

To All UNICEF Long Term Agreement holders for Pharmaceuticals

RE: COMPLIANCE WITH TEMPERATURE MONITORING REQUIREMENTS FOR TIME- AND TEMPERATURE-SENSITIVE PHARMACEUTICAL PRODUCTS

Dear Sir/Madam,

UNICEF would like to remind all vendors of their obligation to comply with the transport and transit storage requirements for DAP and FCA shipments of Time-and-Temperature Sensitive Pharmaceutical Products (TTSPPs). It is essential that all TTSPPs are transported under conditions that ensure product temperatures remain within acceptable limits throughout the entire shipping and transit process. The use of appropriate temperature monitoring devices is a critical component of this compliance. Please refer to below clause in all UNICEF issued purchase orders:

"Supplier is responsible to provide transport and storage temperature information on shipping documents and Certificate of analysis.

The transport and storage temperature MUST be visibly indicated on external packaging such as Shippers and pallets. Supplier is responsible to include additional labelling requirements such as "Do not freeze", "Protect from light", "Store and transport in dry condition" on all external packaging.

In case there is any doubt as to the transport and storage temperature, the information provided by the supplier specific to a purchase order shall supersede the temperature range specified in this PO text.

It is the responsibility of the supplier and freight forwarder to ensure that product temperature conditions are maintained within acceptable limits during transport and transit. Regardless of the mode of transport, it should be possible to demonstrate that the product has not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilised when planning transportation."

Transport and transit storage requirements are outlined in the technical specifications available at the following link:

[Technical requirements for pharmaceutical and nutrition products | UNICEF Supply Division](#)

Suppliers are required to include temperature monitoring devices in both DAP and FCA shipments.

For FCA incoterm shipments, the manufacturer is responsible to inform the freight forwarder (FFW) on the type of equipment required for sea freight and/or temperature requirement for air freight, and to include data loggers. It is the role of the FFW to arrange for appropriate transport conditions, as agreed with UNICEF when deemed possible and otherwise propose alternative transport solutions for UNICEF's review and agreement.

For DAP incoterm, the Long-Term Agreement (LTA) holder is responsible for shipping of the pharmaceutical product in accordance with the transport and storage temperature conditions for respective products.

We therefore request that all bookings issued **effective 1st August 2025** to UNICEF Supply Division for TTSPPs be made within the recommended temperature storage conditions with data loggers and this will be verified upon receipt at the destination.

For any questions, comments or queries, please address your email to sd.ttssp@unicef.org

Yours Sincerely,



Francisco Blanco
Chief, UNICEF Medicine and Nutrition Centre

ANNEX

1.1 Data Logger Specification:

- Both WHO Prequalified and non-WHO prequalified devices that meet the specifications below will be acceptable.
- A list of WHO prequalified Data Loggers may be found from the following website:
https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=35
- **Single-Use Devices:** Must be inserted at the country of origin and used only once.
- **USB-Type: Direct USB interface, without need for cables.**
- **Serialized:** Include serial number reference, number of data loggers and location of data loggers in the shipment (shipper /carton number) on the packing list and **clearly mark the shipper which contains the data logger.**
- **Measurement Capabilities:** Must record temperature over time.
- **Calibration & Activation:** Devices must be calibrated and activated just before shipment dispatch.
- **Battery Life:** The device must support continuous operation to cover the entire expected duration of the shipment, with a safety margin of at least one additional month to account for potential delays due to unfavourable weather conditions, logistical challenges, or other unforeseen circumstances. Longer battery life should be considered where shipment durations are uncertain or prone to extension.
- Powered by only button (coin) cells/batteries in compliance with Section II of PI970.
- **Recording Frequency:** Log initial temperature and then at least every 30 minutes until manually stopped.
- **Self-Disabling:** Once stopped, the device must disable itself and not be restartable.
- **Preset Thresholds:** Must be configured with acceptable high/low temperature limits; alarms should trigger if limits are exceeded.
- **Technical Features:** Sufficient memory, wide temperature range, reliable alarms, and no need for extra software to retrieve data.

1.2 Minimum Data Logger Placement requirements for Sea Freight, unless otherwise validated by the company:

- 2 data loggers per reefer container, irrespective of the container size.
- **Logger 1:** Place at the back of the cargo area at the worst-case location, regardless of the number of pallets or boxes.
- **Logger 2:** Place high in the front of the cargo area near the door, regardless of the number of pallets or boxes.
- Please clearly identify which pallet / shipper or carton contains the data loggers (e.g., shipper or carton number) in the packing list and clearly mark with a visible sticker.

1.3 Minimum Data Logger Placement requirements for Air Freight, unless otherwise validated by the company:

- 1 data logger per shipment.
- Place the data logger inside a randomly selected shipper carton. This carton should then be placed in the center of a randomly chosen pallet within the shipment.
- Please clearly identify which pallet /shipper or carton contains the data loggers (e.g., shipper or carton number) in the packing list and clearly mark with a visible sticker.

1.4 Minimum Data Logger Placement for Road Freight, unless otherwise validated by the company:

- Company to ensure access to temperature monitoring records from temperature-controlled vehicles.
- 2 data loggers for non-temperature-controlled vehicles based on a risk-assessment to ensure no impact on the quality and integrity of the product.
- **Logger 1:** Place at the back of the cargo area at the worst-case location, regardless of the number of pallets or boxes.
- **Logger 2:** Place high in the front of the cargo area near the door, regardless of the number of pallets or boxes.
- Please clearly identify which pallet / shipper or carton contains the data loggers (e.g., shipper or carton number) in the packing list and clearly mark with a visible sticker .