PHARMA
Corrective Action Preventive Action (CAPA)

- **How to request a CAPA report to Air France KLM Martinair Cargo?**
  Guidelines to customers

DOCUMENT : Instructions for CAPA requests
Air France KLM Martinair Cargo

Edition		
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GLOBAL INFORMATION

- This document aims at giving clear instructions to customers about how to request CAPA reports to enable better understanding of needs/expectations between involved parties, and to ensure that all necessary elements are gathered to conduct an investigation.

- These guidelines are part of a more global strategy to improve the overall CAPA report process.

- All Customers requesting CAPA reports are invited to carefully follow these instructions in order to improve CAPA analysts' working efficiency, quality of the investigation and response time.

- This is a document that specifies the process for customers to request an investigation report. Nothing of this document is intended to replace current agreements or SLAs between customers and AFKLMP.

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Terms-Definitions-Acronyms

ACE	Electric Active Container
ACT	Active container with dry ice
AFKL	Air France KLM
AWB	Air Waybill
CAPA	Corrective Action – Preventive Action
CSO	Customer Service
eCAPA	CAPA registered online by the customer
FWB	Freight Waybill
GMT	Greenwich Mean Time
ICE	Dry Ice – Dangerous Good
PHARMA	Pharmaceuticals
PIL	Special Handling Code for Pharma shipment
POD	Proof Of Delivery
Salesforce	System supporting CAPA report process
SHC	Special Handling Code
SLA	Service Level Agreement
SM	Sales Manager
T°	Temperature
UTC	Coordinated Universal Time

1. GENERAL

AFKL Cargo implemented and is maintaining an irregularity and complaint procedure for Pharma shipments.

All events such as temperature deviations, damaged packaging, delays, or missing shipments*, can happen due to operational issues and can be managed via this investigation procedure.

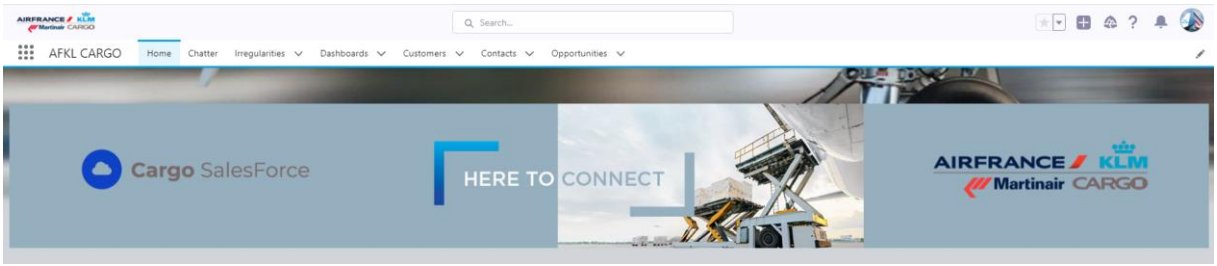
*a shipment is considered/declared 'missing' minimum 21 days after shipping. Before this period of time, it is very likely that the shipment is retrieved.

An investigation will be initiated when the shipper/forwarder is able to prove the occurrence of one of the above irregularities.

This investigation shall provide corrective and/or preventive action(s) in order to avoid the recurrence of the irregularity in the future.

2. WHO CAN REQUEST A CAPA REPORT?

Currently, customers can express the need for an investigation report to their AFKL Sales Managers and provide them with all necessary inputs beforehand.



3. PRE-REQUISITES TO REQUEST A CAPA REPORT

- Investigations will be initiated **only in the occurrence of a temperature excursion, damage, delay, or missing shipment**.

  Indeed, if there is a need for information regarding an operational matter/issue (misrouting, offload, delay, etc), especially if the shipment is still being transported, customers are invited to directly contact Customer Service.

- Only Pharma shipments (SHC **PIL**) will be subject to an investigation report. The relevant product codes and SHC be:
    - **Specialized/Customized Pharma,**
        - +2+8 (COL PIL)
        - +15+25 (CRT PIL)
        - +2+25 (ERT PIL)
    - **Active and Hybrid products,**
        - ACT or ACE PIL
        - PIP PIL.

  Pharmaceuticals that are booked under another product are not eligible for a CAPA report.

- In the event of temperature excursion, an investigation shall be conducted if the deviation is **greater/lower than 1°C** and occurred for **more than 20 minutes**.

- Temperature deviations must be based on **data loggers** located on the packages. The **exact location** of the used data loggers (e.g. inside or outside the package) must be stated in the investigation request.

- If **active trackers** were used: the brand/type/reference of each tracking device and the packing list must be provided upon investigation request.

- **Only data loggers presenting a deviation must be shared.**

- Customers are required **to select the 2 data loggers that show the most extreme points of deviation** and to insert them in the investigation request. This will considerably ease the analysis of the relevant data loggers. Indeed, pharmaceutical shipments are not split so data from 2 loggers are sufficient to conduct an investigation.
  The **time zone** where the deviation happened is also required.

- Description of the irregularity must be as detailed as possible:
    - precised **Time Zone** of the recording chart must be specified (UTC, GMT)
    - **actual deviation time** (from and until when the deviation has occurred)
    - **peak of deviation** (min-max T°) measured by customer's external logger must be specified

- **A timetable containing all recorded temperature for the entire journey of the shipment is mandatory and therefore must be provided** (Excel/CSV format), this will allow better comprehension of the occurred events.
  A graph showing the T° trends and highlighting the deviations would also be appreciated.

- In case of **damage**, the investigation request shall contain **pictures** of the shipment, and the **POD** must be provided (when available).

- In case of an ACT T ° deviation: customers must provide the dry ice calculation sheet.

4. DISCLAIMER

- Standard response time for both Air France and KLM is 10 business days providing that all pre-requisites mentioned here above are fully met.

- **CAPA requests submitted more than 30 days after the transportation date may not receive a complete investigation report and/or may result in a delay as more time will be necessary to conduct the investigation.**
  In line with EU GDP, data are kept at least 5 years. However other potential relevant information, such as CCTV, are not in scope and in most cases cannot be retained after 30 days. Hence, there is no guarantee that a complete report may be submitted and thus a CAPA report to be duly provided (the investigation may be less accurate and more difficult).

- Investigations requiring additional information – such as in-flight temperature records, truck temperature records, outstation handling, etc – from third parties as well as from suppliers (Envirotainer, Dokasch, etc) may also require more time and consequently may prolong the response time in order to conduct the investigation.

- **Corrective/Preventive actions:** if the initial investigation reveals that the shipment was handled in line with the SLA and upfront provided information on the route and station capabilities (as shared with customers), corrective and preventive actions will not be provided.