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**Specification for the purchase of the drug buprenorphine hydrochloride in sublingual tablets.**

1. **Details on the Company that makes the procurement (Buyer)**

The International Charitable Foundation "Alliance for Public Health" (hereinafter Alliance) is a professional organization which in cooperation with the key civil society organizations, Ministry of Health and other governmental bodies is fighting HIV/AIDS in Ukraine, managing prevention programs and providing high-quality support and financial resources to the local organizations. All these efforts are aimed at achieving universal access to comprehensive HIV/AIDS services in Ukraine and efficient community-based epidemic response based on the achieved results and best practices. As an independent legal entity registered in Ukraine since 2003 and after obtaining managerial independence since January 2009, Alliance shares the values and remains a member of the global International HIV/AIDS Alliance partnership (international charitable organization combining 30 organizations from different countries, with the Secretariat located in the city of Hove, Great Britain).

Alliance’s mission is to reduce the spread of HIV infection and AIDS mortality, as well as alleviate negative impact of epidemic through supporting community action against HIV/AIDS in Ukraine and disseminating effective approaches to HIV prevention and care throughout Eastern Europe and Central Asia.

The main programs carried out by the Alliance are supported by the Global Fund to fight AIDS, Tuberculosis and Malaria (hereinafter the Global Fund).

The Goods are supplied (provided) in scope of fulfilment of the programme «Assessing the values and preferences, feasibility, effectiveness and cost-effectiveness of delivery long-acting depot buprenorphine (LADB) as part of routine treatment of opioid dependence in low- and middle-income countries: a multicenter international study»

2. Basic conditions and requirements

2.1. Total amount of buprenorphine hydrochloride before purchase

|  |  |  |
| --- | --- | --- |
| № | Dosage | Number of tablets |
| 1 | Sublingual buprenorphine tablet 2 mg | 1000 |
| 2 | Sublingual buprenorphine tablet 4 mg | 750 |
| 3 | Sublingual buprenorphine tablet 8 mg | 400 |

2.2. a deviation of the actually purchased quantity of products within +/- 20% of the above volumes is allowed at the buyer's discretion;

2.3 Release form: sublingual tablets.

2.4 Only sublingual tablets of the following dosages are accepted for purchase: 2 mg, 4 mg, 8 mg.

2.5 Number of tablets in 1 package: no more than 100.

2.6 The expected delivery time to Cairo, Egypt of the full volume determined by paragraph 2.1. of this specification, no later than December 1, 2024. However, the participant is invited to provide his own forecasts regarding the possible terms of delivery of the batch of goods.

2.7 Terms of delivery:

i. for companies resident in Egypt: delivery to 3 recipient warehouses, (Heliopolis Psychiatric Hospital (Al-Matar), Maamoura Hospital for Mental Health and Addiction Treatment, Abbassia Hospital for Mental Health and Addiction Treatment

ii. for non-residents of Egypt: DAP Cairo airport (Incoterms 2010).

2.8 The prices of all tender proposals must be declared in US dollars. The declared price must include all necessary costs, taxes and fees, which are mandatory for this basis of delivery.

2.9 A supply contract will be concluded and payment for the delivered products will be made in US dollars;

2.10 Products must be delivered without VAT!

2.11 Terms of payment:

50% advance payment after signing the contract / 50% payment upon product delivery

Or

100% upon delivery of products.

**3. Raw materials**

3.1 Pharmaceutical products offered for this procurement must be manufactured from quality-assured raw materials obtained from a licensed manufacturer or its authorized distributor. This rule applies to active and auxiliary substances.

**4. Registration requirements**

4.1. The medicinal product offered by the tenderer must be registered in one of the countries with a strict regulatory policy (EU countries, USA, Canada, Australia, Japan)

4.2. If the product is not registered under Egyptian law, the customer will be able to obtain a one-time permit for the import of such medicinal product. The estimated time for obtaining such a permit is 2 months. At this time, finished products assembled and ready for delivery must wait for permission at the shipper's warehouse.

**5. Licensing**

5.1 Pharmaceutical products proposed for this procurement must be properly licensed for sale by the regulatory authority of the country of manufacture. A valid certificate(s) must be provided (eg "Certificate of Free Sale", "Drug Registration Card", etc.) showing the dosages of Buprenorphine Hydrochloride Sublingual Tablets offered for this purchase.

5.2 Certificates must be valid for at least 6 months from the date of submission of the application for participation in the tender. If the certificate expires less than 6 months from the date of submission of the application for participation in the tender, a letter explaining the current status of license renewal or extension must be provided.

**6. Compliance with good manufacturing procedures (GMP)**

The certification stating that the pharmaceutical products offered under this purchase are manufactured in compliance with good manufacturing practices (GMP) shall be provided. Each Bidder shall submit certificates of GMP compliance of manufacturer (hereinafter – GMP certificate) for each production site in use for the manufacturing of buprenorphine hydrochloride in sublingual absorption tablets designated for supply within the framework of this bidding process.

The GMP certificate for each production site shall contain the date of the most recent authorized inspection to this site.

Certificates shall be valid at least for the six month period starting from the date of submission of the bid. If certificates expire earlier than in 6 month since submission of the bid, the explanatory letter providing the current status of the renewal or prolongation of the certificates have to be attached.

**7. Primary container**

The primary container should maintain the quality, safety and stability of the product contained. All packaging must be properly sealed and tamper-proof. All packaging components must meet criteria of the product registration documents for pharmaceutical packaging by the manufacturer’s national regulatory authority.

1. **Labelling of primary container and Instruction for use.**

The labelling of primary container for each pharmaceutical product shall be made in accordance with the registration dossier.

Instruction for the product use to be made in English or Arabic.

1. **Lots per order**

The supplier shall form the order using the fewest number of manufacturing lots possible. Preference will be given to proposals that, ceteris paribus, will guarantee one series for each dosage.

1. **Shelf life**

Total shelf life of drugs has to be not less than 3 years.

At the time of inspection or preparation for delivery to the country of destination, no more than 20% of product shelf life shall have expired since the date of manufacture shown on the batch release or Certificate of analysis (conformance).

If requested the supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data to validate stated shelf life of the product.

1. **Quality**

Products and packaging shall be free of defects that impair their serviceability, affect their shelf life, or detract from their appearance.

1. **Content of one’s bid**

Bidders are required to submit the following documentation:

i. Documents certifying the participant's registration as a legal entity

ii. If the Participant is not a product manufacturer, provide a copy of the documents certifying the right to offer products issued by the product manufacturer (Authorization letter, distributor certificate, power of attorney, etc.)

iii. A copy of a valid license for sale (for example, "Certificate of free sale", "registration card of medicinal product", etc.), issued by the authority regulating the circulation of pharmaceutical products in the country of origin of the medicinal product, in accordance with clause 5 of this specification.

iv. A copy of valid GMP certificates in accordance with Clause 6 of this specification.

v. A document confirming the registration of the medicinal product in countries with a strict regulatory policy, in accordance with clause 4 of this specification.

vi. Completed annexes to the Specification: Annex No. 1 (competition participant form), Annex No. 2 (table of price offers), Annex No. 3 (confirmation of compliance of the participating company and its products with the technical and organizational criteria of this specification), Annex No. 4 (final beneficial owners of tender participants)

vii. Instructions for medical use of the drug in English or Arabic;

1. **Key criteria for evaluation of tenders:**
   * 1. product conformity with specification requirements;
     2. product price;
     3. time of delivery

# Annex 1 to the Specification

Bidder’s Information

Please fill in the table below

|  |  |  |
| --- | --- | --- |
|  | Company name |  |
|  | Company address (registration) |  |
|  | Actual address of the company (location) |  |
|  | Head of the company (position, name, surname) |  |
|  | Telephone number of the Head of the company |  |
|  | e-mail of the Head of the company |  |
|  | Contact person for submitting Bids |  |
|  | Telephone number of contact person |  |
|  | e-mail of contact person |  |

Dated this \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20...

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name, surname, patronymic\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position: \_\_\_\_\_\_\_\_\_\_\_\_\_

Annex 2 to the Specification

Please fill in the table below as quotations of your company under this bid.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| # | INN, dosage form | Proprietary trade name of the product | Country of origin | Qnty, tablets | Number of tablets in 1 pack | Price of 1 pack, without VAT, upon terms of delivery said in clause 1 of the specification |
| 1 | Buprenorphine Hydrochloride,  sublingual absorption tablets, strength 2.0 mg |  |  | 1000 |  |  |
| 2 | Buprenorphine Hydrochloride,  sublingual absorption tablets, strength 4.0 mg |  |  | 750 |  |  |
| 3 | Buprenorphine Hydrochloride,  sublingual absorption tablets, strength 8.0 mg |  |  | 400 |  |  |

Please indicate the proposed terms of payment\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name, surname, patronymic\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Annex 3 to the Specification

Please fill in the table below as the Bidder’s declaration of compliance with the technical and organizational criteria of the specification.

| # | Specification criteria | Confirmation of compliance with the criteria or declaration of discrepancy to the criteria |
| --- | --- | --- |
|  | Offered product is in compliance with clause 2 of the specification. |  |
|  | Active and supplementary substance raw materials are in compliance with clause 3 of the specification. |  |
|  | Compliance with the registration and licensing requirements of clauses 4 and 5 of the specification |  |
|  | Primary container is in compliance with clause 6 of the specification. |  |
|  | Manufacturer ensures labelling and Instruction for use in compliance with clause 7 of the specification. |  |
|  | Consent to comply with the requirements under clause 8 of the specification. |  |
|  | Consent to ensure the products shelf-life in compliance with clause 9 of the Specification. |  |
|  | Ensuring compliance with the requirements of clause 10 of the Specification. |  |
|  | Ensuring compliance with the requirements of clause 11 of the Specification. |  |
|  | In case of being awarded with contract, the company agrees to conclude the contract based on the draft contract that is part of tender documentation under this bidding. |  |
|  | Maximum time needed for the manufacturer of offered products to provide Buyer with certificates of quality for each batch of manufactured products, to be calculated in days since the date of the conclusion of supply contract. |  |

Dated this \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20...

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_