Section VI: Contract Management

1. Contracting process

The contractual process covers the formalization of a contract, the delivery schedule/plan, receipt of goods and payment.

2. Establishment of the Long-Term Agreement (LTA)

2.1. Conditions of the Long Term Agreement

UNOPS intends to enter into non-exclusive Long Term Agreement(s) (LTA(s)) with each awarded bidder for the supply of an undetermined quantity per key.

For LTAs subscribed, the following shall apply:

- Type: Single-supplier LTA;
- Validity: For an initial period of one (1) year with the possibility of extension for an additional period of two (2) years at the discretion of UNOPS and subject to satisfactory performance of the contractor and availability of funds;
- Coverage: United Mexican States;
- LTA Prices: Unit prices will be in the currency of the bid.
- Price adjustment: Subject to annual price adjustment;
- Minimum Quantities: UNOPS shall have no obligation to procure a minimum quantity of goods from the Contractor during the LTA period.

2.2. Extension of the LTA

Any extension to the validity of the LTA shall be formalized in writing through an amendment to the LTA. At a minimum, the following conditions must be met for the extension of the LTA:

- Satisfactory performance of the contractor;
- The price of the goods included in the LTA is reasonable.

3. Celebration of the Contract

3.1. Purchase Order

The Purchase Order (PO) is the contractual instrument that formalizes the commercial relationship between the parties as indicated in the invitation to bid, following the contract model described in Section V: Annexes to the Contract.

The PO will be issued in the same currency as the bid currency.

UNOPS will request the presence of the awarded bidder (Legal Representative) either in person or virtually for the signature of the PO. The method of signature will be informed to the supplier through the following e-mail: gestioncontratos.mexico@unops.org.

In the event that the document is to be signed in person, an original copy will be given to the supplier, as well as a copy of the procedures for delivery of goods and the management of payment to suppliers.

3.2. First Purchase Order Process

In conjunction with the issuance of the purchase order, UNOPS will issue an LTA upon notification of the outcome to the awarded bidder, once the bidder submits the required documents indicated in paragraph 3.4. of this section.

3.3. Process of issuing a Purchase Order from the LTA

The following procedure shall apply for placing orders against this agreement (second purchase order and thereafter):

- UNOPS will send a request for quotation to the Contractor for one or more lots included in the LTA, as required;
- The unit prices indicated in the LTA are fixed for the first year of the LTA agreement. However, in accordance with the terms of the LTA agreement, if at the time of issuance of the Purchase Order there is a market price reduction, if applicable, such reductions will be applied to UNOPS;
- Once the lot prices have been confirmed, UNOPS will proceed to issue a Purchase Order once the bidder submits the required documents indicated in numeral 3.4. of this section;
- The Purchase Order will be sent via email to the Contractor;
- The deadline for delivery of the goods shall be from the receipt of the Replacement Order issued within the framework of the contract (Purchase Order) by the Contractor.

3.4. Documents to be submitted for the issuance of a Purchase Order

For the subscription of the contract, the bidder must submit:

- Identification document of the Legal Representative;
- Power of Attorney;
- In case the bidder does not have an OneUNOPS registration number or the bidder already has an OneUNOPS registration but wishes to modify its information:
    - OneUNOPS Supplier Profile Form (to be shared at the time of the notification of results);
    - Bank Information Support;
    - Copy of canceled invoice.
- Contact information of the Health Officer (institutional email and institutional telephone number);
- Sanitary Registration or Commercialization Authorization issued by COFEPRIS;
- Summary document of a maximum of two (2) pages, where a brief description of what is contemplated in its internal procedures, for the execution of the processes of:
    - Recall system;
    - Complaints and claims management system;
    - Description of product destruction methods;
    - Pharmacovigilance master plan in accordance with NOM-220-SSA1-2016, Installation and operation of pharmacovigilance;
    - Description of the CAPA system;
    - Supplier management, and;
    - List of third-party laboratories authorized by COFEPRIS with which the company performs quality control analysis of the products.

UNOPS reserves the right to request an uncontrolled copy of the complete procedure, when necessary. UNOPS may audit the Quality Management System (QMS) and shall have the authority to decide on which

process to audit, as well as perform product review and inspection, in accordance with section 6. Audit, inspection, and product analysis of this section.

The maximum time for the delivery of this documentation shall be five (5) working days after the award notification. UNOPS will inform the method of delivery of the documentation at the time it is requested.

In addition, UNOPS may request any other document to verify the information provided.

4. Delivery Plan

A. The Delivery Plan is an integral part of the PO and constitutes the schedule and periodicity in which deliveries must be completed at the warehouses;

B. The Delivery Plan may not be modified without prior approval from UNOPS;

C. The goods to be contracted will be delivered to the Warehouses located in Mexico City, the Metropolitan Zone, and the State of Mexico at 11 delivery locations;[1]

D. The bidder must have the capacity to make the first delivery as of July 2022. However, the final delivery plan will be agreed upon during the contract formalization stage;

E. UNOPS may request the contractor to anticipate the deliveries according to INSABI's needs and contractor's availability;

F. Subsequent deliveries will be made on a monthly basis as indicated in the Delivery Plan;

G. UNOPS, at INSABI's request, may request changes to the delivery addresses of goods, as long as it is within Mexico City, the metropolitan area, and the State of Mexico, for which the contractor will be notified fifteen (15) calendar days in advance of such change, without this implying an additional cost.

H. The Replacement Orders issued under the contract (Purchase Order) issued by UNOPS will have a period of 15 calendar days for the contractor to make the physical delivery of the goods.

5. Goods Receipt

Upon receipt of the goods, they will be subject to review to verify that the technical characteristics are identical to those requested and those offered in the technical offer. At the time of receipt, entry, and storage at the established place, the product will be subject to inspection. The supplier must send the evidence of delivery to UNOPS within a maximum timeframe of twenty-four (24) hours after the goods have been delivered to the designated Logistics Operator / Warehouse. Receipt of the goods should not be understood as an acceptance of the goods by INSABI to UNOPS, which is one of the requirements for the lapse of time for payment of the invoice to commence, in accordance with section 7.

5.1. Reception

The contractor must send with each product delivery a copy of the Certificate of Analysis (CoA) of the delivered lot to the UNOPS quality assurance area. This information will be sent to calidad.mexico@unops.org.

The execution of this process is the responsibility of INSABI. On a regular and random basis, UNOPS may participate as an observer of the operations.

The guidelines of requirements, documents and conditions required for deliveries will be made available to the contracted bidders in a timely manner. The preparation of this document is the responsibility of INSABI who will inform the warehouse personnel responsible for the reception of the contracted goods.

Notwithstanding that additional documentation may be required, the Contractor is obliged to deliver, as applicable, the following documentation to INSABI, directly or through INSABI's designated agents:

1. (i) Sanitary Registration in force issued by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), ~~or equivalent document issued by the regulatory agency recognized by the latter;~~ or (ii) Valid Certificate of Orphan Drug Recognition.

[1] See Appendix 4.

2. Release document issued by COFEPRIS, if applicable.
3. Analytical or quality certificate per lot in Spanish or full translation into Spanish.
4. Letter against hidden defects.
5. Replacement commitment letter form (Letter of Exchange).
6. Graphic report of Cold Network monitoring.

In addition to the above information, in the case of controlled drugs (groups I, II, and III), contractors, through the logistics operator indicated by INSABI, shall provide the following documentation at the delivery points:

1. Sanitary License.
2. Notice of the Sanitary Responsible, stamped by COFEPRIS.
3. Notice of annual estimates of narcotic and psychotropic drugs, if applicable.

The documentation may be modified at INSABI's request. However, UNOPS will socialize the delivery procedures with the contractors during the signing of the purchase order.

The contractor must send a copy of the product quality analysis certificate to calidad.mexico@unops.org on the same day the goods are delivered to the logistics operator.

5.2. Replacement of goods

The exchange or replacement must be made (i) within fifteen (15) calendar days of UNOPS notification to exchange the goods, (ii) at the same point of delivery, and (iii) at no cost to UNOPS and/or INSABI, (iv) prior to the expiration of the drug; and in accordance with the form included in Appendix 3: Replacement Commitment Letter Format, of this section.

6. Product auditing, inspection, and analysis

6.1. Product Inspection

At this stage of the UNOPS process, it will apply ISO 2859-1 Sampling procedures and tables for inspection by attributes.

The AQL (Acceptance Quality Level), defined for the different defects is:

Type of defect	AQL sterile products	AQL non-sterile products
Critical	0.1%	0.65%
Major	0.40%	1.0%
Minor	6.5%	6.5%

Routine use will be made of general inspection plans (where samples are non-destructive). If for any reason, a special inspection is required, it will be carried out. The different inspection levels (I, II, III) will be taken into account, as well as the normal, reduced, or rigorous inspection sampling plans.

Special levels S-1, S-2, S-3, and S-4 can be used when relatively small sample sizes are required and higher sampling risks can be tolerated. If for any reason, a special inspection is required, it will be performed.

The selection of the level of inspection and the sampling plan will be determined by the characteristics of the drug and the history of receipt of the product.

UNOPS during the inspection process will make use of different sampling tools, which will be established according to the characteristics of the product, lot sizes, and delivery history of the contractor.

The types of sampling to be used are:

- Random;
- Convenient sampling;

- Systematic;
- Stratified;
- By groups;
- Any other is considered relevant according to the needs of the process.

Prior to the distribution of drugs, UNOPS reserves the right to carry out the inspection directly at the Contractor's premises. For this purpose, the Contractor shall coordinate with UNOPS the delivery milestones well in advance. Exceptionally, this process will be carried out at the delivery locations prior to entry into the logistics operator's inventory. At the time of inspection, UNOPS will verify the following aspects:

1. Storage conditions
2. Certificate of quality control analysis of the finished drug for each batch of drugs delivered. This document must specify the reference pharmacopeia.
3. General aspects such as:
    - Approved quality condition;
    - Duly sealed boxes;
    - Collective boxes in a good state of conservation (not wet, without tears or stains, etc.);
    - Collective boxes properly identified as to their contents and legible legends;
    - Collective boxes containing products from the same lot;
    - Collective boxes without visible contamination;
    - Consistency between collective, secondary or primary packaging;
    - Texts or legends appropriate to the product description;
    - Primary, secondary or collective packaging with legible labels and printing;
    - Design and manufacture or appropriate packaging in primary or secondary packaging;
    - Containers with stated contents and in good condition;
    - Primary packaging. It will be verified as long as it does not affect the security seals of the secondary packaging;
    - Secondary packaging in good condition;
    - Containers with complete data as required;
    - Lot number that corresponds to the product delivered in primary or secondary packaging. The lot number must agree with the lot assignment system submitted at the time of contracting;
    - An expiration date that corresponds to the product delivered in primary, secondary, and collective packaging. According to the approved expiration periods;
    - Matching in brand, origin, or manufacturer in relation to what is stipulated in your offer, order, and delivery;
    - Corresponding instructions in Spanish or simple translation into Spanish;
    - Products with original packaging without alterations;
    - Products that do not show physical characteristics such as evident deterioration, color, texture, appearance, presence of foreign particles, sediments, filtration, rupture, precipitate, porosity, among others.

If the product lot fails inspection for attributes or irregularities in the quality of the drugs during the distribution of the products, according to the contracted specifications, UNOPS will notify the Contractor for the return of the lot or replacement of defective units.

The contractor shall submit a written commitment to replace the products that show defects at the time of receipt, entry, and during storage in the warehouses indicated in the Purchase Order. The contractor shall replace them with products in perfect condition that conform to the defective quantities. Replacements shall be made within fifteen (15) calendar days of notification by UNOPS.

6.2. Sampling and Quality[2][3] Analysis Tests

In order to verify compliance with the specifications described in the invitation to bid and to ensure the quality of the drug[4], the following is established:

6.2.1. Sampling stage

Sampling for quality control analysis of the drug may be performed randomly from the lots delivered by the contractor.

Prior to the distribution of drugs, UNOPS reserves the right to take samples directly at the Contractor's premises before delivery. For this purpose, the Contractor shall coordinate delivery milestones with UNOPS well in advance.

Exceptionally, this process will be carried out at the delivery points after the product has entered the logistics operator's inventory; in this case, the Contractor shall replenish the quantity of product samples taken at the corresponding delivery points.

The quantities required according to the pharmaceutical form of the drug shall be determined in accordance with the Pharmacopoeia of the United Mexican States, reference pharmacopeias or own test methods validated by the manufacturer.

The Contractor shall ensure the storage of retention samples within the framework of the Mexican technical definitions. If investigations of a product lot are required, the contractor shall provide these samples to UNOPS.

6.2.2. Analysis of samples

Drugs may be subjected to quality control analysis tests as stipulated in the General Health Law, in the applicable articles, in accordance with the provisions of the Pharmacopoeia of the United Mexican States and its Supplements (applicable according to the date of manufacture of the product), in the official Mexican standards, international guidelines, reference pharmacopeias or in the absence of these, according to the manufacturer's own validated methodologies.

The analysis of the samples may be carried out at any time UNOPS deems appropriate or at the request of INSABI. The Contractor shall be notified in writing of the procedure to be followed.

UNOPS reserves the right to refer samples to a laboratory for quality analysis of pharmaceutical products and to determine the analyses to be performed considering the following guidelines:

a. Quality analyses may be performed in third-party laboratories authorized by COFEPRIS with which the pharmaceutical laboratory already has a contractual relationship and with which the respective analytical transfer has been developed.
b. Quality analyses whose transfer and analytical validation have been performed in the company's own laboratory may be performed in this laboratory; however, a third-party laboratory authorized by COFEPRIS must be selected and contracted for the development of pharmacopeial tests (e.g. sterility, dissolution, particle content, etc.).
c. If the laboratory does not have either of the above two options, it must select a third-party laboratory authorized by COFEPRIS in accordance with its contracting policies.

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[2] quality.
(1) In general, the essential nature of a product and the totality of its attributes and properties, which determine its suitability for the purposes for which it is intended. In the case of a drug, its quality would be determined by its identity, purity, content or potency and any other chemical, physical, biological or manufacturing process properties that influence its aptitude to produce the effect for which it is intended.
2) Suitability of the drug for its intended use, which is determined by: a) its efficacy, weighted with respect to its safety, according to the statement labeled or promoted by the manufacturer; and b) its conformity with respect to the specifications of identity, concentration, purity and other characteristics. It is understood that these two groups of factors are interdependent, since the specifications are established to ensure efficacy and safety.

[3] quality, inspection of quality (quality control). An expression that appears in some WHO documents as a translation of quality control and that should be avoided so as not to confuse quality control with the inspection activities of pharmaceutical establishments, especially production establishments.

[4] The quality analysis tests performed by UNOPS are complementary and do not replace those required by COFEPRIS in the import and batch release processes and any other tests required by Mexican regulations.

d. In accordance with local regulations, imported biotechnological and/or orphan drugs will not be tested locally.
e. UNOPS may request the supplier to accompany the product with its product release analysis.

The cost of the quality control analysis and related shipping costs shall be assumed by the contractor. The contractor shall deliver to the laboratory designated for the quality control analysis, the finished product specification, analysis methodology, and all those documents that guarantee conformity in the execution of the analysis.

In the event that the entity performing the analysis does not have available the pattern or standard of reference of the drug subject to analysis, the Contractor shall be required to cancel the payment for the acquisition of such pattern or shall provide it.

If the drug fails the quality control analysis or irregularities are detected in accordance with the contracted specifications, UNOPS will notify the Contractor to withdraw and replace the lot(s) at its cost, within a maximum period of fifteen (15) working days after having been notified by UNOPS. Such irregularities and/or deficiencies detected in the quality control of the drugs may result in the culpable termination of the contract and the corresponding quality guarantee may be enforced.

6.3. Audit

UNOPS reserves the right to conduct quality audits to verify compliance with the Quality Management System of the Contractor, analytical laboratories, and logistics operators.

Audits will be conducted to assess the compliance of UNOPS suppliers' and strategic partners' operations, as well as the relevant regulatory framework and UNOPS quality standards.

7. Payment management

- For companies legally incorporated in the United Mexican States, payment will be made according to the currency of the offer.
- For companies legally incorporated abroad, regardless of the currency of the offer, payment will be made in United States Dollars (USD) at the official United Nations exchange rate in effect on the date of payment.
- The cost of bank transfers between the origin of the funds and the supplier's bank account shall be assumed by the supplier.
- UNOPS agrees to make payment of one hundred percent (100%) of the price of the goods accepted by the Instituto de Salud para el Bienestar (INSABI), within forty-five (45) calendar days after UNOPS receives (i) from (INSABI,) the acceptance of the goods in accordance with the Specific Agreement and its amendments (note that INSABI has thirty (30) calendar days, following delivery of the goods, to review, accept or reject the goods. However, if after this thirty (30) calendar day deadline, INSABI has not accepted or rejected the goods, an implied acceptance of the goods will apply); and (ii) from the Contractor, the documentation listed in the following paragraph:
- Commercial invoice; and
- Additional documentation as requested on a case-by-case basis.

The documentation and procedure may be modified; however, UNOPS will provide contractors with the supplier payment procedure during the purchase order signature stage.

8. Supplier Performance Evaluation

UNOPS will supervise the performance of the supplier (contractor) on an ongoing basis throughout the entire contract period in accordance with UNOPS rules and procedures as set forth in the UNOPS Procurement Manual Item 13.2 and 13.2.1.

Performance evaluation is done in terms of Timely delivery of goods, the quality of goods, effective and timely communication, compliance with other contractual terms and conditions, commitment to sustainability, etc.