**SECTION 4**

**Criteria for award and checklist of documents required**

Following documents should be attached to the filled-in sections #-8

Please ensure that all documents necessary to enable objective evaluation are attached to your response to this ITB:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Award Criteria** | **Corresponding document** | **Yes** | **No** | **Reference** |
| **Compliance of Bidder with Qualifications Requirements** | | | | |
| Minimum 3 years of experience in similar nature and minimum 2 similar contracts fulfilled over the past 3 years | 1. Certificate of Registration of the business, including Articles of Incorporation, or equivalent document if Bidder is not a corporation |  |  |  |
| 2. Statement of Satisfactory Performance (Reference letters) from the Top 3 Clients in terms of Contract Value the past 3 years. Please provide reference letters to prove experience in similar nature of contracts |  |  |  |
| Minimum annual turnover over the past 2 years shall equal to no less than 75% of the total amount to be contracted | 3. Latest Audited Financial Statement (Income Statement and Balance Sheet) including Auditor’s Report for the past 2 years |  |  |  |
| **Compliance of product/quoted with product standards and requirements (please complete checklist for each product quoted)** | | | | |
| 1.1. Medical products must be produced and controlled in accordance with product standards and quality system standards recommended by the World Health Organization (WHO) AND/OR the International Medical Devise Regulators Forum (IMDRF) (former Global Harmonization Task Force (GHTF). In order to be compliant with this criterion bidders will be requested to provide one of the following pre-market approval(s) / market clearance(s) (please refer for details to Section 3 of ITB). | Medical Device license (Canada), OR |  |  |  |
| EC Full Quality Assurance Certificate or EC Production Quality Assurance Certificate cate or EC Type-Examination Certificate (CE/ Conformité Européenne mark) or / Conformité Européenne 92/42 or CE/ Conformité Européenne 98/79, OR |  |  |  |
| TGA Production Quality Assurance Certificate or TGA Type-Examination Certificate or TGA Full Quality Assurance Certificate issued by Therauptic Goods Administration), OR |  |  |  |
|
| PMDA (Pharmaceuticals and Medical Devices Agency) approval or JMHLW (Japan Ministry of Health, Labour and Welfare) Minister’s approval, OR |  |  |  |
|
| PMA (pre-market approval) letter or BLA license (Biologics License Application) or 510k device letter issued by US Food and Drug Administration |  |  |  |
| 2.1. The proposed product(s) must have registered/certified for the use in Ukraine (please refer for details to Section 3 of ITB) | Registration Certificate issued by the State Administration on Pharmaceutical Products and Drugs Service of Ukraine, OR |  |  |  |
| Declaration of Conformity with the requirements of technical regulations issued for the use in Ukraine (Resolution of the Cabinet of Ministers of Ukraine #753, #754, #755) |  |  |  |
| AND |  |  |  |
| Evidence of at least one successfully completed supply of this product in the similar volume in/to Ukraine within the past three years confirmed by medical institution/diagnostic center/laboratory center (since March 2014) |  |  |  |
| 1.2.a./2.2.a. Suppliers and manufacturers must provide an evidence of conformity\* to at least one of the following conformity with the following Quality Management System standards as recognized by GHTF standard | ISO 13485, OR |  |  |  |
| ISO 9001, OR |  |  |  |
| United States QS (21 CFR part 820), OR |  |  |  |
| Japan QS Standard for medical devices |  |  |  |
| 1.2.b./2.2.b. Suppliers and manufacturers must provide an evidence of GMP certification of manufacturing site by PIC/S authorities | A copy of valid GMP Certificate issued by PIC/S authorities for the manufacturing site(s) of the proposed product(s) |  |  |  |
| Availability of valid registration/certification in Ukraine at the time of supply as defined in Section 3, (if, at the moment of the bid submission, the quoted medical products are not registered in Ukraine but comply with the quality requirements of this ITB (OPTION 1), a Commitment letter shall be provided) | Option A: A copy of a valid registration certificate for every medicinal product quoted issued by the Ministry of Health of Ukraine AND/OR Declaration of Conformity with the requirements of technical regulations (Resolution of the Cabinet of Ministers of Ukraine #753, #754, #755 dd. 02.10.2013) |  |  |  |
| Option B: If, at the moment of the bid submission, the quoted medicinal products are not registered/certified in Ukraine but comply with the quality requirements of this ITB, a Commitment letter (Annex 2) from the bidder acknowledging acceptance of the terms and conditions for undertaking a registration/certification procedure (see Section 3, para #3 Registration/Authorization for use in Ukraine for details) . By submitting the Bid, the Bidder automatically agrees to maintain and renew registration/certification for these products until their shelf life expiration. |
| Compliance with shelf life, packing and labelling requirements (please refer for details to Section 3 of ITB). | Please provide Information on shelf life in the Form 7 Technical Bid Form |  |  |  |
| Acceptability of the Transportation/Delivery Schedule (please refer for details to Section 3 of ITB) | Please provide Information on delivery schedule in the Form 7 Technical Bid Form |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **List of other documents required for evaluation of Bidder** | **Yes** | **No** | **Reference** |
| List of Shareholders and Other Entities Financially Interested in the Firm owning 5% or more of the stocks and other interests, or its equivalent if Bidder is not a corporation |  |  |  |
| Valid Certificate of Authorization to act on behalf of the Manufacturer in case the bidder is not a Manufacturer. |  |  |  |
| All information regarding any past and current litigation during the last five (5) years, in which the bidder is involved, indicating the parties concerned, the subject of the litigation, the amounts involved, and the final resolution if already concluded. |  |  |  |
| Quality Certificate (e.g., ISO, etc.) and/or other similar certificates, accreditations, awards and citations received by the Bidder, if any |  |  |  |
| Environmental Compliance Certificates, Accreditations, Markings/Labels, and other evidences of the Bidder’s practices which contributes to the ecological sustainability and reduction of adverse environmental impact (e.g., use of non-toxic substances, recycled raw materials, energy-efficient equipment, reduced carbon emission, etc.), either in its business practices or in the goods it manufactures, if any available |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **List of other documents required for evaluation of product quoted (please complete checklist for each product quoted)** | **Yes** | **No** | **Reference** |
| Instruction for the use in accordance with the legislation of Ukraine. In case quoted medicinal products are not registered/certified in Ukraine, instructions for the use in the original language shall be provided. |  |  |  |
| Technicalspecification of product quoted |  |  |  |
| Safety data sheet (SDS) of the product |  |  |  |
| Patent Registration Certificate/s, (if applicable) or relevant license/s (if available) |  |  |  |

**Annex 1**

**BRIEF SUMMARY**

**1. On the simplified procedure of state registration of medicinal products procured with involvement of the international organizations**

The procedure of state registration (re-registration) of medicinal products was approved by the Cabinet of Ministers of Ukraine Resolution No. 376 of 26.05.2005.

State registration of the medicinal products procured by international organizations is provided by the Ministry of Health of Ukraine pursuant to an application and subject to an opinion of the MoH State Expert Centre (hereinafter referred to as the Centre) drawn up on the basis of results of the expert examination of the registration materials for their authenticity, conducted according to the procedure specified by the MoH of Ukraine.

Information on the procedures for state registration may be found under the below links:

1. Law of Ukraine "On Medicines"

<http://zakon2.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80>

2. Decree of the Cabinet of Ministers of Ukraine dated 26.05.2005 № 376

<http://zakon5.rada.gov.ua/laws/show/376-2005-%D0%BF>

3. Decree of MOH of Ukraine dated 03.11.2015 № 721

<http://zakon2.rada.gov.ua/laws/show/z1453-15>

**2. On additional relevant information on VAT for bidders. This information is provided for references only and UNDP should not be hold accountable for any details. Bidders are encouraged to check the details with relevant authorities directly.**

Operations on supply (transfer) of pharmaceuticals and medical products shall be temporarily, until March 31, 2019, exempt from VAT, if importation and/or supply is done under contracts with specialized procurement organizations listed in the Law of Ukraine ‘On Public Procurement’, concluded with the objective of implementing agreements between the central executive body of Ukraine in charge of developing and implementing the national health policy and a relevant specialized procurement organization within the framework of budget programmes for implementation of public health action plans and/or comprehensive programme activities in the health sector.

Provided VAT exemption condition may not be applied under the Ukrainian legislation. VAT amount should be clearly indicated in a separate line (if applicable).

For more information on VAT exemption, please refer to the following legislation documents:

1. Tax Code of Ukraine, Chapter #XX Transitional Provisions, Section #2; Paragraph #38 on conditions of temporary VAT exemption of medicines and medical products that are procured by specialized organizations for the National Public Health Programme to the Ministry of Health (MoH) in Ukraine: <http://zakon2.rada.gov.ua/laws/show/2755-17/page45>

2. Decree of the Cabinet of Ministers of Ukraine #1153 dated 02.12.2015 on the procedures of importation, supply and targeted use of medicines, medical devices that are VAT exempted:

<http://zakon3.rada.gov.ua/laws/show/1153-2015-%D0%BF>

***Prices specified shall remain firm and not be increased. In case Offeror increase price after awarding contract, UNDP will consider this as a ground for contract termination, liquidating Bid or Performance Security amount and either awarding the next qualified Bidder or initiating a new bidding process.***

**Annex 2.**

**Commitment letter**

*(This should be written in the Letterhead of the Bidder. Except for indicated fields, no changes may be made in this template.)*

Insert: Location

Insert: Date

To: [*insert: Name and Address of UNDP focal point]*

Dear Sir/Madam:

We, the undersigned, hereby offer to supply the goods required for [*insert: title of goods and services required as per ITB*] in accordance with your Invitation to Bid dated  **.**

We hereby commit to register/certify the below listed products as per current Ukrainian legislation requires.

Products:

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. ….

We fully understand and recognize that UNDP is not bound to accept this Bid, that we shall bear all costs associated with its preparation and submission, registration fees and that UNDP will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the evaluation.

We remain,

Yours sincerely,

Authorized Signature [*In full and initials*]:

Name and Title of Signatory:

Name of Firm:

Contact Details:

*[please mark this letter with your corporate seal, if available]*

**Annex 3.**

**Certificate of Authorization**

**to act on behalf of the Manufacturer in case the Bidder is not a Manufacturer**

*(This should be written in the Letterhead of the Manufacturer. Certificate shall cover all items for which the company is bidding)*

Insert: Location

Insert: Date

To: [*insert: Name and Address of UNDP focal point]*

Dear Sir/Madam:

We, the undersigned, who is established manufacturer or producer of [*insert name of products*], hereby authorize [*name and address of Bidder*] to submit a Bid, and subsequently sign and implement the contract, against the [*insert: title of goods and services required as per ITB*] for the supply of following products:

Products:

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. ….

For and on behalf of Manufacturer or Producer:

Yours sincerely,

Authorized Signature [*In full and initials*]:

Name and Title of Signatory:

Name of Firm:

Contact Details:

Section 5: Bid Submission Form[[1]](#footnote-1)

*(This should be written in the Letterhead of the Bidder. Except for indicated fields, no changes may be made in this template.)*

Insert: Location

Insert: Date

To: [*insert: Name and Address of UNDP focal point]*

Dear Sir/Madam:

We, the undersigned, hereby offer to supply the goods and related services required for [*insert: title of goods and services required as per ITB*]in accordance with your Invitation to Bid dated  **.**We are hereby submitting our Bid, which includes the Technical Bid and Price Schedule.

We hereby declare that:

1. All the information and statements made in this Bid are true and we accept that any misrepresentation contained in it may lead to our disqualification;
2. We are currently not on the removed or suspended vendor list of the UN or other such lists of other UN agencies, nor are we associated with, any company or individual appearing on the 1267/1989 list of the UN Security Council;
3. We have no outstanding bankruptcy or pending litigation or any legal action that could impair our operation as a going concern; and
4. We do not employ, nor anticipate employing, any person who is or was recently employed by the UN or UNDP.

We confirm that we have read, understood and hereby fully accept the Schedule of Requirements and Technical Specifications describing the duties and responsibilities required of us in this ITB, and the General Terms and Conditions of UNDP’s Standard Contract for this ITB.

We agree to abide by this Bid for **120 days***.*

We undertake, if our Bid is accepted, to initiate the supply of goods and provision of related services not later than the date indicated in the Data Sheet.

We fully understand and recognize that UNDP is not bound to accept this Bid, that we shall bear all costs associated with its preparation and submission, and that UNDP will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the evaluation.

We remain,

Yours sincerely,

Authorized Signature [*In full and initials*]:

Name and Title of Signatory:

Name of Firm:

Contact Details:

*[please mark this letter with your corporate seal, if available]*

Section 6:

Documents Establishing the Eligibility and Qualifications of the Bidder

Bidder Information Form[[2]](#footnote-2)

Date: *[insert date (as day, month and year]of Bid Submission*]

ITB No.: *[insert number of bidding process]*

Page \_\_\_\_\_\_\_\_of \_\_\_\_\_\_\_\_ pages

|  |  |  |
| --- | --- | --- |
| 1. Bidder’s Legal Name *[insert Bidder’s legal name]* | | |
| 2. In case of Joint Venture (JV), legal name of each party: *[insert legal name of each party in JV]* | | |
| 3. Actual or intended Country/ies of Registration/Operation: *[insert actual or intended Country of Registration]* | | |
| 4. Year of Registration in its Location: *[insert Bidder’s year of registration]* | | |
| 5. Countries of Operation | 6. No. of staff in each Country | 7.Years of Operation in each Country |
| 8. Legal Address/es in Country/ies of Registration/Operation:*[insert Bidder’s legal address in country of registration]* | | |
| 9. Value and Description of Top three (3) Biggest Contract for the past five (5) years | | |
| 10. Latest Credit Rating (Score and Source, if any) | | |
| 11. Brief description of litigation history (disputes, arbitration, claims, etc.), indicating current status and outcomes, if already resolved. | | |
| 12. Bidder’s Authorized Representative Information  Name: *[insert Authorized Representative’s name]*  Address: *[insert Authorized Representative’s Address]*  Telephone/Fax numbers: *[insert Authorized Representative’s telephone/fax numbers]*  Email Address: *[insert Authorized Representative’s email address]* | | |
| 13. Are you in the UNPD List 1267.1989 or UN Ineligibility List ? ☐ YES or ☐ NO | | |
| 14. Attached are copies of original documents of:  ☐All eligibility document requirements listed in the Data Sheet  ☐If Joint Venture/Consortium – copy of the Memorandum of Understanding/Agreement or Letter of Intent to form a JV/Consortium, or Registration of JV/Consortium, if registered  ☐If case of Government corporation or Government-owned/controlled entity, documents establishing legal and financial autonomy and compliance with commercial law. | | |

Joint Venture Partner Information Form (if Registered)[[3]](#footnote-3)

Date: *[insert date (as day, month and year) of Bid Submission*]

ITB No.: *[insert number of bidding process]*

Page \_\_\_\_\_\_\_\_ of\_\_\_\_\_\_\_\_pages

|  |  |  |
| --- | --- | --- |
| 1. Bidder’s Legal Name: *[insert Bidder’s legal name]* | | |
| 2. JV’s Party legal name: *[insert JV’s Party legal name]* | | |
| 3. JV’s Party Country of Registration: *[insert JV’s Party country of registration]* | | |
| 4. Year of Registration: *[insert Party’s year of registration]* | | |
| 5. Countries of Operation | 6. No. of staff in each Country | 7.Years of Operation in each Country |
| 8. Legal Address/es in Country/ies of Registration/Operation: *[insert Party’s legal address in country of registration]* | | |
| 9. Value and Description of Top three (3) Biggest Contract for the past five (5) years | | |
| 10. Latest Credit Rating (if any) :Click here to enter text. | | |
| 1. Brief description of litigation history (disputes, arbitration, claims, etc.), indicating current status and outcomes, if already resolved. Click here to enter text. | | |
| 13. JV’s Party Authorized Representative Information  Name: *[insert name of JV’s Party authorized representative]*  Address: *[insert address of JV’s Party authorized representative]*  Telephone/Fax numbers: *[insert telephone/fax numbers of JV’s Party authorized representative]*  Email Address: *[insert email address of JV’s Party authorized representative]* | | |
| 14. Attached are copies of original documents of: *[check the box(es) of the attached original documents]*  ☐All eligibility document requirements listed in the Data Sheet  ☐Articles of Incorporation or Registration of firm named in 2.  ☐In case of government owned entity, documents establishing legal and financial autonomy and compliance with commercial law. | | |

Section 7: Technical Bid Form[[4]](#footnote-4)

|  |
| --- |
| ***INSERT TITLE OF THE ITB*** |

|  |  |
| --- | --- |
| **Name of Bidding Organization / Firm:** |  |
| **Country of Registration:** |  |
| **Name of Contact Person for this Bid:** |  |
| **Address:** |  |
| **Phone / Fax:** |  |
| **Email:** |  |

|  |
| --- |
| **SUBSECTION 3.1: EXPERTISE OF FIRM/ ORGANISATION** |
| *This section should fully explain the Bidder’s resources in terms of personnel and facilities necessary for the performance of this requirement.*  1.1 Brief Description of Bidder as an Entity: Provide a brief description of the organization / firm submitting the Bid, its legal mandates/authorized business activities, the year and country of incorporation, and approximate annual budget, etc. Include reference to reputation, or any history of litigation and arbitration in which the organization / firm has been involved that could adversely affect or impact the delivery of goods and/or performance of related services, indicating the status/result of such litigation/arbitration.  1.2. Financial Capacity: Based on the latest Audited Financial Statement (Income Statement and Balance Sheet) describe the financial capacity (liquidity, stand-by credit lines, etc.) of the bidder to engage into the contract. Include any indication of credit rating, industry rating, etc.  1.3. Track Record and Experiences: Provide the following information regarding corporate experience within at least the last five (5) years which are related or relevant to those required for this Contract.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Name of project** | **Client** | **Contract Value** | **Period of activity** | **Types of activities undertaken** | **Status or Date Completed** | **References Contact Details (Name, Phone, Email)** | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |

|  |
| --- |
| **SUBSECTION 3.2 - SCOPE OF SUPPLY, TECHNICAL SPECIFICATIONS, AND RELATED SERVICES** |
| *This section should demonstrate the Bidder’s responsiveness to the specification by identifying the specific components proposed, addressing the requirements, as specified, point by point; providing a detailed description of the essential performance characteristics proposed; and demonstrating how the proposed bid meets or exceeds the specifications.*  2.1. Scope of Supply: Please provide a detailed description of the goods to be supplied, indicating clearly how they comply with the technical specifications required by the ITB **(please see Annex 4 – Annex 4 should be submitted in both PDF and EXCEL formats)**; describe how the organization/firm will supply the goods and any related services, keeping in mind the appropriateness to local conditions and project environment.  2.1.1 Please describe the Freight Forwarder details and Arrangements. Ability to provide/coordinate necessary shipping services, including air, sea and cold chain delivery (if required)  2.1.2 Please provide the detailed Implementation Schedule.  **Delivery lead time is a factor of a crucial importance in this project. Please make all possible efforts to propose supply of all requested quantities within shortest timeframe possible. In case partial delivery is proposed, please provide suggested time schedule.**  *A supporting document with full details may be annexed to this section.*  2.2 Statement of Full Disclosure: This is intended to disclose any potential conflict in accordance with the definition of “conflict” under Section 5 of this document, if any.  2.3 Other: Any other comments or information regarding the bid and its implementation. |

1. *No deletion or modification may be made in this form. Any such deletion or modification may lead to the rejection of the Bid.* [↑](#footnote-ref-1)
2. *The Bidder shall fill in this Form in accordance with the instructions. Apart from providing additional information, no alterations to its format shall be permitted and no substitutions shall be accepted.* [↑](#footnote-ref-2)
3. *The Bidder shall fill in this Form in accordance with the instructions. Apart from providing additional information, no alterations to its format shall be permitted and no substitutions shall be accepted.* [↑](#footnote-ref-3)
4. *Technical Bids not submitted in this format may be rejected.*  [↑](#footnote-ref-4)