Section III: List of Requirements

1. Technical specifications, quantities, and delivery plan/schedule

To know the drugs required in this invitation, please refer to document MD_0302ES_v00 Requerimiento por lote.xlsx

2. General requirements

2.1. Product expiration date

Products must have the following validity at the time of delivery:

- In general, **not less than 12 (twelve) months** from the date of receipt at the delivery points/locations indicated in the Purchase Order by UNOPS;
- For those drugs that, due to their nature, have a useful life of less than 12 (twelve) months, they must prove with the granted Sanitary Registration, that the goods have a shorter useful life from their date of manufacture, and must invariably submit a **letter of commitment of replacement** in which they are obliged to exchange within fifteen (15) calendar days from the notification to exchange the goods, at no cost to UNOPS, those Goods that are not consumed within their useful life;
- If for any reason, there is a shortage of products in the market, UNOPS may accept products with an expiration date lower than those specified above, subject to prior risk analysis.

Exceptionally, UNOPS may authorize the delivery of products with an expiration period of less than 12 (twelve) months, but not less than 9 (nine) months counted from their arrival at the delivery points/locations indicated in the Purchase Order. On such occasions, the Supplier shall submit a **replacement commitment letter**, in accordance with the attached form in Section VI: Contract Management, indicating the lot(s) to be delivered, the shelf life at the time of delivery, the delivery locations, and the corresponding quantities.

In these exceptional cases, the Supplier shall replace products that expire or are close to expiring at discretion of the Instituto de Salud para el Bienestar (hereafter - “INSABI”) by replacing them with products that meet all the requirements established for the awarded key and that comply with the minimum shelf life stipulated in the invitation to bid.

2.2. Product Matching

The goods must match exactly to the active ingredient(s) expressing the concentration in the form of Base and Salt if specified, pharmaceutical form, method of administration, and presentation required for each product.

The match will be verified through:

- The Sanitary Registration;
- In the event that the description of the offered goods is not fully detailed in the Sanitary Registration, the Reduced Prescribing Information (IPP-R) and/or label (final artwork and photograph or final design model of the labeling of the primary and secondary packaging) will be verified.

2.3. Characteristics of materials (Packaging / Container / Labeling)

In line with United Nations measures aimed at responsible production and consumption as well as care for the environment, we encourage efforts to eliminate single-use plastics, avoid unnecessary packaging, and/or consider more environmentally and sustainable alternatives such as, among others, biodegradable or recycled packaging and labels, recyclable and/or reusable packaging, the take-back option (for packaging), or obtaining packaging raw materials from sustainable sources, such as cardboard obtained from a sustainably managed forest that is certified according to FSC, SFI, PEFC or equivalent standards. In addition, the use of sustainable inks and glues should be promoted.

2.3.1. Primary Packaging[1]

It must be inert, must isolate and protect drugs sensitive to environmental factors (light, temperature, and humidity) until their expiration date.

The materials of the primary packaging of the intermediate products or the drug should not be reactive, additive, absorbent, adsorbent, in such a way that may affect their quality (Mexican Official Standard NOM-164-SSA1-2013, Good manufacturing practices for drugs 10.5.2).

The physical, chemical and toxicity characteristics for each type of packaging material and the substances used to coat the inside of drug containers will be determined by the corresponding Standard (Health Supplies Regulation, second section, article 18).

Drug containers must have closure systems that make it evident to the user that they have not been opened prior to purchase and that prevent accidental handling by children, as established in the Pharmacopoeia of the United Mexican States or in the corresponding Standard (Regulation of Health Supplies, second section, article 21).

Only substances or products authorized by the Ministry of Health of the United Mexican States shall be used as propellants in aerosol containers (Health Supplies Regulations, second section, article 22).

Drug containers must have microbiological control systems, where the acceptance criteria are established in the Pharmacopeia of the United Mexican States or reference pharmacopeia.

The containers must correspond to what is approved in the Sanitary Registration / Commercialization Authorization issued by COFEPRIS.

2.3.2. Secondary Packaging[2]

The secondary packaging must be resistant, in such a way that it allows the necessary protection of the primary packaging. The use of materials that ensure the required conditions of resistance of the secondary packaging for the handling of the drug will be accepted.

Containers and commercial presentations must correspond to what is approved in the Sanitary Registration / Commercialization Authorization issued by COFEPRIS. Secondary containers must present an insert, package insert, or product instructions as long as it is approved by COFEPRIS.

If during the contract execution, modifications are generated in the artwork of the packaging material, the laboratory is obliged to notify UNOPS of this change and describe the date on which the product will reflect the new artwork. In addition, the change authorization certification issued by COFEPRIS, which endorses the change, must be attached.

2.3.3. Collective or Tertiary Packaging[3]

It is the supplier's responsibility to define the stowage and the quantities contained in a tertiary container for the safety, conservation, handling and proper storage of the product. It must comply with the following specifications:

- Cardboard box or other material resistant to stowage; in such a way as to facilitate handling, transport, and storage, without risk of damage, sealed with tape to ensure the integrity of the contents, conservation, transport, and storage;
- The packaging material of the jars for boxes and internal subdivisions must be sufficiently resistant (thick cardboard);
- Specify the number of boxes contained in the tertiary packaging;
- Specify the number of boxes that can be stacked on top of each other per pallet;

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[1] Primary packaging, to the elements of the container-seal system that are in direct contact with the drug or herbal remedy. Source: NOM-072-SSA1-2012 Standard.

[2] Secondary packaging, to the components that are part of the packaging in which the drug or herbal remedy is commercialized or supplied and are not in direct contact with the drug or herbal remedy. Source: NOM-072-SSA1-2012 Standard.

[3] Collective packaging means packaging containing a defined number of packages of finished product of a single product and of the same lot. Source: NOM-072-SSA1-2012 Standard.

- The size of the package should be consistent with the contents;
- In the case of balances (less than full box), the box containing the balance must be clearly identified.
- All corrugated boxes must be identified with the finished product label, which must present at least the following information and characteristics:

    a. Generic denomination

    b. Presentation

    c. Pharmaceutical form

    d. Destination

    e. Date of Manufacture (format: dd/mm/yyyy)

    f. Date of Expiration (format: dd/mm/yyyy)

    g. Product lot number

    h. Manufacturer's Data

    i. Minimum size 4" x 4"

    j. Key according to the Compendium of National Health Supplies

    k. Total of contained pieces

    l. In the case of collective boxes of leftovers, the word "REMAINDER" must be included on the label and the total number of pieces contained must be adjusted.

    m. Conservation and storage data as detailed below:

    n. Precautionary signage is used according to the nature of the product.

    o. For cytotoxic drugs, a yellow background label must be placed on each collective box (corrugated). With a minimum size of 1 1/2 "x 5/8".

2.4. Labeling

2.4.1. General Information

A label is understood as any label, tag, mark, or graphic image that has been written, printed, stenciled, marked, embossed, debossed, stamped, engraved, adhered, or sealed on any material likely to contain the drug or herbal remedy, including the container itself.

The instructions and labels of primary, secondary, and collective containers must be in Spanish or a simple translation into Spanish and comply with the regulations of NOM-072-SSA1-2012 and authorized by COFEPRIS.

When the information is expressed in a language other than Spanish, it may be up to the same size and typographic proportionality, without opposing or contravening the text in the Spanish language. As described in NOM-072-SSA1-2012 numeral 5.29.

Exceptions to labeling will only be accepted for imported products covered by recognition agreements that are authorized by COFEPRIS, e.g., importation with labeling in English from the country of origin. The authorization of these exceptions must be demonstrated through a formal document issued by COFEPRIS.

2.4.2. Labeling of primary packaging, secondary packaging, and collective packaging

Drugs must contain on the primary or secondary packaging the legend "Property of the Health Sector" or "Not for Sale" and on the secondary packaging the 12-digit code number of the product; in the case of medicines that do not contain secondary packaging, it must be expressed on the primary packaging. This information may be presented by means of additional labels or text introduced by coding equipment, without covering the original information.

Product labeling must be presented in accordance with the following provisions of basic indispensable requirements for drug labeling and be in accordance with what is authorized by COFEPRIS:

No.	Elements of the Label	Packaging	Defines
1	Distinctive Denomination	Primary, Secondary	Commercial
2	International Nonproprietary Name (generic name)	Primary, Secondary, Collective box	Drug
3	Pharmaceutical form	Primary, Secondary, Collective box	Condition of use
4	Drug Concentration	Primary, Secondary	Amount of Drug
5	Formula	Primary, Secondary	Composition
6	Dosage or posology	Primary, Secondary	Administration
7	Method of Administration	Primary, Secondary	Way of consumption
8	Conservation and storage data	Primary, Secondary, Collective box	Stability
9	Warning and cautionary legends	Secondary	Consumption precautions
10	Expression of the alphanumeric key of Sanitary Registration	Primary, Secondary	Identification of the authorization
11	Lot Number	Primary, Secondary	Traceability
12	Expiration Date	Primary, Secondary	Shelf life
13	Manufacturing Date	Primary, Secondary	Start of shelf life
14	Manufacturer's Data	Primary, Secondary	Traceability
15	Content	Primary, Secondary	Contents in the presentation
16	Instructions	Primary, Secondary	Indications to patients or professionals

The aforementioned is not exhaustive, therefore the particular labeling conditions of each drug are listed in NOM-072-SSA1-2012 and its applicability is subject to the provisions of such standard and the authorization by COFEPRIS.

2.5. Tests of interchangeability

The products offered must comply with the interchangeability tests required in the Official Mexican Standard NOM-177-SSA1-2013 or the Agreement published in the DOF: 03/05/2021 "Emergency Modification to the Official Mexican Standard NOM-177-SSA1-2013", the Agreements published in the DOF on 19/09/2017, 14/06/2018, 14/09/2018, 05/11/2018, 30/12/2019 and the others that modify, complement or replace it, that

is, the agreements that determine the type of test to demonstrate interchangeability of generic drugs and define the criteria to be applied to them. Likewise, they must be in accordance with the Decree published in the DOF on 31/05/2021 "Decree by which several provisions of the Regulation of Health Supplies are amended, added and derogated".

For products without Sanitary Registration / Commercialization Authorization issued by COFEPRIS that have Sanitary Registration / Commercialization Authorization issued by Regulatory Agencies / Prequalification with equivalence recognition, clinical studies from the country of origin may be submitted as evidence to initiate the consideration of sanitary registration and be recognized by COFEPRIS as long as they comply with the quality, safety and efficacy requirements. However, studies performed in Mexico will be a requirement for the authorization of extensions to sanitary registrations, confirming the bioequivalence of the drug, which will also be subject to focused pharmacovigilance. The evaluation of regulatory compliance is in charge of COFEPRIS and is guaranteed by the Sanitary Registration / Commercialization Authorization granted by the stated entity, which is a condition for the execution/signing of the contract.

2.6. Product Release

The products offered must comply with the applicable requirements for product release, and demanded in the Mexican Official Standard NOM-059-SSA1-2015 "Good Manufacturing Practices for Medicines", the agreement published in the DOF: 16/07/2014 "Agreement by which the Guidelines are issued to authorize the distribution or sale of lots of biological products", the Agreement published in the DOF: 19/03/2021 "Agreement establishing the Guidelines for the issuance of temporary authorizations of health supplies, for health care establishments and the temporary certification of good manufacturing practices for health supplies that contribute to the eradication and mitigation of the SARS-CoV2 virus (COVID-19)"; and other applicable regulations.

The bidder that offers products without Sanitary Registration / Commercialization Authorization issued by COFEPRIS that have Sanitary Registration / Commercialization Authorization issued by Regulatory Agencies / Prequalification with equivalence recognition, must keep in mind that for the execution/signing of the contract the Sanitary Registration / Commercialization Authorization granted by COFEPRIS is required. Therefore, for the importation and fulfillment of deliveries in the contract execution process, the drug has Sanitary Registration / Commercialization Authorization issued by COFEPRIS and therefore must comply with the applicable local regulations. The evaluation of the regulatory compliance for the importation and release of the product is in charge of COFEPRIS.