GDF's experience in transport of medical products: challenges and opportunities

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2023 Joint UNICEF, UNFPA, and WHO Meeting, Copenhagen, 27 November – 1st December 2023

GDF's Goal for Storage and Transport of Temperature Sensitive TB medicines and diagnostics tests

Goal:

Ensure that TB medicines and diagnostics tests are stored and transported as per approved storage conditions along the supply chain and until the delivery place as per agreed INCOTERM with the clients to ensure quality of supplied TB products by GDF

Objectives:

1. Ensure that TB products are stored in warehouse/s compliant with Good Distribution Practices (GDP) for medical products
2. Ensure that transport type used is compliant with TB products storage conditions
3. Implement risk management approach in case 1 and/or 2 is not available to reach the final destination

Storage Conditions and Transport Type required

Most of the TB medicines must be stored below 30°C and most of the TB diagnostics tests must be stored in cool (+2° to + 8°C)

Transport Type	Conditions	TB medicines	TB Diagnostics tests
Cold chain transport	Temperature controlled transport (active or passive controls) with temperature range between 2 – 8°C	N/A	Yes
Controlled ambient transport	Temperature controlled transport with temperature range aimed to be between 15 – 25°C - Sea: reefer containers - Air: Controlled ambient shipment bookings - Land: airconditioned trucks/vans	Yes	N/A
General cargo transport	Uncontrolled (regular) transport - Sea: dry containers - Air: General cargo shipment bookings - Land: non-airconditioned trucks/vans	No	No

GDF's Challenges

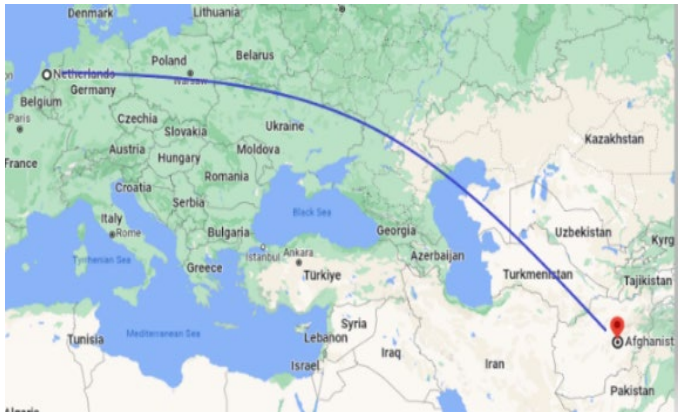
Challenges with cold chain and controlled ambient transport type for TB products access:

- Longer delivery timing dependent on availability of reefers and controlled air shipment options (limited air carrier possibility)
- Some destinations do not have capabilities at (air)port for controlled temperature handling
- Transport routes with transit/s increase temperature excursion risks during unloading and loading steps (more difficult to control than during storage)
- Added costs and variable surcharge fee for temperature controlled cargo

Delivery delays and high freight costs lead to risk of stock outs and unaffordability of TB products

How GDF's Addresses these Challenges (1)

Find the transport route that meets storage/transport conditions or that mitigate the risk of temperature excursion

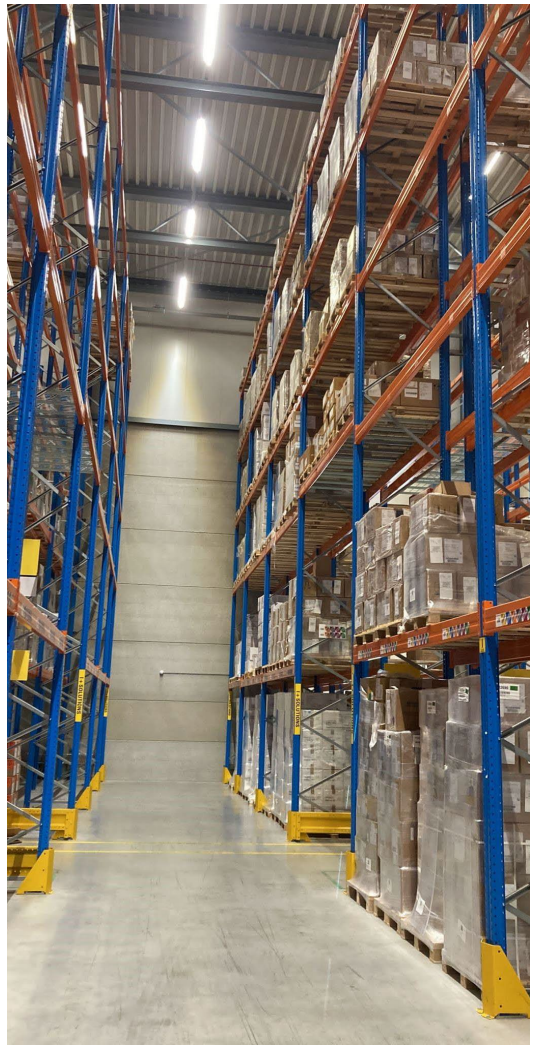


Humanitarian Emergency in Afghanistan

Challenge: Between September 2021 and the second quarter of 2022, cold chain transport into Afghanistan was not possible due to the volatile political situation

GDF Actions and Results: Close collaboration between GDF, supplier and freight forwarder, led to successful delivery of GeneXpert cartridges to Afghanistan during this period by using a combinaison of routes with the aim to have the longest transport route under cold chain conditions and the last shortest mile into Afghanistan under ambient temperature as authorized by the supplier according to stability studies.

How GDF's Addresses these Challenges (2)



Use of the GDF's Strategic Stockpile (SRS)

The SRS is a key part of GDF's strategy to ensure clients receive expedited access to quality-assured TB medicines.

- ✓ More than 50% of TB medicines supplied to countries are from the SRS
- ✓ SRS is replenished on a regular basis against GDF's client orders and forecasts
- ✓ TB medicines from the different suppliers (mainly from India) are consolidated and sent to the SRS in Netherlands by reefer containers.
- ✓ Quantity of reefer containers needed for SRS is less than for direct shipments

Better transport planning reduce the risk of unavailability and cost of reefer containers

How GDF's Addresses these Challenges (3)

Classify TB medicines sensitive to temperature excursion and control their transport conditions

- ✓ GDF has identified the list of TB medicines sensitive to temperature excursion
- ✓ These TB medicines are shipped to countries, only with controlled ambient transport and with data loggers
- ✓ Suppliers are requested to provide stability data under stress conditions to allow GDF to evaluate the impact on the quality of the medicine in case of temperature excursion

GDF's Opportunities

The join UN QA working group

The joint UN QA working group is serving as a platform:

- ✓ to drive cooperation in the Quality Assurance along the supply chain and to a practical level,
- ✓ to reduce fragmentation in regulatory and quality assurance harmonization by developing strategic solutions for improving collaboration and coordination through a mix of forward-looking road mapping, needs assessment and gap analysis techniques.

GDF submitted a request to the UN QA group to work on the development of a risk management decision tree for the shipment of temperature sensitive medicines and diagnostics

Asks to suppliers

What are supplier's practices for shipment of medicines/ diagnostics?

Do suppliers use data loggers for their shipments of medicines / diagnostics?

If use of data logger,

how many? which type? which range? How data are managed?

Do suppliers have data stability under stress conditions for medicines / diagnostics?

How suppliers handle temperature excursion for medicines / diagnostics?

Thank You