PHARMA AERO

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**Pharma.Aero** Bedrijvenzone Machelen Cargo 706B, 1830 Machelen

WHITE PAPER

# PROJECT: PHARMA QUICK REFERENCE GUIDE

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# 1. Abstract

Pharma.Aero's mission is to ensure the safe and reliable transportation of life science and MedTech products, by fostering collaboration among stakeholders along the end-to-end supply chain to address genuine challenges faced by our industry.

As part of our mission, in June 2022, the Pharma Quick Reference Guide (QRG) Project was launched to create a set of guidelines for the fast and safe transportation of the Time and Temperature Sensitive Products (TTSPs) to airports that are located in remote or geopolitically sensitive regions. In the process of designing the Pharma QRG, our project team identified the critical points of the import air cargo process, its stakeholders and their responsibilities. The main deliverables of the project are a set of three checklists to be filled in by various stakeholders in specific moments of the transportation process. The checklists' templates represent the main deliverables of the project and were included in a detailed, and comprehensive Technical Report destined for Pharma.Aero membership only. The current White Paper presents the project's methodology and findings, together with a set of conclusions and recommendations.

# 2. Introduction

In today's world we are being constantly challenged to find solutions for urgent, unplanned deliveries of healthcare products to people in remote, underdeveloped, or geopolitically sensitive regions. In such extraordinary circumstances, we must ensure that even the Time & Temperature Sensitive Pharmaceuticals (TTSP) are delivered in proper conditions, regardless of the local airport setup.

Efficient and timely coordination among the multiple international stakeholders is vital for a successful TTSP transportation. Based on the existing standards in place and the expertise of its global network of members, Pharma.Aero initiated the Pharma Quick Reference Guide (QRG) Project to identify all essential information needed by all stakeholders when transporting TTSP in extraordinary circumstances (emergency situations) to airports in remote, underdeveloped or geopolitically sensitive regions. The Pharma QRG is a methodology that could be used in addition to existing TTSP quality certification programs in place. It is designed exclusively to ensure the minimal basic approach for a safe, successful TTSP transportation in extraordinary circumstances and is not meant to replace any of the existing quality certification programs (e. g. CEIV, GDP, ISO).



# 3. Methodology

The project has initially been designed in four Work Packages. Also, an intermediate step of testing was decided during the project to validate the outcome of packages 1 and 2.

| Mid July 2022 | End September 2022 | October-December 2022 | February 2023 | March-April 2023 |
|---|---|---|---|---|
| WP1 | WP2 | TEST PHASE | WP3 | WP4 |
| Identify the minimum requirements (based on existing standards) for a transport plan and the key players of the Airport | Identify typical constraints (potential challenges) and possible workable solutions in a Pre-flight Checklist and an Arrival Checklist | Real Life Testing of Designed Checklists | Issue Guidelines and Checklist for stakeholders to successfully transport TTSP | Publication Technical Report to our Members and White Paper to the Industry |

Various workgroups have been organized to identify the requirements of a transport plan and the main stakeholders involved. A process-oriented approach has been used to determine the critical control points.

The checklists have been reviewed ensuring that they are:

**Complete & Comprehensive**
no missing information

**Accurate & Meaningful**
data required relevant and not overloaded

**Workable & Easy to use**
data is easy to collect

## PROJECT TEAM

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# 4. Results

## 4.1 Key Players & Responsibilities

The first important objective was to identify the main stakeholders and their associated responsibilities. While the project team offered a high-level description of the end-to-end process, from the manufacturer to the destination, the project focused on the last segment of the process, the import at the destination airport. A comprehensive list of stakeholders, together with their responsibilities and a detailed presentation of the information flow was provided as part of the project's Technical Report, shared with Pharma.Aero members only.

### Important observations:

- *The information flow needs to be accurate, timely and complete.*
- *Sharing and cascading the information is critical.*
- *Some of the steps often lack formalization, either by not sharing, receiving or confirming information. These pitfalls happen more likely at the handler at the destination airport (in this specific case where the airport is not in the known network as located in a remote area and/or emergency geopolitical region).*
- *The highest risk at arrival is represented by the lack of confirmation of capacity and availability in terms of storage.*
- *The local customs represent a key stakeholder that is essential to a smooth arrival/import process..*
- *The customs clearance process should be facilitated by the consignee.*
- *Timely data sharing is crucial to enable successful end-to-end transportation.*



## 4.2 Checklists

The Critical Control Point (CCP) is a point, step, or procedure at which controls, or checks can be applied to prevent or reduce a hazard or risk to an acceptable level[1]. Identifying the CCP for transporting TTSP and designing appropriate checklists at critical process steps would therefore contribute to the success of the transport chain.

While conducting the assessment of the import process, in order to identify the key stakeholders, their associated responsibilities and the information flow, the project team identified additional Critical Control Points. The need for an additional checklist, the Planning Checklist (not previously foreseen in the project's charter), emerged as an important risk mitigation. The Planning Checklist is part of the preparations prior to the transport, to help identify necessary adjustments to the route or to the packaging, and to prevent risks of miscommunication and mishandling along the transport chain up to the destination. Therefore, Work Package 2 deliverables encompass the 3 following checklists:

### Planning Checklist

- To be activated ahead of the booking
- Collects information about: Shipping requirements, Capacity, Capabilities
- To be filled in by: Freight Forwarder, Airline, Ground Handling Agent

### Pre-flight Checklist

- To be activated before confirming the booking
- Based on the Planning Checklist
- To be filled in by the Airline
- The Airline confirms the shipment, routing and flight information prior to shipping.
- It is to be sent to the destination airport (together with the guidance materials that are explained in the next chapter) to ensure smooth handling of the TTSP shipment.

### Arrival Checklist

- Operational Checklist
- To be used by the Ground Handler at destination.
- Identifies each critical step that must be adhered to enable collection of critical operational times that will demonstrate that handling at destination was performed as planned.



1 IATA Time & Temperature Control Regulations

## 4.3 Guidelines

The success of the TTSP distribution starts with respecting the industry accepted standardized communications through affixing the Time and Temperature Sensitive label to the shipments and indicating the transport temperature range on the Master Air Waybill[2]. In this way, each stakeholder along the distribution chain knows the specific handling requirements.

In the context of shipping to airports in remote and/or emergency geopolitical regions, it is highly probable that the destination airport has no standard operating procedures in place and moreover is unlikely to be IATA CEIV Pharma or GDP certified, hence the pressing need for providing clear and concise instructions and guidelines.

### a. Raising Awareness Training for Staff

The staff should be trained before starting the physical operational flow.

This Quick Reference Guide focuses on identifying the relevant information to be given to the staff at destination (Raising Awareness Training) combined with sharing clear instructions, in a fast, lean and focused manner.

### b. Good Practices upon Arrival

Good practices upon arrival have been shared with the different stakeholders on the following steps:

1. Aircraft unloading
2. Ramp transfer
3. Handover to the warehouse
4. Receiving and break-down
5. Storage




2 See IATA time and temperature-controlled regulations, chapter 17, for guidance

# 5. Conclusion

This project identifies the critical steps and highlights the best practices that would ensure a successful air transportation of TTSPs.

Shipping TTSPs to airports located in remote and/or emergency geopolitical regions requires smooth and timely communication among the various stakeholders. Every critical step must be recorded, and records must be kept, as there is a need to demonstrate the successful handling and transportation process.

One of the key points is that when temperature cannot be kept within the specified range, the exposure time needs to be limited.

The checklists can be useful tools:

- To collect essential information to take the best decision in terms of packaging, routing, and booking.
- To transfer the necessary information in an organized way to each relevant stakeholder so that each step can be performed as required.
- To act as a step-by-step guide on how to handle TTSPs upon arrival at destination airport.
- To collect the operational information demonstrating the proper handling at destination.
- To gather and align efforts of the key stakeholders.

To complement these checklists, specific guidance materials have been drawn up to facilitate staff training at destination airports.

The project team focused on the content rather than on the form. When these checklists and guidance materials are widely used, there might be an opportunity to upgrade the format to a web application and smart app, easily reachable and guaranteeing real-time communications. It can even become an important and easy-accessible tool, both ensuring direct information and hands-on training.

"The COVID pandemic has again highlighted that time- and temperature-sensitive pharmaceuticals must be handled properly, regardless of the local airport setup, and always in compliance with all relevant regulations and always without affecting product integrity.

The Quick Reference Guide is a useful and simple tool to quickly establish the needed checks and balances and to make sure the appropriate due diligence is done for GDP compliance when sending life-saving medication to remote areas."

*- Andy Faes, Regional Manager Healthcare Vertical Europe at Expeditors.*

"The COVID-19 pandemic was a highly unusual period for the logistics industry. Whilst logistics supply chains are accustomed to dealing with a variety of crisis situations in different parts of the world, the scale and enormity of the pandemic brought forth several vulnerabilities. The unprecedented chaos caused by COVID forced companies to shift the focus towards business continuity by building resiliency and flexibility. Newly approved vaccines and medication had to be rolled out direct to market, in large volumes, to the most remote parts of the world in short periods of time, while protecting security and integrity of products.

Shippers and supply chain partners were galvanized to adapt and collaborate continuously to overcome ever evolving geographical boundaries and restrictions to access the most remote parts of the world. Often, not enough information was available about locations and capabilities to enable quality risk management.

The Pharma.Aero QRG Project aims to provide a useful tool that can be deployed in such instances where more complex evaluations are not possible. It enables forwarders and airlines to participate simultaneously and provide shippers with a quick oversight of the shipping route to determine packaging, destination measures and any additional arrangements required to ensure safety and efficacy of much needed products to end patients."

*- Rashmi Karnad, Manager Climate Control Product – Pharma at Qatar Airways Cargo*

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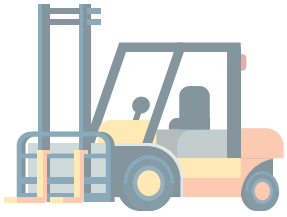

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