Section II: Evaluation Criteria

In evaluating each bid, UNOPS will follow the criteria and procedures described below.

1. General indications

1.1. About the evaluation methodology

The evaluation process will be carried out in stages under the following methodology:

- **First evaluation stage:**
    - **Evaluation of formal and eligibility criteria (preliminary examination of bids)**

      Compliance with Article 28 of the Instructions to Bidders section as detailed in 2.1 below will be verified. Bids that meet the formal, and eligibility criteria will proceed to the evaluation of the qualification criteria.

      The bids will be examined for apparent clerical errors, arithmetic errors will be corrected, and ties, if any, will be resolved. Then the bids will be ranked according to unit price.

    - **Evaluation of qualification criteria (bidder prequalification)**

      The evaluation of the bidder's capabilities will be carried out based on the review of the submitted documentation taking into account the criteria defined in section 2.2 below.

      Bidders who pass this evaluation will be accredited with the status of pre-qualified for future procurement processes for medicines and/or medical supplies; therefore UNOPS will notify in writing the outcome of the pre-qualification. Prequalified status does not necessarily mean that they will be invited to a limited competition as indicated in section 5.6 of the Procurement Manual version 7.

      Prequalification will be valid for 24 months from the date of notification. Bids that meet the qualification criteria will be eligible for the lot evaluation stage.

      Bidders who were prequalified in previous processes executed by UNOPS for the supply of medicines and/or medical supplies, and whose prequalification is still valid at the date of submission of bids do not need to be re-qualified.

      Upon completion of this first stage of evaluation; UNOPS will report the results of the evaluation of the preliminary examination of bids, and prequalification of the bidder. Only those bids that qualify after the preliminary bid review, and prequalification of the bidder will proceed to the next stage of evaluation.

- **Second evaluation stage (evaluation of bids by lot):**
    - **Evaluation of the qualifying administrative criteria:**

      This stage will be carried out in accordance with section 2.3 below:

        - Verification of quantities offered;
        - Verification of delivery plan/schedule

      The bids that meet the administrative criteria will be qualified to continue with the evaluation of technical criteria.

    - **Evaluation of the technical qualifying criteria**

      The technical evaluation of the bids will be carried out as indicated in section 2.4 below; according to the order of priority by unit price.

    - **Evaluation of complementary technical criteria**

      The offer with the lowest unit price that passed the evaluation of the technical qualification criteria will be submitted to the complementary technical evaluation as indicated in numeral 2.5 below.

- **Third evaluation stage (price and financial capacity evaluation):**

  The bids that pass the evaluation of the complementary technical criteria will be submitted to the price and financial capacity analysis as indicated in section 2.6 below.

UNOPS reserves the right to proceed or not with the full evaluation of the bid if within one of the stages the bidder fails to comply with one of the criteria requested in any of the evaluation stages indicated.

1.2. Award

UNOPS will award:

- Purchase Order for the quantities of the Second Semester 2022 to sign a Purchase Order set forth in *Section III: Schedule of Requirements*, and;
- Long Term Agreements (LTA) in order to be able to issue new purchase orders in the future if additional quantities are required to those contracted under this process. The projected/estimated quantity to be procured through an LTA is as indicated in Section III List of Requirements, file Requerimiento por lote, in the column *Cantidad proyectada a adquirir año 2023 a través de LTA*.

The Purchase Order and the Long-Term Agreement will be the contractual documents governing this bidding process and may include one or more lots.

The award of the Contract/Purchase Order to each bidder shall be up to the limit of the bidder's financial capacity as defined in subsection 2.6 below of this section.

The Health/Sanitary Registration issued by COFEPRIS must be submitted no later than five (5) calendar days after notification of award. In case of failure to provide the Health/Sanitary Registration within the required deadline, UNOPS reserves the right to revoke the award.

Details on the contract template applicable to this process are available in *Section V: Contract Template*.

1.3 UNOPS right to change quantities

At the time of contract award, UNOPS reserves the right to modify (increase or decrease) the required quantity of one or more lots indicated in Section III: Schedule of Requirements by up to 20% (upward or downward), without any changes to the unit price of the affected lot(s) or other terms and conditions of the bid.

Any downward variation in excess of the UNOPS entitlement will be proposed to the bidder with the first-ranked bid of eligibility for the affected lot, allowing withdrawal of its bid, maintaining the bid, or submitting a counter-bid for the affected lot.

UNOPS reserves the right to accept or reject the counter bid submitted and to negotiate with the bidder whose bid has been evaluated as the second-lowest substantially compliant bid.

1.4. Joint Venture bids/offers

Different companies can partner to form a joint venture.

In order to submit a bid as a joint venture within the eSourcing platform; it is recommended to create a user ~~must be created~~ in UNGM in the name of the joint venture. In addition to this, each member must register in UNGM with the individual information of each company.

The joint venture must be supported by an agreement duly notarized (see suggested model in Form C: Joint Venture Agreement) which must:

- Indicate the name of the joint venture;
- Indicate that all members will be jointly and severally liable for the fulfillment of any contract resulting from the process;

- One of the members of the joint venture must be the manufacturer, importer, holder, or legal representative of the holder, and must be registered and indicated in the Sanitary/Health Registration / Commercialization Authorization issued by COFEPRIS[1] as indicated in numeral 2.4;
- Designate one of the members as the leader, who must be a manufacturer of at least one of the products offered. This member shall be designated to receive payments;
- Designate the legal representative leader of the consortium as the representative of the joint operation to sign the bid and the contract;
- Indicate that the term of the joint venture shall be for at least two (2) years from the day following the deadline for submission of bids in the General tab of the eSourcing system;
- Indicate the lots for which you participate as a joint venture;
- To be signed by each of the legal representatives of the members of the joint operation;
- Indicate the percentage of participation of each of the members and their responsibilities in accordance with Form D: General information of the joint venture;
- Be duly notarized before a notary public.

With regard to the leader of the joint operation, he/she shall:

- Be the signatory to the contract, therefore it must have the authority to make binding decisions on behalf of the joint venture during the process to incur obligations and receive instructions for and on behalf of each and every member of the joint venture as well as the execution of the entire contract, including payments;
- Be responsible for bid submission on behalf of the joint venture through the eSourcing system;
- Submit bid security on behalf of the consortium, the security must be in the name of the lead member of the joint venture;
- Act as a point of contact for communications with UNOPS.

It is acceptable for a member of the joint venture to bid individually for one or more lots if it does not compete with:

i. The joint operation in which it is an integral part of the same lot, and;

ii. Another member of the joint operation on the same lot.

1.5. Apostille of documentation

UNOPS reserves the right to request from any bidder the certification of the documentation submitted in simple copy, and the legalization as total or partial apostille of the documentation issued and/or signed or certified by foreign authorities at any time during the process prior to the signing of the contract, or as a condition for the subscription of this contract.

1.6. Language of the bid

In accordance with Article 28 of Section I: Instructions to Bidders, documents submitted in a language other than English or Spanish must be submitted with a certified translation into English or Spanish.

Although the language of the bid may be any of the languages indicated in the Tender Particulars tab in the eSourcing system; the official language of all documents issued by UNOPS under this invitation for bids shall be Spanish.

1.7. Information of the contract type

Information in reference to the contract is set forth in Section V: Contract Model.

[1] For those Sanitary Registrations (SR) that are not issued by COFEPRIS, the information will be verified according to what is stated in ~~Annex D~~ Form G, and validated with the SR issued by COFEPRIS attached to the contract.

1.8. About the price offer

Unit prices are required to be quoted to **two (2) decimal digits**.

In the case of bids with more digits than those indicated, the unit prices shall be rounded to the number of decimal digits indicated according to the currency of the bid. The rounded unit prices shall constitute the unit prices of the bid for all purposes of this process as well as of the resulting contract(s).

The total amounts per lot will be expressed to two (2) decimal digits, by rounding at the time of calculating the total amount of each lot.

2. Criteria

2.1. Formal and eligibility criteria (preliminary evaluation)

The criteria to be evaluated under the acceptance/rejection condition are listed below.

All bidders must comply with the criteria listed below unless explicitly stated otherwise.

Criteria
1. The bidder complies with the eligibility conditions indicated in Section I, Article 4 of this document.
1.1. The bidder is a private, public or government-owned legal entity, or any association that has the legal capacity to enter into a binding contract with UNOPS. In case of a joint venture, each partner must meet this criterion.
1.2. The bidder does not have any conflict of interest to participate and must disclose any actual or potential conflict of interest in the Bidder/Partner Information Form for a joint venture (Form E). In the case of a joint venture, each member must meet the criterion by completing the corresponding Form E.
1.3. The bidder is not, at the time of submitting the bid or during any stage of the evaluation process, on the ineligibility lists indicated in Article 4 of Section I of this document. UNOPS will verify the ineligibility lists and in addition the bidder must submit the Affidavit included in Form E. In the case of a joint venture, each member must meet the criteria.
1.4. The bidder adheres to the principles of the United Nations Supplier Code of Conduct and the principles of the United Nations Global Compact by filling out Form B. In the case of a joint venture, each member shall comply with the criteria. To do so, you must declare compliance in the questionnaire *Licitante Individual y/o Operaciones Conjuntas Declaración Cumplimiento de código de conducta de proveedores de Naciones Unidas* available in the eSourcing Questionnaires tab.
2. The bidder accepts the terms of the contract and confirms the validity of its bid.
2.1. The bidder accepts the general and special conditions of contract and confirms the validity of its bid as required in the eSourcing Details tab, having declared this in the bid cover letter (Form A: Submission of Bid). In case of a joint venture, only one form applies for the joint venture.
2.2. The person signing the bid has authorization, which must be demonstrated by submitting the power of attorney granted to the signatory of the bid and the personal identification document of the Legal Representative or Mandatory. In case the person is a non-Mexican national, a copy of the biographical page of the passport must be submitted. In case of joint operation, the joint operation agreement must be included.
3. The Manifest/bid security is in compliance with the eSourcing system Details tab.

3.1. Conforms to the corresponding format [Bid Support Manifest (Form B, Option 1) or Bid Security (Form B: Option 2)], according to the conditions indicated.
3.2. It complies with the required validity.
3.3. In the case of Bid Security, the United Nations Office for Project Services (UNOPS) is designated as the beneficiary.
3.4. In the case of a Bid Security, it is issued by an entity acceptable to UNOPS.
3.5. In the case of a Bid Security, it is in the same currency of the bid and with the required amount.

2.2. Qualification Criteria (Prequalification)

The criteria to be evaluated under the acceptance/rejection condition are listed below.

Criteria
1. Legal constitution of the bidder, seniority and commercial line of business.
1.1. The bidder is currently prequalified for which they must submit the Notification of Prequalification letter in any of the bidding processes conducted by UNOPS for the December 2020 procurement of drugs and/or medical supplies (ITB/2020/17938, ITB/2020/17978, ITB/2020/17979, ITB/2020/18035 and/or ITB/2020/18036). Prequalified bidders may complete Form C: Prequalified Bidder Information in which they may submit documentation that has been modified since prequalification was received. UNOPS reserves the right to request any additional information resulting from the review of the changes indicated.
1.2. The bidder has been legally constituted for at least three (3) years as of the deadline for submission of bids and the business line of the bidder is related to the purpose of this process. Prequalified bidders are not required to submit this documentation again. If it has been modified since prequalification, Form C should be used to update the information/documentation. In the case of a non-prequalified joint venture, this criterion applies to all members of the joint venture.
2. The bidder provides the required information on Forms D and/or E.
2.1. Bidder provides the complete information required in Form D: Joint Venture General Information. Applicable to joint ventures only.
2.2. The bidder provides the complete information required on Form E . In the case of individual bidders, only Form E.1: Individual Bidder or Leader (Member 1) of a joint venture information is required to be completed. In the case of pre-qualified bidders, each member is required to complete a Form E. Form E.1: Individual or Lead Bidder (Member 1) Information for a joint venture is to be completed by the lead member. The remaining forms (E.2, E.3, E.4 and E.5) should be completed by the other members of the joint venture, using one form for each member.
3. Legalized joint operation agreement. Applicable only to joint operations. In the case of a prequalified joint venture, the agreement must comply with the required term, and the bidder must submit the amendment to the agreement using Form C: Prequalified Bidder Information.
3.1 Includes the name of the joint operation.
3.2. It states that all members are jointly and severally liable for the fulfillment of the contract.
3.3. It is duly notarized or by a public broker duly authorized by the Public Brokerage of the Government of Mexico.
3.4. Designate one of the members as leader.
3.5. The member designated as leader of the joint operation complies with the conditions established in this document.
3.6. Appoints the legal representative of the lead member as representative of the joint operation to sign the bid and contract.

3.7. It is valid for at least two (2) years from the day following the deadline for submission of bids.
3.8. Indicates the lots for which the joint operation is bidding.
3.9. It is signed by each of the legal representatives of the members of the joint venture.
3.10. Detail the percentage of participation of each of the members as well as the responsibilities of the same in congruence with the information provided in Form D: General information of the joint operation.
4. Bidder's experience in contracts for similar goods.
4.1 The bidder has experience in the satisfactory execution of contracts for similar[2] goods, in the last three (3) years, the amount of which is greater than MXN 1,500,000.00 or its equivalent in USD at the United Nations[3] exchange rate in effect at the deadline for submission of bids. Bidders must complete Form F: Bidder's Experience and for each experience submit invoices, final receipt certificate, delivery note, or its equivalent. In the case of a joint venture, the experience of each member shall be cumulative to meet this criterion. Prequalified bidders should not submit this documentation again. If the documentation has been modified since prequalification, Form C must be used to update the information/documentation.
5. Liquidity Ratio
5.1. The liquidity ratio[4] is equal to, or greater than, 0.75, for which the bidder must submit the Financial Statements for the last two (2) immediately preceding fiscal years (2020 and 2019) certified by a Certified Public Accountant or equivalent, as well as the valid Certified Public Accountant's Certification (or equivalent), issued by an entity that endorses the public accountant to exercise his/her functions in the country of origin. In the case of a joint venture, the liquidity ratio for each year shall be calculated as the sum of the current assets of all the members of the joint venture divided by the sum of their current liabilities. Prequalified bidders are not required to provide this documentation. However, the bidder may submit with its bid financial statements using Form C: Prequalified Bidder Information for Financial Capacity Calculation Purposes, as indicated in Article 2.7. Financial Capacity.
6. Supplier commitment to sustainability
6.1. The bidder shall demonstrate its commitment to incorporate sustainability into its own operations (in accordance with social, environmental and economic considerations). The bidder shall comply with the following points: 1. Complete the Bidder's Sustainability DRIVE Questionnaire, as well as the Sustainability Practices Information Form and submit them as part of its bid. 2. Submit the completed Sustainability Practices Information Form as part of your bid; 3. Provide at least one (1) of the following documents: a. Expired Supplies Return Plan: General plan for removal of expired pharmaceuticals from delivery points for proper disposal; b. Accessibility: Document detailing the inclusion of Braille labels on packaging, labeling or instructions to ensure easy handling and use by visually impaired persons; c. Environmental Management System: Documentation confirming that the manufacturers producing the drugs have valid ISO-14001 EMS[5], EMAS[6] or similar certification. Applicable to all individual bidders or joint ventures, prequalified or not. With regard to items 1 and 2, in the case of a joint venture, the lead member must comply with the aforementioned criteria, UNOPS reserves the right to request the questionnaire/form from the other members of the joint venture at a later date.
7. Gender Equality
7.1. Gender Mainstreaming in Contract Execution Following the UNOPS Gender Parity Strategy and Gender Equity Strategy in line with the UN System Gender Equality Strategies, the bidder must complete the self-assessment using the WEP tool (available at

[2] The term "similar" shall be understood to mean drugs, medical supplies or healing materials.
[3] Available at https://treasury.un.org/operationalrates/OperationalRates.php.
[4] Liquidity ratio = Current assets / current liabilities.
[5] Environmental Management Systems (EMS).
[6] EU Eco-Management and Audit Scheme (EMAS).

https://weps-gapanalysis.org) to understand its contribution to advancing gender equality and gender parity and attach the outcomes with its bid. Applicable to all individual bidders or joint ventures, prequalified or not.

2.3. Administrative Criteria

2.3.1. Tie/Draw resolution

In the event of a tie, UNOPS may use at its discretion - without prejudice to any action it takes to ensure non-collusion among bidders - the "Best and Final Offer" (BAFO) methodology to identify the lowest priced bid for lots with a price tie. To this end, bidders will be notified in writing and requested to submit their Best and Final Offer for the affected lot.

Bidders may not change the specifications of the product offered or any of the conditions of the bid (delivery times, terms, special conditions, etc.) and only the unit price may be changed.

Subsequently, a new price comparison will be made on the affected lot. If a tie persists, UNOPS reserves the right to re-solicit a BAFO or reject bids for that lot.

2.3.2. Qualifying Administrative Criteria

The criteria per lot (key) to be evaluated under the acceptance/rejection criteria are listed below.

Criteria	Source for Verification
The offer is for the total required quantities for supply of the Second Semester 2022 to sign a Purchase Order	Form H: technical offer per lot
The bid undertakes to comply with the conditions indicated in paragraph 4.D. Scheduling of deliveries in Section VI: Contract Management.	Form H: technical offer per lot

2.4. Qualifying Technical Criteria

Listed below are the criteria per lot (key) to be evaluated under the pass/fail basis.

2.4.1. Medicines WITH Health/Sanitary Registration, or Commercialization Authorization issued by COFEPRIS

Criteria	**Evaluation of the Criterion**
The drug has commercialization approval	Health/Sanitary Registration, or Certificate of Orphan Drug Recognition issued by COFEPRIS. In case the Sanitary/Health Registration or Commercialization Authorization is expired or the approval of extension is pending, it is required to submit additionally the request for extension of the Sanitary/Health Registration or Commercialization Authorization indicating the process number, and the name of the product for the lot(s) offered. For sanitary/health registrations, the request for an extension must have been filed with COFEPRIS at least 150 calendar days before the date on which the term of the sanitary/health registration expires. When the last day of the deadline for filing the extension is a non-business day it will be understood to be extended until the following business day. For orphan drugs, the extension requests must have been submitted to COFEPRIS at least 30 calendar days prior to the date on which the Certificate of Recognition of Orphan Drugs expires. When the last day of the deadline for filing the extension is a non-business day, it will be understood to be extended until the following business day. In any case, late requests for extension will only be accepted when suspensions of terms or extensions of the deadline for submitting extensions are published in the Official Gazette of the Federation, and the bidder must attach such publication.
The bidder is registered and indicated in the Sanitary/Health Registration, or	The bidder must appear as manufacturer, importer, holder, or legal representative of the holder (in the case of joint venture, at least one of the members), and must be registered and indicated in the Sanitary/Health Registry or Commercialization Authorization of COFEPRIS.

Commercialization Authorization.	When the bidder submitting the bid is the manufacturer or importer registered in the Sanitary/Health Registry or Commercialization Authorization, Format D must be submitted: Authorization of the Holder or Legal Representative registered in the Sanitary/Health Registry.
Matching of the product offered with the exact description of the key tendered.	The bidder must submit Form F: Statement of Technical Compliance of the drug. The exact description of the key according to Section III: List of Requirements, will be validated in the documents submitted with the bid. It should be noted that for solid pharmaceutical forms, the equivalences defined in the Mexican Pharmacopoeia in force at the deadline for submission of bids will be taken into account, and that complies with the description of the key according to Section III: List of requirements.

2.4.2. Drugs WITHOUT Health/Sanitary Registration or Commercialization Authorization issued by COFEPRIS that have Health/Sanitary Registration or Commercialization Authorization issued by Regulatory Agencies or Prequalification with equivalence recognition.

Criteria	Evaluation of the Criterion
The drug has commercialization approval	Sanitary/Health Registration or Commercialization[7] Authorization issued by any of the Regulatory Agencies with recognition of equivalence listed in Appendix 1 of this section or, Certificate of prequalification of the drug in validity and issued by the WHO. Exceptionally, a copy of the certificate of free sale issued by any of the Regulatory Agencies with recognition of equivalence listed in Appendix 1 of this section may be submitted. In the case of drugs whose description includes a Medical Device that requires sanitary/health registration in Mexico and this is not in the Sanitary or Health Registration / Commercialization Authorization or submitted pre-qualification, additionally, a valid Sanitary Registration / Commercialization Authorization for the Medical Device issued by: i) the Pharmaceuticals and Medical Devices Agency of Japan or, ii) the Food and Drug Administration of the United States of America or, iii) Health Canada of Canada, or, iv) the Federal Commission for the Protection against Sanitary Risks of Mexico, must be submitted. In accordance with Mexican regulations, the bidder must request a Health/Sanitary Registration from COFEPRIS that includes both the drug and the medical device. In case the Sanitary Registration or Commercialization Authorization is expired or pending approval of extension by the Regulatory Agency with recognition of equivalence, submit the application for extension of the Sanitary Registration or Commercialization Authorization indicating the number and date of entry of the process, and name of the product for the lot(s) offered. The request for an extension must have been submitted to the Regulatory Agency with recognition of equivalence, before the date on which the validity of the sanitary/health registration or commercialization authorization expires and in accordance with the times foreseen within the Regulatory Agency's own regulatory framework.
The bidder is registered and indicated in the Sanitary/Health Registry or Commercialization Authorization.	The bidder must correspond to the manufacturer, importer, Holder or Legal Representative of the Holder (in the case of joint venture, at least one of the members) that will be registered and indicated in the Sanitary Registry that will be issued by COFEPRIS; for which purpose, the bidder must complete the corresponding fields of Form G: Declaration of Technical Compliance of the drug. When the bidder submitting the bid is the manufacturer or importer that will be registered in the Sanitary Registry issued by COFEPRIS, it must submit Form D: Authorization of the Holder or Legal Representative enrolled in the Sanitary/Health Registration.
Matching of the product offered with the exact description of the key tendered.	The bidder shall submit Form G: Statement of Technical Compliance for the drug. The exact description of the key according to Section III: List of Requirements, will be validated against the documents submitted with the bid. It should be noted that for solid pharmaceutical forms, the equivalences defined in the Mexican Pharmacopoeia

[7] A Commercialization Authorization is an official document issued by the competent Regulatory Authority to commercialize or distribute a product in accordance with the regulatory and legal framework in force.

	in force at the deadline for submission of bids will be taken into account, and that complies with the description of the key according to Section III: List of requirements. If the commercial presentation of the product listed in the Sanitary Registration or Commercialization Authorization or Prequalification with Recognition Agreement differs from the one required, the bidder must obtain a Sanitary Registration issued by COFEPRIS that includes the required commercial presentation.

2.5. Complementary Technical Criteria

Listed below are the criteria per lot (key) to be evaluated under the pass/fail basis.

2.5.1. Drugs WITH Sanitary Registration or Commercialization Authorization issued by COFEPRIS

Criteria	Evaluation of the criterion
The manufacturer has the required license or authorizations ~~a Good Manufacturing Practices Certificate.~~	Certificate of Good Manufacturing Practices. The certificate must correspond to the authorized establishment(s) in the Sanitary Registration or Commercialization Authorization submitted, and where the product is manufactured. In the event that the manufacturing and packaging operations are carried out in different establishments or more than one registered plant, the certificate of the plant(s) where the product offered will be manufactured and reconditioned must be provided, and may be reviewed by UNOPS during the contract execution. The Good Manufacturing Practices Certificates must include the production line for the manufacture of the drug. In case the Good Manufacturing Practices certificate has expired or is pending a visit for renewal, an additional document certifying the request for renewal of the certificate prior to its expiration must be submitted. Renewals of Good Manufacturing Practices Certificates issued by COFEPRIS must have been submitted 180 calendar days prior to the date on which the certificate expires. When the last day of the deadline for the renewal request is a non-business day, it will be understood to be extended until the following business day. Untimely applications for renewal of the certificate will only be accepted when suspensions of terms or extensions of the deadline are published in the Official Gazette of the Federation, for which the bidder must attach such publication. Renewals of Good Manufacturing Practices Certificates issued by Regulatory Agencies other than COFEPRIS must be submitted within the timeframe established within the respective regulatory framework of the Regulatory Agency issuing the Certificate submitted. Additionally, submit the sanitary license or its equivalent, issued by the National Regulatory Agency of the country where the plant(s) in which the product is manufactured are located. In the event that the manufacturing and packaging operations are carried out in different establishments or more than one registered plant, the sanitary license or its equivalent of the plant(s) where the offered product will be manufactured and packaged must be provided and may be reviewed by UNOPS during the contractual performance. The sanitary licenses or their equivalent must unequivocally state the types of activities authorized at the production facilities.
The bidder has the required license or authorization	If the bidder does not correspond to the manufacturer registered and indicated in the Sanitary Registration or Commercialization Authorization of COFEPRIS, in addition, the bidder must submit a notice of operation or of sanitary responsibility or authorization issued by COFEPRIS, as applicable to the bidder.
The drug complies with the labeling approved by the corresponding Regulatory Agency.	Photograph or final model of the labeling of the primary and secondary container; and additionally the final labels of the primary and secondary containers approved by COFEPRIS.

The thermolabile drug complies with the special conditions for its commercialization.	When the drug must be stored under a cold chain, the bidder must submit its own and/or the logistics operator's Cold Chain Master Plan to which it entrusts the distribution from the point of departure to the delivery points indicated in Appendix 4 of this document. This document should describe the system to avoid breakage of the cold chain, calibration of measuring equipment, and handling of excursions.
The drug complies with the quality criteria offered.	Analytical certificate of the drug (last batch manufactured and not older than five years), showing compliance with the acceptance parameters established according to the type of product, indicating the code of the document describing the analysis methodology followed or the reference pharmacopeia and version. In case the product has not been manufactured/commercialized, submit the analytical certificate of the pilot batches.

2.5.2. Drugs WITHOUT Sanitary Registration or Commercialization Authorization issued by COFEPRIS that have Sanitary Registration or Commercialization Authorization issued by Regulatory Agencies or Prequalification with equivalence recognition.

Criteria	Evaluation of the Criterion
The manufacturer has the required license or authorizations ~~a Good Manufacturing Practices Certificate.~~	Certificate of Good Manufacturing Practices. The certificate must correspond to the authorized establishment(s) in the Sanitary Registration or Commercialization Authorization submitted, and where the product is manufactured. In the event that the manufacturing and packaging operations are carried out in different establishments or more than one registered plant, the certificate of the plant(s) where the product offered will be manufactured and reconditioned must be provided, and may be reviewed by UNOPS during the contract execution. The Good Manufacturing Practices Certificates must include the production line for the manufacture of the drug. Certificates of Good Manufacturing Practices issued by COFEPRIS and the Regulatory Agencies listed in Appendix 2 of this section are acceptable. In case the Good Manufacturing Practices certificate has expired or is pending a visit for renewal, an additional document certifying the request for renewal of the certificate prior to its expiration must be submitted. Renewals of Good Manufacturing Practices Certificates issued by COFEPRIS must have been submitted 180 calendar days prior to the date on which the certificate expires. When the last day of the deadline for the renewal request is a non-business day, it will be understood to be extended until the following business day. Untimely applications for renewal of the certificate will only be accepted when suspensions of terms or extensions of the deadline are published in the Official Gazette of the Federation, for which the bidder must attach such publication. Renewals of Good Manufacturing Practices Certificates issued by Regulatory Agencies other than COFEPRIS must be submitted within the timeframe established within the respective regulatory framework of the Regulatory Agency issuing the Certificate submitted. Additionally, submit the sanitary license or its equivalent, issued by the National Regulatory Agency of the country where the plant(s) in which the product is manufactured are located. In the event that the manufacturing and packaging operations are carried out in different establishments or more than one registered plant, the sanitary license or its equivalent of the plant(s) where the offered product will be manufactured and packaged must be provided and may be reviewed by UNOPS during the contractual performance. The sanitary licenses or their equivalent must unequivocally state the types of activities authorized at the production facilities.
The bidder has the required license or authorization	If the bidder does not correspond to the manufacturer registered and indicated in the Sanitary Registration or Commercialization Authorization of COFEPRIS, in addition,

	the bidder must submit a notice of operation or of sanitary responsibility or authorization issued by COFEPRIS, as applicable to the bidder.
The drug complies with the labeling approved by the corresponding Regulatory Agency.	Photograph, or model of the label design of the primary and secondary containers approved by the Regulatory Agency or Prequalification with Recognition Agreement. In addition, submit the design of the labeling and labels of the primary and secondary packaging in Spanish or English. In case of another language submit ~~or~~ a ~~simple~~ certified translation into English or Spanish.
The thermolabile drug complies with the special conditions for its commercialization.	When the drug must be stored under a cold chain, the bidder must submit its own and/or the logistics operator's Cold Chain Master Plan to which it entrusts the distribution from the point of departure to the delivery points indicated in Appendix 4 of this document. This document should describe the system to avoid breakage of the cold chain, calibration of measuring equipment, and handling of excursions.
The drug complies with the quality criteria offered.	Analytical certificate of the drug (last batch manufactured and not older than five years), showing compliance with the acceptance parameters established according to the type of product, indicating the code of the document describing the analysis methodology followed or the reference pharmacopeia and version. In case the product has not been manufactured/commercialized, submit the analytical certificate of the pilot batches.
Proof of initiation of the Sanitary Registration application process ~~before~~ in COFEPRIS.	Application for Sanitary Registration ~~before~~ in COFEPRIS, submitted in a term not to exceed ten (10) working days, once requested by UNOPS during the evaluation stage of complementary technical criteria. The bidder must appear as manufacturer, importer, holder, or legal representative of the holder, and must be registered and indicated in the Sanitary Registration process before COFEPRIS. The drug to be registered must match the exact description of the key according to Section III: List of Requirements. The Sanitary Registration issued by COFEPRIS will not be required for the evaluation, however, it is a condition for the signature of the contract as indicated in Section VI. Contractual Management, numeral 3.4 Documents to be submitted for the subscription of the Purchase Order.

2.6. Price Evaluation

The bids with the lowest price per lot that have passed the evaluation of the supplementary technical criteria will be submitted to:

2.6.1. Analysis of bid price reasonableness

UNOPS will verify that the price corresponds to a reasonable price in accordance with the regulations and procedures to which UNOPS is subject.

A reasonable price is understood to be that which, after a comparison analysis with local historical prices, valid bid prices and, if applicable, international purchasing prices, for the drug in the same commercial presentation and unit of measure required, is considered reasonable in relation to market conditions in order to guarantee the best quality to price ratio. In the event that the price is not reasonable in the opinion of UNOPS, UNOPS may seek to negotiate the bid price or reject the bid.

2.6.2. Negotiation

UNOPS reserves the right to invite the lowest substantially compliant bidder to negotiate for one or more lots when its bid price is considered unreasonable or when it is a candidate for the award of multiple lots, in which case UNOPS will notify the bidder in writing of its intention to negotiate and instructions as to how the negotiation will be conducted.

Following the negotiation, UNOPS will verify the reasonableness of the negotiated bid price, which does not imply an award.

2.7. Financial Capacity

For prequalified bidders, the Financial Capacity shall be calculated using the documentation previously submitted. However, the bidder may submit with its bid updated financial statements using Form C: Prequalified Bidder Information.

To determine the financial capacity of a bidder, the following procedure shall be applied:

- Financial capacity limit [A]: The sum of sales for the last two (2) fiscal years. In the case of bidders in a joint operation, the financial capacity limit will be calculated on the basis of the sum of the capacities of their members. The financial capacity of the bidders' subcontractors will not be taken into account;
- Estimated Amount to be Awarded [B]: Sum of all lot amounts of quantities for the Second Semester 2022 to sign a Purchase Order for which the bidder is the lowest technically qualified bidder;
- Bids in other processes [C]: In cases where the bidder participates in several bidding processes executed by UNOPS at the same time, the awards already made in those processes will be taken into account;
- Balance of contracts in execution [D]: Sum of the balances as of the date of the bid opening for contracts signed with UNOPS;
- Total amount [E]: Total resulting from the sum of all values [B] for the bidder in the process plus bids in other processes [C], and the balances of contracts under execution [D].

If the Bidder's Financial Capacity Limit [A] is less than the Total Amount [E], i.e. if A < E, UNOPS reserves the right to determine the lots to be awarded in a manner most favorable to UNOPS, including the following options, but not limited to:

- In the case of prequalified bidders, request the most recent Financial Statements;
- Partially award one or more lots (keys) within the UNOPS variation right according to clause 1.3 of this section;
- Award one or more lots to another bidder whose price is reasonable and who has the financial capacity;
- If there are no other qualified offers, one or more lots may be rejected in order to obtain the most favorable configuration for UNOPS.

If required, currency conversion will be made using the United Nations exchange rates in effect at the deadline for submission of bids.