Appendices

Appendix 1: Regulatory Agencies / Prequalifications with equivalence recognition agreements for the application of Sanitary Registration / Commercialization Authorization

America

- United States of America - Food and Drug Administration (FDA)
- Canada - Health Canada (HC)
- Argentina - National Administration of Drugs, Food and Medical Technology (ANMAT)
- Brasil - National Agency for Sanitary Vigilance (ANVISA)
- Chile - Public Health Institute (ISP)
- Colombia - National Institute for Drug and Food Surveillance (INVIMA)
- Cuba - Center for Statewide Drug Quality Control (CECMED)

Oceania

- Australia - Administration of Therapeutic Products (TGA)

Europe

- European Commission (Including the belonging National Regulatory Agencies)
- Switzerland - Swiss Agency for Therapeutic Products (Swissmedic)

Some members of the Pharmaceutical Inspection Cooperation Scheme

- Germany - Federal Ministry of Health (BMG)
- Germany - Laender's central authority for health protection in relation to medicinal products and medical devices (ZLG)
- Austria - Agency for Health and Food Safety
- Belgium - Federal Agency for Drugs and Medical Devices
- China (Taipei) - Food and Drug Administration of Taiwan
- China (Hong Kong) - Hong Kong Pharmacy and Poisons Board
- Croatia - Croatian Agency for Medicines and Health Products
- Denmark - Danish Drugs Agency
- Slovenia - Drugs and Medical Devices Agency
- Spain - Spanish Agency of Drugs and Medical Devices
- Estonia - State Agency for Drugs
- Finland - Finnish Drug Agency
- France - French National Agency for the Safety of Drugs and Medical Devices
- France - Agency for Food, Environmental and Occupational Health and Safety
- Ireland - Medical Devices Regulatory Authority

- Italy - Italian Drug Agency
- Japan - Ministry of Health, Labor and Welfare
- Japan - Pharmaceuticals and Medical Devices Agency
- Latvia - State Drug Agency
- Liechtenstein - Health Office
- New Zealand - Drugs and Medical Devices Safety Authority
- Norway - Norwegian Drug Agency
- The Netherlands - Health inspection and youth care
- Poland - Main inspection of pharmaceutical products
- Portugal - National Authority of Drugs and Medical Devices
- United Kingdom - Drugs and Healthcare products Regulatory Agency
- Czech Republic - State Institute for Drug Control
- Czech Republic - Institute for State Control of Biological Products and Veterinary Drugs
- Republic of Korea - Ministry of Food and Drug Safety of the Republic of Korea
- Slovak Republic - State Institute for Drug Control
- Romania - National Agency for Drugs and Medical Devices of Romania
- Sweden - Swedish Medical Products Agency
- Switzerland - Swiss Agency for Therapeutic Products

Drugs prequalified by the World Health Organization's Prequalification Program for drugs and vaccines

Available at: https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products

Appendix 2: Regulatory Agencies with Good Manufacturing[1] Practice Certificates

- Australia - Administración de Productos Terapéuticos (TGA)
- Canada - Health Canada (HC). The Certificate of Pharmaceutical Product issued by this regulatory agency is acceptable.
- United States of America - Food and Drug Administration (FDA). The Certificate of Pharmaceutical Product issued by this regulatory agency is acceptable.
- Japan - Ministry of Health, Labor and Welfare (MHLW)
- Republic of Korea - Ministry of Food and Drug Safety of the Republic of Korea (MFDS).
- United Kingdom - Drugs and Healthcare products Regulatory Agency (MHRA)
- Switzerland - Swiss Agency for Therapeutic Products (Swissmedic)
- Agencia Europea de Medicamentos (EMA)
- Argentina - National Administration of Drugs, Food and Medical Technology (ANMAT)
- Brazil - National Health Surveillance Agency (ANVISA)
- Chile - Institute of Public Health (ISP)
- Colombia - National Institute for Drug and Food Surveillance (INVIMA).
- Cuba - Center for State Control of the Quality of Drugs (CECMED)
- Germany - The German Ministry of Health (BMG) and the Laender Central Authority for Health Protection (ZLG). All German drug authorities listed on the ZLG website are considered recognized authorities.
- Austria - Federal Office for Safety in Health Care
- Belgium - Federal Agency for Drugs and Medical Devices (AFMPS)
- Bulgaria - Bulgarian Drug Agency
- Chinese Taipei - Taiwan Food and Drug Administration (TFDA)
- Croatia - Croatian Agency for Drugs and Medical Devices HALMED
- Cyprus - Pharmaceutical Services (CyPHS)
- Denmark - Danish Drug Agency
- Slovakia - State Institute for Drug Control (SIDC)
- Slovenia - Drugs and Medical Devices Agency (JAZMP)
- Spain - Spanish Agency of Drugs and Health Products (AEMPS)
- Finland - Finnish Drug Agency
- France - National Agency for the Safety of Drugs and Health Products (ANSM)
- Greece - National Drug Organization
- The Netherlands - Health and Youth Care Inspectorate
- Hong Kong - Pharmacy and Poisons Board of Hong Kong
- Hungary - National Institute of Pharmacy and Nutrition
- Ireland - Health Products Regulatory Authority (HPRA)
- Italy - Italian Drug Agency
- Norway - Norwegian Drug Agency

[1] Good Manufacturing Practices Certificates are subject to review and acceptance by COFEPRIS at the time of evaluating the documentation submitted by the bidder to obtain its sanitary registration.

- Poland - Chief of Pharmaceutical Inspection
- Portugal - National Authority for Drugs and Health Products, IP
- Czech Republic - State Institute for Drug Control
- Romania - National Drug Agency
- Singapore - Health Sciences Authority (HSA)
- Sweden - Medical Products Agency

APPENDIX 3: REPLACEMENT COMMITMENT LETTER TEMPLATE (LETTER OF EXCHANGE)

Instructions: Use this Form in accordance with the following conditions:

- **With legalized or notarized signature;**
- **One letter per product must be submitted;**
- **A single letter may be submitted for multiple delivery locations as long as each and every one is listed.**

We, [Contractor's Name], under Purchase Order No. [purchase order number] for the supply of the product described below:

Key	Description	Quantity to be delivered	Amount	Delivery Date
[Insert]	[Insert]	[Insert]	[Insert]	[Insert]

WE DECLARE that:

The lot(s) of the product to be delivered has a shelf life of less than twelve (12) months counted from its entry into the delivery points; as detailed below:

Delivery Location	Maximum quantity subject to replenishment or replacement	Expiration date of the goods included in the received lot
[Insert]	[Insert]	[Insert]
[Insert]	[Insert]	[Insert]
[Insert]	[Insert]	[Insert]

THEREFORE,

WE UNDERTAKE to replace the above-referenced products, in whole or in part, if the following conditions are present:

1. Quality defects in an inspection by attributes;
2. Expiration of the product before being delivered to the final beneficiary(ies).

In both cases, it will be carried out under the following conditions:

1. Deadline: within fifteen (15) calendar days from UNOPS notification to replace the products;
2. Place: at the same delivery location, and;
3. Cost: no cost and/or fee for UNOPS and/or INSABI.

I hereby sign this document at [place], on [day] of the month [date] of the year [year].

Name of Contractor's Legal Representative]

[Signature of Contractor's Legal Representative]

[Contractor's Stamp]

Appendix 4: Delivery Points - Logistic Operator

Deliveries of keys procured by UNOPS will be made to the delivery addresses of the logistics operators. The distribution of the quantities of each logistic operator will be informed by UNOPS during the process of issuance of Replenishment Orders. In the event of a change (inclusion or elimination) of any delivery address, UNOPS will promptly inform the contractors, guaranteeing that the delivery points will always be maintained in Mexico City, Metropolitan Zone and State of Mexico, with a total of 11 locations.

#	Logistic Operator	Address
1	Integradora Logística en Salud, S.A. de C.V.	ILS Almacén Lerma. Av. Prolongación Industrial Automotriz No. 33 Bodega E, Colonia Parque Industrial Lerma, C. P. 52000, Toluca, Estado de México. ILS Almacén Vallejo. Poniente 146 No.544, Col. Nueva Vallejo Alcaldía Gustavo A. Madero Ciudad de México C.P. 07720
2	BIRMEX	Avenida Industria Automotriz número exterior 18 número interior 3-C, Col. Parque Industrial Lerma Municipio Lerma Estado de México C.P. 52004
3	Médica Farma Arcar, S.A. de C.V.	MFA Almacén Lerma. Av. Industria de la Logística No 9, Col. Ex Hacienda Doña Rosa, Lerma Estado de México, C.P, 52000 MFA Almacén Texcoco. Calle Reforma No 201 San Joaquín Coapango Mun. Texcoco Estado de México C.P. 56243 Calle Tepanntitla s/n la Purificación Tepantitla Texcoco
4	Levic, S.A. de C.V.	LEVIC Almacén Tláhuac. Mar de la Tranquilidad Mz. 110 Lt. 10 Col. Selene, C. P. 13420, Tláhuac, Ciudad de México LEVIC Almacén Lerma. Av. Prolongación Industrial Automotriz No. 33 Bodega E, Colonia Parque Industrial Lerma, C. P. 52000, Toluca, Estado de México.
5	GNK Logística, S.A. de C.V.	GNK Almacén Lerma. Avenida Industria Automotriz número exterior 18 número interior 3-C, Col. Parque Industrial Lerma Municipio Lerma Estado de México C.P. 52004
6	Vantage Servicios Integrales de Salud, S.A. de C.V.	VANTAGE Almacén Tizayuca. Av. Diligencias No. 53 Col. Tepojaco Municipio, Tizayuca Hidalgo, C.P. 43823
7	Dibiter, S.A. de C.V.	DIBITER Almacén Granjas Esmeralda Iztapalapa: Trigo No. 16, col. Granjas Esmeralda, Alcaldía de Iztapalapa, C.P. 09810, Ciudad de México
8	SILODISA	Carretera Lago de Guadalupe Km 27, 5 Col, San Pedro Barrientos, 54010 Tlalnepantla de Baz, Méx.
9	SEDENA	Avenida Industria Militar No. 1088, Lomas de San Isidro Naucalpan de Juárez, Estado de México Avenida Industria Militar S/N, Lomas de Sotelo, Miguel Hidalgo, Ciudad de México.
10	SEMAR	Canal de San Juan y Tezontle s/n, Colonia Ejército Constitucionalista, Alcaldía Iztapalapa, C.P. 09929
11	Compañía Internacional Médica (CIMSA)	Carretera Lago de Guadalupe km. 27.5 S/N LOTE 2 CEDIS 1 B1, Colonia: San Pedro Barrientos Tlalnepantal de Baz, Estado de México. CP 54010

APPENDIX 5: GLOBAL DELIVERY MANAGEMENT PROCESS

Equipo de Cadena de Suministro de UNOPS enviará por correo electrónico las órdenes de reposición (OR) correspondientes a un determinado contrato que en UNOPS se instrumenta a través de una Orden de Compra (Purchase Order - PO).

Proveedor deberá solicitar una cita con el operador logístico (OL) correspondiente en hasta 48 horas después de haber recibido la OR de UNOPS, pactando fecha y hora; siempre respetando la fecha máxima de entrega establecida en la OR.

Proveedor deberá realizar la entrega de los bienes requeridos en la OR en el OL.

Proveedor deberá enviar la evidencia de entrega al equipo de Cadena de Suministro de UNOPS.
Este proceso deberá ser completado dentro de las 48h posteriores a que la OR haya sido entregada en su totalidad, con firma y sello correspondiente, al igual que las remisiones.

El equipo de Cadena de Suministro de UNOPS le informará en caso de que haya alguna inconsistencia en la recepción de evidencias de entrega.

El proceso detallado será enviado a los oferentes contratados junto a las primeras Órdenes de Reposición.