public Health" is not obliged to recognize as the winner of this tender the cheapest from an economic point of view or any of the tender offers received.

We confirm that our company, from a legal and organizational point of view, is able to fulfill the obligations assumed by submitting this tender offer.

Signed by me, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

who holds the position of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (head of the enterprise)

on behalf of the company \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_ (number) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (month) 20\_\_\_\_\_\_\_\_ (year).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (signature)

**Annex# 2 to the Specification for the purchase of medicine Naloxone.**

General information

Please fill in the table below:

|  |  |  |
| --- | --- | --- |
| 1. | Full name of the company |  |
| 2. | Legal address of the company |  |
| 3. | Mailing address of the company |  |
| 4. | General manager of the company (name, title) |  |
| 5. | Contact phone of the company manager |  |
| 6. | Contact person on Application submission issues |  |
| 7. | Contact person phone number |  |
| 8. | Email |  |

Signed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

holding the position of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

on behalf of the company \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_ (day) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (month) 20\_\_\_\_\_\_\_\_ (year).

# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (signature)

**Annex# 3 to the Specification for the purchase of medicine Naloxone.**

Price offer.

The offer is provided under the following conditions:

1. The price of the products is given on the terms of delivery in accordance with the requirements of clause 2 of the specification.

2. The price is given in US dollars;

3. The supply contract will be concluded and payments will be made in:

• hryvnias of Ukraine for residents of Ukraine

• US dollars with non-residents of Ukraine.

4. For contracts with residents of Ukraine: payments will be made in Ukrainian hryvnias in accordance with the official exchange rate of the National Bank of Ukraine on the day of invoicing.

5. The offer is valid for 90 days from the date of submission and the price cannot be changed during this period.

6. Basis of delivery: see clause 2 of the specification.

7. Terms of payment: see clause 2 of the specification.

8. "Expected delivery time in days" means the maximum period of time in calendar days required to deliver 100% of the ordered quantity of products. The period begins with the signing of the contract and ends with the date of delivery of the last package of products to the destination.

Please complete the table below.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **№** | **Goods** | **Dosage form options** | **Units to be procured** | **Brand Name and form**  **Quantity of items in 1 pack, pcs** | **Country of origin** | **Total shelf life** | **Remaining shelf life** | **Price for unit of Goods, USD, with VAT** | **Total amount,**  **USD, with VAT** | **Expected supply time in days** |
| **1** |  |  |  |  |  |  |  |  |  |  |

Signed by me, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

acting in the capacity of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(legal entity director)

on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_ (day) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (month) 20\_\_\_\_\_\_\_\_ (year).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (signature)

**Annex# 4 to the Specification for the purchase of medicine Naloxone.**

by signing this form, we confirm the following assurances, which are important for the conclusion of the contract with the ICF "Alliance for Public Health":

1. The Company (the legal entity that submits this and other documents for participation in the tender is specified below), any of its directors (members of the board of directors), members of the Company, its ultimate beneficial owner/owners, its officials or employees of the Company , or any agent, affiliate or other person acting on behalf of the Company, is not currently subject to US sanctions administered by the Office of Foreign Assets Control of the US Department of the Treasury or the US Department of State, the United Nations Security Council Nations, the European Union, Her Majesty's Treasury of the United Kingdom or other authorized sanctioning body.
2. The Company, and/or a member of the Company, and/or the ultimate beneficial owner of the Company are not included in the sanctions list of the National Security and Defense Council of Ukraine (in accordance with Article 5 of the Law of Ukraine "On Sanctions").
3. Personal special economic and other restrictive measures (sanctions) have not been applied to the Company's goods, services and/or works in accordance with Article 5 of the Law of Ukraine "On Sanctions".

**Composition of the final beneficiaries of the participant**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of the organization/ person's full name** | **Registration code/passport data** | **Registration address** | **Citizenship** | **Is the organization/ person included in the sanctions lists of the USA, the European Union, and Ukraine.** |
|  |  |  |  |  |
|  |  |  |  |  |

# *[signature] [position]*

Authorized to sign a commercial proposal for and on behalf of:

*[the company name] Company seal*