Requirements for Storage and Transportation of Time and Temperature Sensitive Health Products

GDF's experience for transport of medical products, challenges and opportunities

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Presentation Outline

Objectives and overview of GDF approaches

Time and temperature sensitive products

Current practices

Challenges

Opportunities and take-away messages

GDF's Goal for Storage and Transport of Temperature Sensitive TB medicines and diagnostic products

Objective:

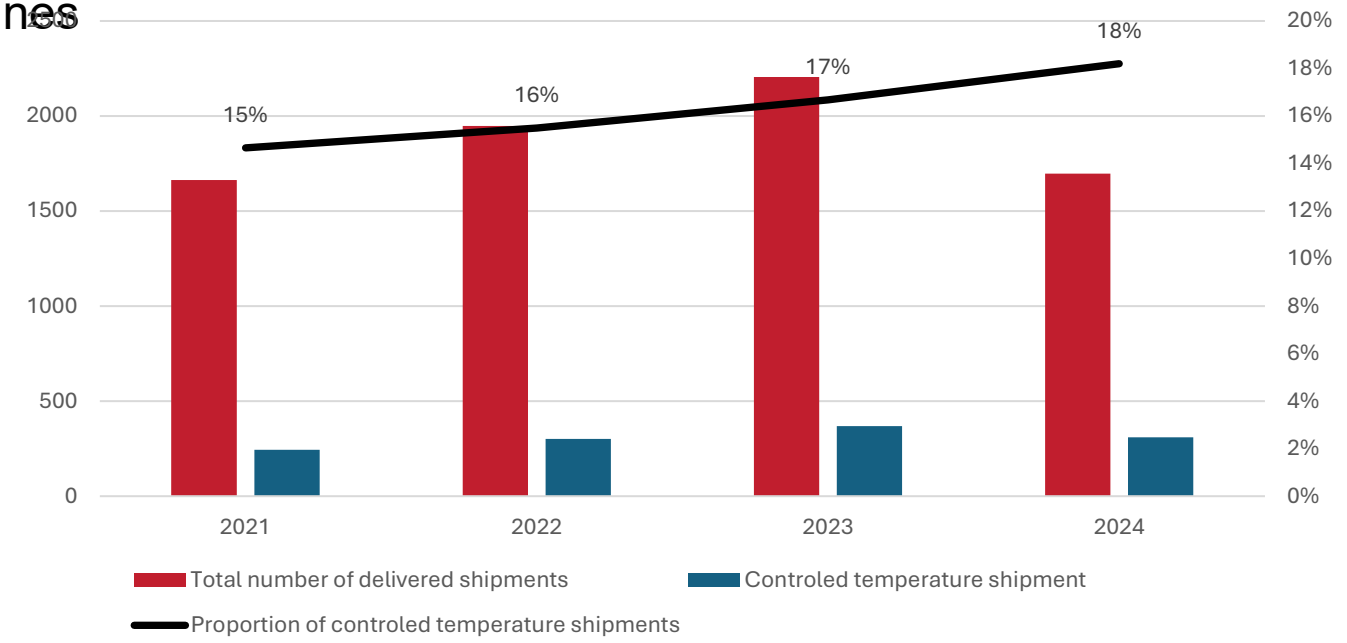
To deliver TB medicines and diagnostics products safely and efficiently to the customers destination, adhering to approved transport and storage conditions, Good Distribution Practices (GDP), and agreed INCOTERMs

Key Considerations:

1. Cold Chain Integrity
2. Appropriate Transport mode
3. Agreed Delivery Timelines
4. Considering Risk based approaches

Overview of GDF approaches

- Global Drug Facility (GDF): Supplied TB medicines and diagnostics to over 165 countries since its inception in 2001
- Unique Aspects of GDF Logistics management:
  - Through Procurement Agent (PA) for medicines
  - In-house for Diagnostics
- Mindful of temperature and storage requirements of TB medicines and diagnostic kits during transportation
- Ensures integrity from collection points until delivery to consignee



As of 28th of November 2024

Time and Temperature-Sensitive Products handling

- Sensitive TB medicines requiring data loggers.
- TB medicines consignments for clinical trials with data loggers.
- TB diagnostic products requiring cold chain conditions (Cool Cargo: 2 - 8 °C, Controlled Room Temperature: 15 - 25 °C or Dry ice: -80 to -18°C).
- Dangerous goods requiring to be kept at specific temperatures.
- Diagnostic products transported by sea and requiring a cold chain due to long transit times.

Transportation mode:

Air | Sea | Road

Depending on incoterms and/or destination

Current transportation practice: GDF and Contracted PA

Sea Shipments:

- Reefer containers for all medicines for Inbound shipments and Outbound shipments to ports that have the required infrastructure
- Dry containers for large and low value diagnostic products

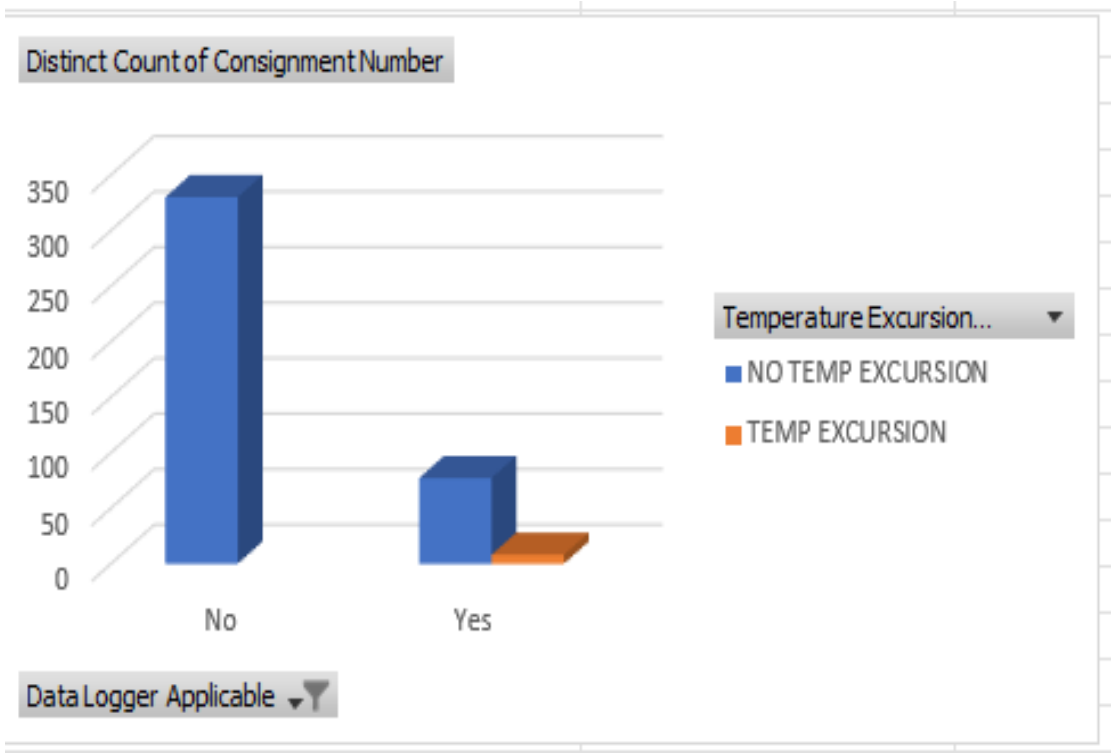
Air shipments:

- General cargo for all TB products with storage conditions of below +30°C, no data loggers
- 15 - 25 °C for sensitive TB medicines and the clinical trial consignments with data loggers
- Cool or 15 - 25 °C cargo for diagnostic products subject to their storage and transportation conditions

Road shipments:

- Given the diversity of the GDF Diagnostics catalogue, most of the available transport temperature setups are used

Q3 – 2024 example of Medicines consignments excursions analysis

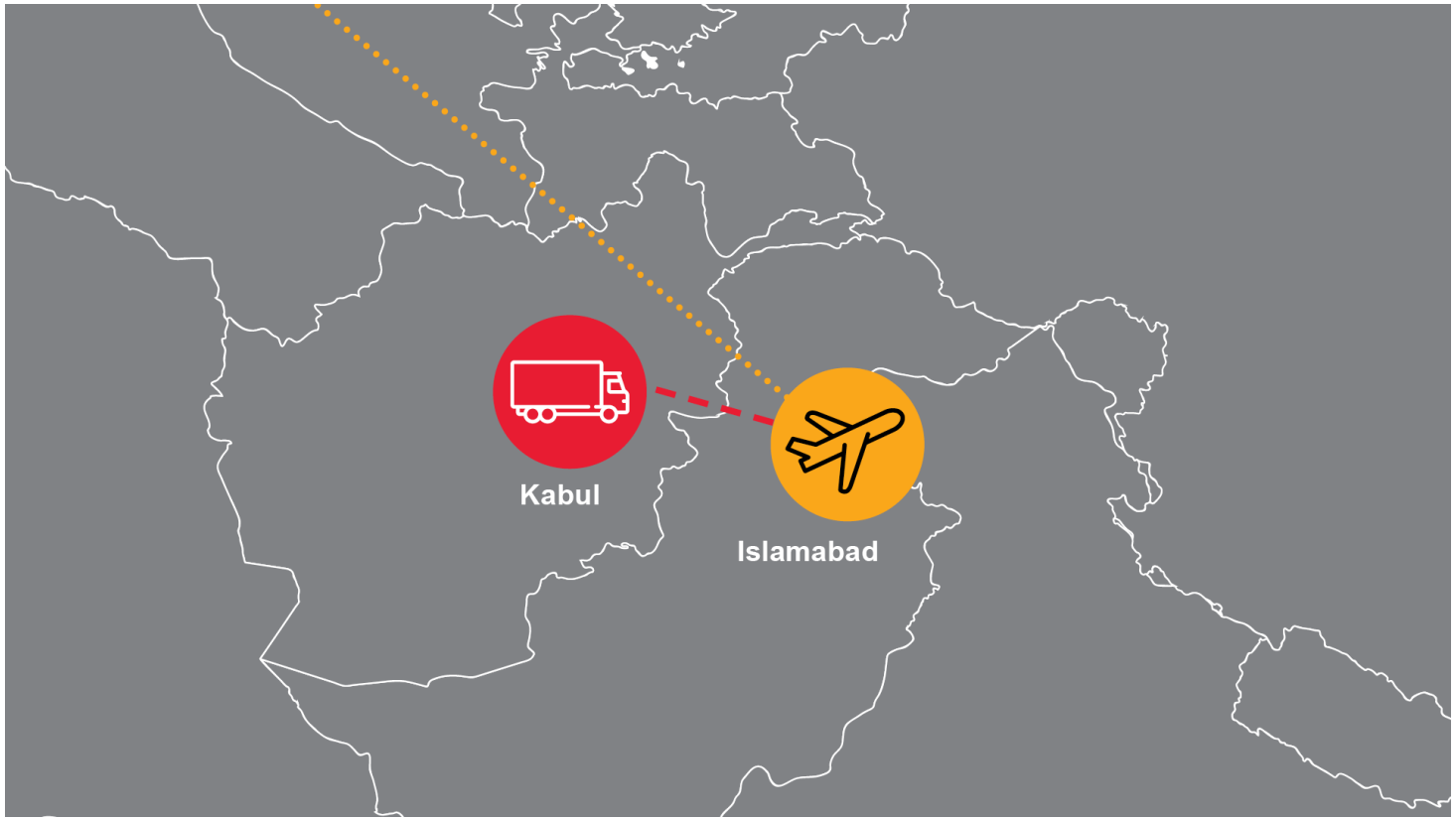


- Total excursions recorded were 8 out of 85 shipments.
- 4 out of the 8 reported excursions were clinical trial shipments
- Of the 8 shipments, 7 were by air and 1 by sea
- 2 of the 8 shipments were direct shipment from the manufacturer to country
- Higher proportion of the excursions was by air transport

Example of special handling to maintain cool transport when no straight-forward solutions are available

Kabul - Afghanistan:

- **Scenario:** No cool cargo solutions for legs to Kabul
- **Solution:** Air freight to Islamabad – Pakistan, then cool truck to Kabul

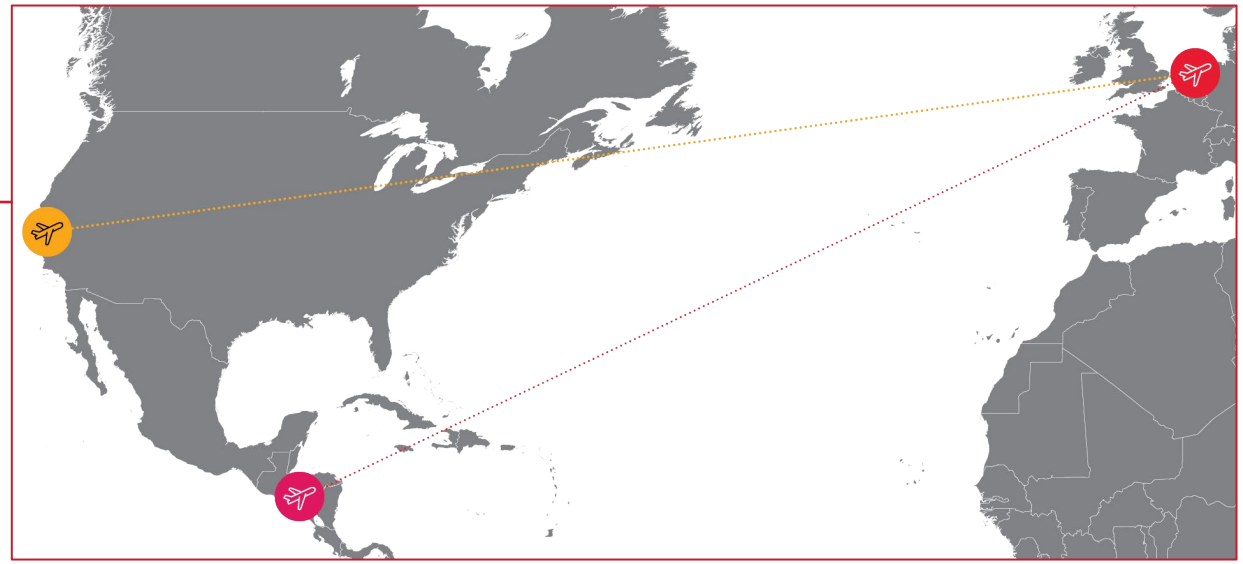


Tegucigalpa – Honduras (TGU):

- **Scenario:** No cool cargo solutions from USA to TGU

Solution 1: Air freight to European hub, then direct flight to TGU

- *Fast and safe, but costly and inefficient*



Solution 2: Air freight from SFO to MIA, then air freight from MIA to Managua – Nicaragua and finally road freight to TGU

- *Long and debatable reliability, but cheaper and more efficient*

Example of product handling adaptation to preserve product stability

- Diagnostic products procured through GDF are frequently transported to regions with extreme temperature fluctuations, such as tropical or desert climates
- Furthermore, these products are often destined for remote and difficult-to-access locations, leading to extended and unpredictable transit times
- Thorough evaluation of each product's storage and transport requirements is then crucial. We are often changing the suppliers transport requirement to match their storage requirements

Example for the case of one of GDF MTB Reagents:

- Storage requirement: +25°C in a dry place, protected from light
- Transport requirements: General Cargo with gel packs lasting 72h
- GDF Decision on transport requirement: +15 - +25°C

GDF's Challenges

Delayed delivery lead-times to unavailability of reefers and controlled air shipment options (limited air carrier)

Some destinations do not have the necessary infrastructure at (air)port for receiving controlled temperature consignments

Transport routes with transit/s increase risks of temperature excursion during handling

Higher freight and handling costs for temperature controlled cargo including the storage

Delivery delays and high freight costs lead to limited access to diagnosis and treatment interruptions

How GDF is addressing these Challenges

Diagnostics

- The current Diagnostics catalogue contains over 580 items with more than 40 transport requirements, necessitating GDF to provide tailor made transport solutions
- Ensure a shared understanding of storage and transport requirements through detailed communication with suppliers, GDF teams, and clients (including requirement of rapid customs clearance)
- Work with GDP and/or GMP certified suppliers, freight forwarders and transporters
- Products requiring controlled temperature transport conditions in air freight are sent with best-in-class carriers and shortest available routing

How GDF is addressing these Challenges

Medicines

- GDF has identified the list of TB medicines sensitive to temperature excursion.
- These TB medicines are shipped to countries, only under controlled ambient (+15 - +25°C) transport conditions 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.
- Engaging with supplier to determine tailor made solutions depending on storage requirements, available excursion data, urgency of product & transport mode.
- Use of SRS to facilitate consolidation of shipments hence minimising carbon footprint.

Opportunities and take-away messages

Technological Solutions – GDF :

- Adoption of thermal blankets for temperature stabilization
- Advance route optimization to minimize transit times
- Passive cooling boxes for diagnostics

HARMONIZE/ALIGNMENT AND IMPROVEMENT

UNA and others:

Develop:

- an algorithm for risk management for shipment of temperature sensitive medicines and diagnostics to facilitate harmonized decision making
- normative guidance on the use of data logger and its placement during product transportation
- harmonize an implementation approach/strategy to reduce carbon footprint

Manufacturers/Suppliers:

Manufacturers to avail supporting data on stability, transport validation including excursion studies when requested

Manufacturers to develop innovative packaging to preserve the product stability during transportation

THANK YOU

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