IATA

Guidance for Vaccine and Pharmaceutical Logistics and Distribution

Set of considerations and awareness on large scale handling, transport and distribution of vaccines, pharmaceutical, life science and medical products.

Edition 2 – 16 December 2020

Contents

LIST OF CONTRIBUTORS:

This guidance document is issued with grateful acknowledgement to the organizations who continuously contribute expert advice and comments on the contents compiled herein.

(Listed in alphabetic order)

☐
- Aviation ISAC

- International Civil Aviation Organization (ICAO)

- International Federation of Freight Forwarders Associations (FIATA)

- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

☐
- The Airport Services Association (ASA)

- The Pan American Health Organization (PAHO)

- UK Civil Aviation Authority - Aviation Security

- World Bank

- World Customs Organization (WCO)

☐
- World Food Programme (WFP)

- World Trade Organization (WTO)

Revision record

Symbol	Meaning
□	Insertion
△	Amendment
⊗	Deletion

Revision table

	Revision	Date	Section(s)	Significant changes
	Edition 1	16 November 2020		First release
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Introduction

Quality in times of crisis cannot be jeopardized despite operational COVID-19 emergency challenges. Today's airfreight logistics capacity is designed to meet planned programs of vaccination distributions in designated countries. In order to now upscale to the capacity required to address global distribution of COVID-19 vaccines adapting infrastructure, processes and resources will be critical to respond effectively to the huge global logistical challenges. Governments, supply chain partners, humanitarian organizations and pharmaceutical manufacturers must collaboratively prepare themselves for a widespread global coordinated response to distribute vaccines to where they are needed in a timely, safe and secure manner. All countries and territories will be impacted, either as a receiver or supplier of vaccines. The upcoming challenge for the supply chain stakeholders is to plan and execute a global network delivery mechanism for the COVID-19 vaccines and associated medical and logistical supply chain supporting the vaccine, life science and pharmaceutical products. This will be on an unprecedented scale; such is the anticipated global demand for COVID-19 vaccines.

The global supply chain is complex, diverse and fragmented. The COVID-19 crisis has exposed the strengths and weaknesses of the different systems in place. This, however, enables opportunities and innovation. IATA has called for increased collaboration as well as cooperation and communication across all parts of the supply chain to ensure the continuous flow of life science supplies and to move vaccines on a global scale in a safe, secure and controlled environment. More than ever supply chain stakeholders will have to share information on their processes and strategies because of the levels of uncertainty. This includes where and how the vaccines will be manufactured, from where, to where will they need to be transported, under which conditions will they have to be handled and how will they be secured.

To ensure industry collaboration, stakeholders across the air cargo supply chain must move away from bilateral relationships and start to foster multilateral partnerships. This will enable that all parties involved are aware and understand what is at stake, learn from each other, establish best practices, align priorities and processes as well as make better use of the information in the segment in which they are operating. The air cargo industry has a key role to play in facilitating this global challenge while instilling public trust and confidence that air transport will provide a safe, reliable and trusted force multiplier.

There are several scenarios different stakeholders in the supply chain are currently exploring and we encourage these simulations and evaluations to be done taking into consideration the need for a risk-based approach during the process. However, the main challenge is undoubtedly to respond to uncertainties, unknowns, and evolving issues. In that regard, IATA will facilitate the sharing of accurate and timely information to the industry to minimize potential distribution challenges and to meet the upcoming demand for vaccines, health, and humanitarian supplies, even as e-commerce and other commercial needs demand additional cargo capacity.

IATA is collaborating with several leading authorities and organizations and global humanitarian agencies, such as the International Civil Aviation Organization (ICAO), United Nations International Children's Emergency Fund (UNICEF), World Food Programme (WFP), World Health Organization (WHO), International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Pan American Health Organization (PAHO), UK Civil Aviation Authority - Aviation Security, World Bank, World Customs Organization (WCO), World Trade Organization (WTO), International Federation of Freight Forwarders Associations (FIATA) who have unique expertise in different aspects of planned vaccination distribution programs and in regional, national and pan region community humanitarian response. A joint information sharing forum has been established to facilitate and ensure industry preparedness when vaccines for COVID-19 are approved and available for distribution.

This document is about planning, preparing and looking at the global considerations as well as draw upon the lessons learned during the crisis, set a precedent for the future and identify how the existing procedures can be efficiently adapted to ensure the fast and safe movement of products using a risk-based approach. Although the set of considerations are for the distribution of COVID-19 vaccines, the current capacity required for routine immunizations must be protected and overall capacity expanded to accommodate COVID-19 vaccines. This document will be subject to regular review and revision as additional information and best practices are made available by the various stakeholders.

1. Constraints, Assumptions and Risks

As supply chain stakeholders prepare themselves for the upcoming challenges, there are many constraints, assumptions and risks that have been identified to date and that will have to be overcome to achieve the common objective of effectively and efficiently supplying globally the necessary medical needs of the global population.

1.1. Constraints

There are multiple constraints and challenges already identified that all those involved in the production, multimodal transport, storage, distribution and disbursement of vaccine will need to address in order to deliver vaccines to where they are needed and minimise wastage and loss.

Considerations include:

- Preparation time for companies to be ready and capable to respond swiftly, in an agile and adaptive and fully compliant way;
- Effective vaccine and number of doses of vaccines required as well as the overall weight, size and volume of shipments;
- Product shelf life, handling and storage environment;
- Uninterrupted temperature-controlled management across the supply chain;
- Possibility of multiple COVID 19 vaccines with different storage and handling requirements;
- Availability of specialized temperature-controlled, infrastructure, facilities, equipment and dedicated resources such as specialist staff;
- The establishment of national vaccine distribution and delivery facilities, temporary or permanent, and the volume of daily capacity;
- Storage and distribution facilities, national, regional, sub regional, with replenishment supply frequency determined by adequate temperature-controlled storage facilities;
- Defined temperature range within which the products should be handled and transported;
- Identify peripheral medical equipment and PPE required by each vaccine disbursement facility;
- Return or disposal logistics associated with empty vaccine vials and used PPE and other medical equipment requiring disposal;
- Compliance with the respective quality and regulatory requirements and air transport regulations (e.g. requirements for correct process, the method of refrigeration used, for the type of batteries applied in track and trace solutions or other equipment or devices);
- Integrated multimodal transport to strengthen the network and the delivery;
- Integrated IT systems;
- Applicable governmental requirements (e.g. customs, security, public health authority etc.);
- Priority customs clearance; keeping physical examination and/or sampling of goods by customs only in exceptional circumstances; ensuring that inspections by other government agencies and inspections by customs are coordinated and, if possible, carried out at the same time;
- Efficient and coordinated move of goods across borders;
- Quality and availability of transport connection and/or land-based networks within countries/regions;
- Effective cross-functional / cross-departmental and cross-organizational coordination';
- Appropriate support and commitment (from senior management or government authorities) to prioritize sensitive shipment movements;
- Handling and temperature transport requirements as well as conditions of vaccines ranging from deep frozen at -80C to the range of +2C to +8C;
- Processes that can demonstrate fully auditable end-to-end integrity of consignments;
- Document accuracy and completeness.

1.2. Assumptions

Based on the existing information, the following non-exhaustive assumptions are presented that should be realized to have a successful global roll-out:
- Pharmaceutical companies will be able to produce the quantities and the quality required to meet global vaccine demands;
- National regulatory agencies will adopt fast tracked approval certifications for vaccines;
- Manufacturing of vaccines will be carried out over time at different locations in the world, meeting the number of doses required globally;
- Aid and public health agencies will be able to mobilize and implement a global delivery mechanism covering the 200+ countries and territories impacted by COVID-19;
- Access to vaccine or its components will be equitably shared amongst nations;
- A supranational body will help coordinate and regulate the trade, availability and access to this critical lifesaving product globally through public health intervention in response to such a pandemic crisis;
- Border agencies will ensure effective and expeditious declaration and clearance;
- Airlines can immediately make available required capacity to respond to the identified demand;
- Vaccines and related supplies will be moved safely, securely, efficiently, and smoothly across air cargo supply chains;
- Ability to track and guarantee end-to-end quality of vaccines during transport through digital sensors and monitoring, whether through data loggers or real time sensor access;
- Temperature-controlled supply chain solutions will ensure product integrity is maintained, even in hot climates;
- Sufficient and appropriate temperature-controlled equipment (e.g. active/passive and aircraft/non-aircraft temperature-controlled containers) are available;
- Handling and transport personnel will be appropriately trained and qualified to handle time and temperature sensitive products;
- The temperature-controlled supply chain will be capable of storing, handling and transporting large scale of vaccines over time;
- Airports and cargo handling capacity (e.g. facility, processes, trained staff) to accommodate sudden increase of extraordinary import / export flow of temperature-sensitive products and medical supplies
- Ground based distribution networks will be capable of guaranteeing temperature integrity at destination as well as on the last mile of delivery;
- Governments and health authorities will identify and communicate replenishment quantities required to enable effective continuous ground support operations;
- Supply chain stakeholders can provide end-to-end data connectivity to ensure transparency, visibility and predictability;
- The COVID-19 vaccines will be shipped at the agreed prioritization and time frame;
- Other cargo not being unnecessarily displaced;

1.3. Risks

When transporting temperature sensitive pharmaceutical products, quality assurance is the key and cannot be jeopardized. Therefore, mitigating the impact of logistical constraints in company's strategies is crucial. This involves identifying risks for each segment in the supply chain and analyzing these in a risk-based approach and designing the controls to mitigate these risks. Engagement with business partners to work collaboratively is essential, and where available, adopt the best practices that are developed from the lessons learned.

Operational risks
- Scarcity of air cargo capacity;
- Delayed / cancelled flights;
- Unannounced deliveries;
- Breakdowns in operational processes;
- Regulatory non-compliance;

- Unsecured environment;
- Acts of unlawful interference;
- Unavailability of temperature-controlled environment;
- Closure/limited operation of airports;
- Seizure of goods by governments in export and transit port;
- Duration of the transport journey;
- Delay in the shipment due to non-compliance with the Dangerous Goods Regulations (DGR).

Product risks
- Absence of stability data and experience of new product development;
- Integrity of the product and security of doses;
- Lack of specialized packaging to protect product;
- Scarcity of raw materials or API to manufacture biologicals and sensitive pharmaceutical products.

People
- Limitations of available manpower;
- Lack of appropriate training and relevant knowledge;
☐   - Insider Threats.

Information
- Lack of coordinated approach and information sharing, unclear instructions and requirements from the manufacturers, unclear instructions and requirements from temperature-controlled equipment manufacturers, etc;
- Lack of reliable data connectivity between stakeholders and lack of full supply chain data visibility;
- Lack or unclear instructions for handling, transporting, delivering and storing biologicals and sensitive pharmaceutical products.

Execution
- Lack of all-party collaboration;
- Broken or unstructured communication channels;
- Prioritization of shipments;
- Lack of preparedness for receiving shipments;
- Administrative blockages;
- Lack of transparency in decision making processes.

2. Community Engagement and Collaboration

IATA has been engaging over the last months with a number of international organizations as well as authorities to seek how critical information can be consolidated and collaboratively shared, to ensure appropriate planning across the temperature-controlled supply chain, from manufacturer to end patient.

Working in a collaborative approach takes place also in the context of the United Nations Sustainable Development Goals (SDGs), a universal call to action to improve the lives and prospects for everyone everywhere on a sustainable path to 2030, especially considering the importance of "Partnerships for the Sustainable Development Goals – SDG 17.

The role of each organization varies while sharing a common objective.

2.1. International Civil Aviation Organization (ICAO)

Address the acute challenges COVID-19 has poses to civil air transport of both passengers and cargo on global scale, ICAO has partnered with its Member States, international and regional organizations, and industry. This partnership has primarily been through its Council Aviation Recovery Task Force (CART) and also includes joint statements and coordination with other UN organizations.

Since the early days of the pandemic, ICAO has provided States the technical guidance to enable flights and their crews to have the needed flexibility to undertake their essential duties in transporting quickly critical humanitarian personnel and cargo across vast distances. It has provided relief through alleviations to the Standards of its Annexes to the Chicago Convention as interim measures to support continued operations during the initial stages of the COVID-19 pandemic. Further, its contributions, such as the Public Health Corridor (PHC) concept, are critical elements to reducing contamination risk for shipments through increased use of contactless tools and procedures.

Ultimately, ICAO will play a key role in restoring and further growing air transport so that it continues to provide needed air connectivity for passengers and cargo—both humanitarian and commercial—to drive global economic recovery.

2.2. International Federation of Freight Forwarders Associations (FIATA)

FIATA is the global voice of the freight forwarding and logistics industry and works in close collaboration with various stakeholders at the international level. With its unique focus on all modes of transport (air, rail, road, sea), FIATA has a leading role to play in ensuring optimal and integrated multimodal transport solutions which will be crucial for the effective transportation and last mile delivery of the future COVID-19 vaccines. Access to and from airports and the improvement of land-based infrastructure are just initial examples to ensure seamless transport of supplies.

FIATA has been working closely with its members and other stakeholders active in the world's supply chains throughout the COVID-19 pandemic to ensure aligned and appropriate responses at the international and national levels. This includes working to ensure a level playing field that allows for a fluid and well-functioning supply chain, encouraging the adoption of appropriate border clearance and trade facilitation measures, and pursuing digital solutions to expedite information flows and data sharing. FIATA is currently active in policymaking discussions with other international organisations to ensure appropriate infrastructure and legal frameworks are in place to strengthen multimodal transport, building on lessons learned from the COVID-19 pandemic. An inclusive approach will be key to developing a resilient supply chain that can withstand heightened demand.

2.3. International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

IFPMA represents the research-based biopharmaceutical companies, and regional and national associations across the world. We facilitate collaboration, dialogue, and understanding within our industry and with other international stakeholders in the health community. We bring the industry and broader health community together to promote policies that foster innovation, resilient regulatory systems and high standards of quality, uphold ethical practices, and advocate sustainable health policies to meet patient and health system needs.

2.4. The Pan American Health Organization (PAHO/WHO)

PAHO/WHO is providing direct emergency response to Ministries of Health and other national authorities in the Americas, for surveillance, laboratory capacity, support health care services, infection prevention control, clinical management and risk communication; all aligning with priority lines of action. The Organization has developed, published, and disseminated evidence-based technical documents to help guide Member States' strategies and policies to manage this pandemic in their territories.

As part of this response, PAHO is procuring PPES, diagnostics kits, syringes, cold chain equipment, waste management supplies and vaccines on behalf of the countries of Latin America and the Caribbean. PAHO is supporting the equitable access to Covid-19 vaccines, preparation to implement vaccination, and co-leading (along with UNICEF) procurements efforts on behalf of COVAX Facility, with PAHO responsible for countries in the Americas.

2.5. United Nations International Children's Emergency Fund (UNICEF)

To ensure global equitable access to the COVID-19 vaccines, UNICEF will be leading the procurement and supply of vaccine as part of the COVID-19 Vaccine Global Access Facility (COVAX Facility), led by the WHO, Gavi - the Vaccine Alliance and CEPI. The role of ICAO, airlines and international transport providers will be critical to this endeavour.

The expected COVAX logistics implications (vaccines cargo volumes, origins, destinations, timelines and cold chain requirements) will be shared as it becomes available.

2.6. World Customs Organization (WCO)

As the only international organization with competence in Customs matters, representing more than 180 Customs administrations across the globe that collectively process approximately 98% of world trade, the World Customs Organization has a leading role to play to ensure that the temperature-controlled supply chain can deliver the required medical supplies across border. During the early stage of the COVID-19 pandemic, the WCO played a key role in reminding the global Customs community to apply internationally agreed procedures and processes to facilitate the cross-border movement of goods, conveyances and crew. This organization also supported WCO Members preparedness for the COVID-19 related challenges (border closures, travel bans, export restrictions, social distancing, lockdowns and closures of non-essential businesses, etc.) by taking several initiatives to gather and communicate as much information as possible.

2.7. World Health Organization (WHO)

The World Health Organization (WHO) and their partners work together on tracking the pandemic, advising on critical interventions, distributing vital medical supplies to those in need and racing to find a vaccine. The WHO launched in April COVAX, bringing together governments, global health organizations, manufacturers, scientists, private sector, civil society and philanthropy, with the aim of providing innovative and equitable access to COVID-19 diagnostics, treatments and vaccines.

2.8. World Trade Organization (WTO)

The World Trade Organization (WTO) is the global international organization which coordinates trade rules between member governments with the primary mission to facilitate cross-border trade flows.

In response to this unprecedented economic and sanitary crisis, the WTO is actively informing, guiding and communicating with its members as well as the wide trade community to lessen disruptions caused by the pandemic. Working towards the reestablishment of normal economic trade flows and improved access to such vital goods, the WTO is advocating for the full implementation of the WTO Trade Facilitation Agreement (WTO TFA), widely recognized as a catalyst to the recovery, specifically for developing and least developed countries. The WTO Trade Facilitation Agreement Facility assists developing, and least developed countries find the support they need to implement this Agreement. Simultaneously, the WTO is collaborating with other international organizations such as the WCO and the WHO to facilitate the distribution and access of pharmaceutical, life science and medical products across borders.

☐ 2.9. World Food Programme (WFP)

The World Food Programme (WFP) is the world's largest humanitarian organization with a vast operational footprint spanning 86 countries, and on any given day has 30 ships on the high seas, over 5,000 trucks on the road and nearly 100 aircraft in the sky. WFP also supports the wider humanitarian community through the WFP-managed network of six United Nations Humanitarian Response Depots, the United Nations Humanitarian Air Service, and as lead of the Logistics Cluster. It was this expertise and history of providing support that led to WFP stepping up to provide the logistics backbone to the global COVID-19 response, quickly standing up a network of hubs and airlinks to transport cargo and passengers to destinations not accessible through commercial means. To-date, WFP has reached 171 countries with its COVID-19 Global Common Services, with over 92,000 m3 of critical health and humanitarian cargo and 25,000 passengers transported to 68 destinations around the world, supporting almost 400 organizations. WFP requested special authorizations and clearances to open national airspaces, otherwise closed to commercial options, for the passenger flights, which were approved and implemented following strict health measures and latest COVID-19 guidance. As the COVID-19 response keeps evolving, WFP will continue to engage with the global health community to assess supply chain needs and to enhance the global and country approach to COVID-19 vaccine delivery through its skills and expertise in logistics. In order to do so, WFP is enhancing its cold chain capability to pursue the goal of filling strategic cold chain gaps during health emergencies, and to maintain its strategic capacity to respond to potential partners' need in the near and medium-term future.

3. Industry Preparedness

The air cargo supply chain plays a key role in the distribution of vaccines in normal times through well-established global time- and temperature-sensitive supply chain and distribution systems. This capability will be crucial not only to the quick and efficient transport and distribution of COVID-19 vaccines when they are available but for all pharmaceutical and life science products as well as humanitarian aid. This can only happen with careful planning, led by governments —brought together through multilateral organizations— and supported by industry stakeholders. This means that in the long term, a network of sustainable infrastructure, technology-driven — brought together through multilateral organizations— initiatives and people are needed.

3.1. Capacity & Connectivity

Governments must consider the current diminished cargo capacity of the global air transport industry. With the severe downturn in passenger traffic, airlines have downsized networks and put many aircraft into remote long-term storage. With the grounded passenger aircrafts, the global route network has been reduced dramatically from the pre-COVID situation.

In planning their vaccine programs, particularly in the developing world, governments must take very careful consideration of the limited air cargo capacity that is currently available. If borders remain closed, travel curtailed, fleets grounded and employees furloughed, the capacity to deliver life-saving vaccines will be very much compromised including the last mile.

The WHO, PAHO, UNICEF and Gavi have already reported severe difficulties in maintaining their planned vaccine programs during the COVID-19 crisis due, in part, to limited air connectivity. Therefore, accessing capacity will be achieved only through cautious planning.

To re-establish global air connectivity, which is critical in facilitating global trade, IATA is working with ICAO and health authorities on the development and deployment of rapid, accurate, affordable, easy-to-use, scalable and systematic COVID-19 testing for all passengers before departure as an alternative to quarantine measures. This may in return help resume a limited level of capacity and connectivity.

WHAT TO CONSIDER:

Government interference
Government rules to increase capacity, e.g. by supporting grant of additional traffic rights on a temporary basis for operations carrying the COVID-19 vaccines where restrictions may apply.

Governments should avoid moving towards nationalization of stock pressurizing the airlines and stakeholders to guarantee access to goods for their own people but ensure equitable and fair access to everyone.

Airlines to ensure prioritization of shipments
Considerations must be taken to ensure to prioritize the movement of essential shipments, including but not limited to vaccines. These priorities should be clear at the time to the concerned parties and followed to the extent operationally feasible.

Capacity expansion with COVID-19 testing roll-out
This process will result in a number of tests to be moved globally, which will represent a huge volume of medical supplies and COVID-19 test kits to transport.

Facilitating freighter charter
Facilitating freighter charter is critical while considering areas such as: feasible airport pairs, easy (worry-free) return of asset (aircraft / non-aircraft containers).

Interline operations and multilateral interline agreements
Process and procedure must be put in place to enable interline operation where possible.

△ 3.2. Operational Environment

Both the infrastructure and the resources will be critical as countries prepare themselves for a massive vaccination in response to COVID-19, impacting all countries and territories. The upcoming challenge for the supply chain stakeholders is to jointly plan and execute a global network delivery mechanism for the COVID-19 vaccines, unlike any situation experienced previously.

3.2.1 Capabilities & Infrastructure

The temperature-controlled supply chain will need to be capable of storing, handling and transporting such a drastic increase in quantities of vaccines and other related medical supplies throughout the journey. The most direct route for deliveries of COVID-19 vaccines is paramount with agreed transit times. Supply chain stakeholders will have to prepare themselves, conduct careful analysis of the existing processes, plan for the necessary processes and prepare for their implementation.

WHAT TO CONSIDER:

Planning on Capabilities
Estimate and evaluate the capacity of handling and storage facilities as well as equipment; and assess ways to increase the capacities in a collaborative, cost effective and sustainable way:
- work and engage with your business partners / suppliers to communicate about scale-up initiatives such as the COVID-19 vaccines or humanitarian aid that will affect space and distribution planning and develop strategies on future use of temporary or mid-term temperature-controlled environments (e.g. refrigerated trucks, reefers units, etc.) including the use of off-airport facilities, equipment or infrastructure;
- establish standard operating procedures with business partners to meet customer's expectations and regulatory requirements;
- refrigeration equipment used to store sensitive pharmaceutical and temperature-controlled shipments must be monitored to ensure its performance is within the defined range and temperature accurate;
- assess the handling and storage capabilities at origin, transit and destination.

☐ **Temperature Controlled Rooms / Freezers**
Consideration must be given to temporary storage areas in cargo terminals such as cool rooms and freezers that are used to hold vaccines where dry ice is present as a refrigerant.

National Occupational Health and Safety Regulations must be complied with. In the absence of such regulations, below are minimum recommendations that should be applied:

- These storage areas present a significant asphyxiation risk from elevated CO_2 levels from sublimating dry ice. Employees that enter the cool room or freezer must be made aware that dry ice is present so that care is taken when entering the cool room / freezer.

- Where dry ice is present the cool room / freezer should be placarded with a warning mark affixed at each access point in a location where it will be easily seen by persons opening or entering the cool room / freezer. An example is shown below. This placard should remain on the cool room / freezer until the following provisions are met:
  a) the cool room / freezer has been ventilated to remove harmful concentrations of CO_2; and
  b) the packages containing the dry ice have been removed.

Figure 1: Asphyxiation warning mark (UN Model Regulations, 21st revised edition, Figure 5.5.2)

Minimal dimension 250 mm

Minimal dimension 150 mm
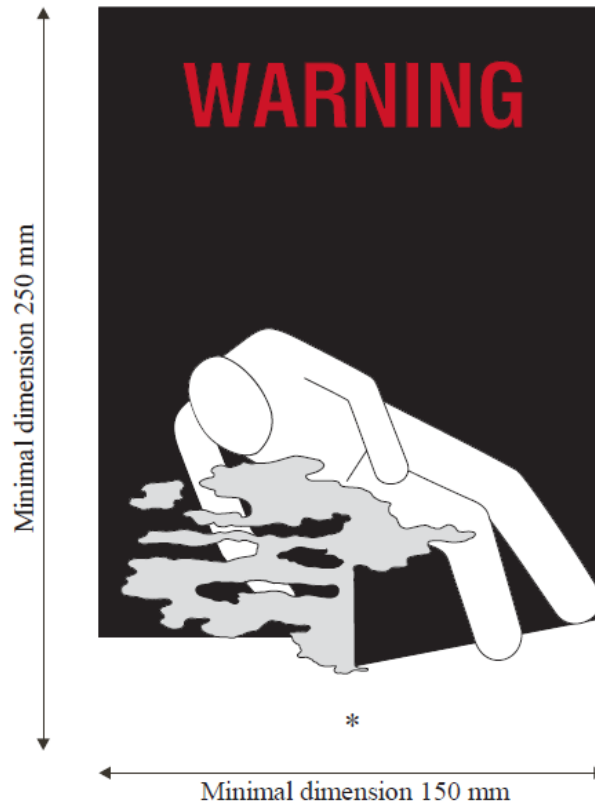
* Insert "DRY ICE" or "CARBON DIOXIDE, SOLID" in letters at least 25 mm high.

Other mitigation actions could include the installation of CO_2 monitors / alarms in the cool room / freezer.

☐ **Ramp Operations**
Consideration must also be given to the loading and unloading of vaccines where dry ice is present as a refrigerant.

National Occupational Health and Safety Regulations must be complied with. In the absence of such regulations, below are minimum recommendations that should be applied:
- Verify the documentation (loadsheet, LIR, NOTOC, CPM, LDM) for the presence of dry ice as a refrigerant (code ICE);
- To avoid asphyxiation prior to entering a compartment where dry ice is present, the compartment door must be opened and allow ventilation as per the company's procedures. In absence of specific instructions, it is important to wait for a minimum of 2 minutes for ventilated cargo holds and 10 minutes for non-ventilated cargo holds before entering the cargo hold compartment;
- A visual detectable damage check should be performed to ensure there is no damage to the packaging or ULD during loading and/or offloading.

Airline's capabilities
During planning it is also important to consider a number of variables that need to be verified before the booking is confirmed and accepted:
- approved airlines in carrying dangerous goods. If the airline does not hold an approval to carry dangerous goods as cargo from their regulatory authority, the airline would not be allowed to handle cargo such as temperature-controlled containers with lithium battery powered data loggers;
- aircraft capacity (e.g. available space, if dry ice is used as refrigerant, the quantity limits on dry ice);
- the capabilities of the airport of departure/transit/arrival;

- airports limited cold and ultra-cold storage in transit and at destination;
- ensuring the right temperature setting in the aircraft.

Airlines should provide a process for transport between the cargo warehouse and the aircraft that minimizes the product exposure to temperatures beyond the allowable range.

Optimizing operational efficiencies
Coordination efforts among the supply chain stakeholders should be made to ensure integrated solutions and processes to maximizing the shipment capabilities to the extent possible

Standards
It is important that stakeholders involved in the shipping, handling and transport of pharmaceuticals and life science products have the most up to date regulations, such as the IATA Temperature Control Regulations (TCR), international and regulatory requirements. This will ensure compliance and integrity of the time and temperature sensitive products along the supply chain.

In addition, to provide visibility and transparency to manufacturers and logistics providers of the level of infrastructure, operations and IATA certified stations, IATA developed the ONE Source industry platform for validated aviation capabilities and infrastructure information. All critical information contained on ONE Source has been verified by IATA to help ensure its accuracy.

3.2.2 Equipment

Equipment used to transport or hold temperature–sensitive healthcare shipments are critical in the overall process. Whether these are aircraft or non-aircraft containers, active or passive Temperature Controlled Containers (TCC), insulated containers, thermal blankets or ramp "cool" dollies.

△ **Aircraft Temperature Controlled Container (TCC):**
- Performance and functionalities of active / passive aircraft Temperature Controlled Containers (TCC) must be made available;
- The aircraft acceptability must be verified to ensure the aircraft TCC are allowed to be loaded aboard the intended aircraft types in accordance with the aircraft Weight and Balance Manual;
- Aircraft TCC may be very heavy due to size and total gross weight, appropriate handling equipment with the appropriate capacities (e.g. lift capacity of forklift, length of fork tines, size of pallet dolly) should be always available at all locations to avoid potential staff injury, mishandling, equipment damage and/ or service interruption;;
- Training for parties who are not typically involved in aircraft ULD build-up procedures;
- Serviceability and air worthiness requirements will need to be met;
- Special handling instructions from the manufacturer of the aircraft TCC will need to be conveyed to all supply chain participants;
- Specific training programs/ requirements for the use of aircraft TCC should be in place;
- Facilitate the transport of aircraft TCC to pharmaceutical manufacturer's facility for acclimatization and loading;
- Facilitate the immediate return of the empty aircraft TCC to allow efficient asset utilization.

Note:
Aircraft TCC is an aircraft container, certified or non-certified under TSO C90, with an integral temperature control system. Aircraft TCC is designed to be directly restrained by the aircraft Cargo Loading System (CLS).

△ **Non-aircraft Temperature Controlled Containers (TCC):**
Non-aircraft TCC may also be used; although non-aircraft TCCs are not aircraft ULDs, considerations on the suitable aircraft type should also be made to ensure operating limitations of the aircraft (e.g. weight and contour limits) are not exceeded as per the aircraft Weight and Balance Manual. Non-aircraft TCC may be very heavy due to their size and total gross weight, appropriate handling equipment with the appropriate capacities (e.g. lift

capacity of forklift, length of fork tines, size of pallet dolly) should be always available at all locations to avoid potential staff injury, mishandling, equipment/ shipment damage and/ or service interruption. Non-aircraft TCC is also valuable reusable and returnable asset, immediate return of the empty units should be arranged to allow efficient asset utilization.

Note:

Non-aircraft TCC is a non-aircraft container with an integral temperature control system. Non-aircraft TCC is usually loaded onto an aircraft pallet and restrained by a compatible aircraft pallet net.

Passive equipment:
Other passive equipment such as thermal blankets may be used; however, their capabilities, the logistics and distribution of those items to the origin, and their return and/or their disposal of waste should be considered. The environmental impact should not be forgotten.

Facilities and equipment for the storage and handling of such equipment must be suitable. Considerations include:
- ULDs must not be placed on the ground. At all times ULDs must be on dollies or in storage racks;
- ULDs must not be lifted or moved by forklifts unless the ULD has a forkliftable base.

Ramp "Cool" dollies
Such devices exist at some airports and can be used to help maintain temperature control while the goods are outside the temperature-controlled facility (e.g. on the ramp or outside the cargo facility).

The device capabilities should be verified as there are no specific aviation related standards beyond the basic Ground Support Equipment (GSE) aspects. The availability of such devices, at origin, destination and/or transit where they are required or desired to be used should be verified.

WHAT TO CONSIDER:

- Planning on available ULDs and their distribution to the origin and final return logistics;
- Depending on the nature of the required transport conditions for the vaccine, it may be necessary to use temperature controlled ULDs. Aircraft ULDs are certified items of aircraft equipment and therefore need to meet certain regulatory requirements and industry standards as described in the applicable airworthiness certification requirements and IATA ULD Regulations (ULDR);

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- Other non-aircraft TCCs require either securing to an aircraft ULD (such as an aircraft pallet and aircraft pallet net combination) or specific loading and securing to the aircraft structure as per the aircraft Weight and Balance Manual;
- Not all aircraft ULDs are suitable for all aircraft types and not all aircraft are designed to transport aircraft ULDs;
- Aircraft TCC and non-aircraft TCC with dry ice and lithium batteries must meet the provisions set out in the IATA Dangerous Goods Regulations (DGR).

Return logistics:
ULDs can typically be used in both directions of travel, however, in the case of specialized ULDs, especially TCC, it may not be the most efficient operational option and therefore reverse logistics considerations need to be made. In addition, the return of ULDs in charter operations should be facilitated preferably multilaterally instead of bilaterally.

3.3. Border Management

Trade movements have been heavily impacted in such time of crisis as government authorities have enacted restrictive measures. IATA's advocacy role led many governments and international regulatory bodies to facilitate the movement of air cargo.

It is critical that International Organisations, such as the WCO / WTO and countries continue to develop and recommend to their Members standards, guidance and best practices measures to facilitate and prioritize the movements of vital life science supplies without disrupting the supply chain. Working effectively with health and customs authorities will, therefore, be essential to ensure timely regulatory approvals, increased security measures, appropriate handling and customs clearance.

In addition to transport preparations, coordination is needed between authorities involved in border management. Governments must also consider priorities for border processes such as acceptance of electronic copies of documents, prior to arrival customs clearance and granting priority on arrival and expedited clearance procedure of those vital shipments to prevent possible temperature excursions due to delays or considering tariff relief to facilitate the movement of the vaccine and life science products.

3.3.1 Facilitation procedures

Border Agencies are requested to work with private sector partners to review their facilitation procedures and measures at borders in order to examine whether further opportunities exist to implement facilitation conventions, standards, tools and guidance that would support the fast processing through contactless means of vaccines, pharmaceutical, life science and medical products at borders. In addition to direct consultation with individual government agencies, national trade facilitation committees provide a good forum for this cooperation and coordination.

WHAT TO CONSIDER:

All actors in the supply chain of those essential shipments should be identified now between border agencies and private sector partners, in order to start developing strategies for:

- The legal and regulatory frameworks to import export and transit shipments of vaccines at both regional and national levels;

- The identification of these essential goods, i.e. finished goods like the COVID-19 vaccine, but also biologic materials (e.g., "drug substance") used in upstream manufacture and testing of COVID-19 vaccines, by considering all vaccines, pharmaceutical, life science and medical products, including their packages (incl. temperature-controlled containers), whose aim is to address the COVID-19 pandemic;

- Once identified, integration of these goods into the lists of critical items issued by the World Customs Organization in cooperation with the World Health Organization and their Harmonized System (HS) classification, so that these goods can be cleared expeditiously in line with established international guidance on disaster relief;

- Necessary capacity needs along with implementing procedures aligned with international standards to ensure the interception of counterfeit and sub-standard (not fit for purpose) vaccines. This includes detection at the border, coordination with international health authorities, and offering real-time exchange of relevant information to fight the trafficking of counterfeit medical supplies;

- The facilitation of the movement of these shipments at borders through the implementation of a series of trade facilitation measures such as:
  - Measures to support compliance and cooperation between border agencies (e.g. exchange of information, bilateral and regional agreements);

- o Common border procedures and simplification of import, export and transit documentation requirements to facilitate the release and clearance of goods;

- o Coordinated joint inspections of goods in temperature- controlled areas;

- o Transparency of information and easy access to cross border trade measures (e.g. appointment of a single, centralized contact point to respond to industry requests for help or information, up to date information published on-line and available through the enquiry point);

- o Procedures for expedited release with the creation of green lanes to accelerate the release process at borders for such shipments and reduce the sheer volume requiring inspection, at acceptable risk to the country;

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- o Let any specific transport equipment (such as temperature-controlled containers) for the safe transport of vaccines and other pharmaceutical and medical products aimed at addressing the COVID-19 pandemic be considered as a ULD (Unit Load Device) and fall under temporary admission (and return) exempt from duty and bond/guarantee requirements;

- o Use of information technology to support the establishment and maintenance of a single window which would expedite the submission of information and/or data requirements for the release and clearance of goods, acceptance of electronic copies/scans of certificates and document instead of original or certified copies in paper, and e-payment to facilitate payment of duties and fees; and

- o The possible introduction of deferral (e.g. separation of the release from the final determination of Customs duties, taxes, fees and charges) of duties, taxes and fees, as well as bond programs and deferred payments with post-clearance audit (in order to move the duty and tax collecting processes away from the border to the inland premises of the importer);

3.3.2 Smart Coordinated Borders

Border agencies should seek out every opportunity to share information, apply smart border measures and implement simplified procedures to the extent possible to expedite vaccines (including COVID-19 vaccines), pharmaceutical, life science and medical products. Due care should be undertaken by all parties to ensure that such products are secured, transported and stored in facilities that do not jeopardize the integrity of such goods.

Customs authorities should ensure that all levels of government (including border agencies) and law enforcement, i.e. national (federal), regional (State or provincial), and sub-national (local) remain coordinated to allow uninterrupted door-to-door delivery of these shipments.

WHAT TO CONSIDER:

Coordination to fight illicit trade of counterfeit medical supplies
To support the permanent and real-time exchange of relevant information to fight the trafficking of counterfeit medical supplies, the WCO and its members should continue to exchange intelligence information, messages and alerts via the secure channels developed under the Intellectual Property Rights (IPR) CENcomm Group.

Emergency border contacts list for humanitarian goods
The World Customs Organization (WCO) has compiled a database of emergency contacts to minimize cargo border blockages and ensure these can be responded to immediately. IATA will be the focal point with the WCO if contacts in countries are needed. Furthermore, the WCO has provided guidance to support the classification of medicines and medical supplies and prioritize their customs clearance. A similar approach should be taken to prioritize other border agency clearance at borders for vaccines.

△ 3.4. Security Environment

Vaccines will be highly valuable commodities. Risk assessment[1] should be performed to determine vulnerabilities and threats, including insider[2] and cyber threats[3,4] to Air Cargo Management Systems, related to transport (safeguarding from tampering and theft). Air Cargo Service and System providers should review physical and cyber controls to reduce the risk of loss of cargo or degradation of connected systems supporting the transport of vaccines.

☐ **Physical Security Measures**
Processes and procedures are typically in place to keep cargo shipments secure, from both, the aviation security and transport of valuables perspective. The potential volume of vaccine shipments, geographical scope of distribution and handling conditions may however require early planning from the point of origin, during the entire transport until loading and the departure of the aircraft, as well as upon arrival (off-loading, storage) to ensure that they are scalable and provide protection against all sorts of interference (including both, aviation security and criminal threats).

In terms of security and screening procedures, given the specificity of the shipments, the procedures relevant for known consignors and/or regulated agents should be preferred. Additionally, consultations with States' appropriate authority are encouraged to verify if conditions of the respective National Civil Aviation Security Programme (NASP) at the point of departure include and allow for special arrangements in vaccines' screening process that are reflective of the ICAO Security Manual Doc. 8973 (Section 13.5.5 and Appendix 33).

☐ **Cyber Security Measures**
In terms of cyber security, IATA along with Aviation-ISAC, recommend airlines to focus on both data and information, as well as the systems supporting the logistics and transport of the vaccines.

Air Cargo Service and System providers engaged in the transport of Covid-19 vaccines are under increased risk of physical and cyber-attack. Aviation-ISAC [5]shares that threat intelligence reveals organized crime groups are seeking to procure vaccine shipments for sale on the black market. Similarly, ransomware groups have targeted the healthcare and aviation sectors during the pandemic. Airlines may be subjected to cyber-attack as they announce their ability to transport vaccines, as seen in one particular event, last November 2020.

Data and information relative to vaccines distribution, should be designated confidential or privileged. This data and information should implement restricted access measures as well as data loss prevention and encryption measures.

Systems processing this data and supporting the transport, including flight operations, are also under increased threat of compromise. Security teams should consider increased continuous monitoring of these systems for both internal and external attempts for unauthorized access. More information on how ransomware attacks unfold can be found via different reference materials and cyber incident response best practices. Note that most of those attacks result in exfiltration of sensitive data, followed by file and network encryption.

Airlines need to make sure their solution providers are using state-of-the art cyber security defence and are maintaining their systems up to date. Airlines and Air Cargo Service and System providers should review their business continuity and or disaster response plan, ransomware incident response plans and ensure the plans have been exercised.

Also, some basic considerations and recommendations are provided below.

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[1] IATA Security Management System Manual Edition 4, chapter 5, Security Risk Assessment
[2] IATA Security Management System Manual Edition 4, chapter 6.4, Insider Threats
[3] https://us-cert.cisa.gov/ncas/current-activity/2020/12/03/ibm-releases-report-cyber-actors-targeting-covid-19-vaccine-supply
[4] https://www.interpol.int/en/News-and-Events/News/2020/INTERPOL-warns-of-organized-crime-threat-to-COVID-19-vaccines
[5] https://www.a-isac.com/

WHAT TO CONSIDER:

- Appropriate security screening facilities and methods throughout the supply chain;
- Maximum usage of Known Consignor and Regulated Agent programs and faster access to such programs for the duration of the COVID 19 Pandemic;
- On airport secure facilities;
- Consignment level shipment tracking sensors;
- Off airport secure storage facilities, minimized quantities in unsecure areas;
- Information flow controls to protect against cyber interference;
- Secure zone access control, consider CCTV monitoring;
- Adequate security measures of all distribution of these are high value shipments including the 'Final Mile' distribution to mitigate the risk of theft or product tampering;
- Final vaccine disbursement facilities to have secure facilities;
- Air Cargo Service and System providers should be updated to the latest version;
- Backup copies should be up to date, and isolated from the other systems, as they could provide the only capacity to put back the systems online rapidly, after an attack
- Solution providers should be consulted on their capacity to sustain cyber-attacks, and support the airlines
- Business Continuity Plan should be devised and/or refreshed to face such malicious events.
- Consult with regional regulator authorities on government intelligence sharing as well as private intelligence sharing working groups for a better understanding and monitoring of the threat landscape.

3.5. Safety Environment

With the capacity crunch, many airlines have repurposed passenger aircraft to be used for just the carriage of cargo and/or mail, including loading cargo in the passenger cabin. Such exceptional operation requires a very robust and comprehensive safety risk assessment involving all parties within the organization following standardized procedures in compliance with defined operating standards and regulations, particularly ICAO Standards and Recommended Practices (SARPs), as well as other ICAO provisions.

However, temperature-controlled vaccines, life science or medical supplies might not all be suitable to be carried in the passenger cabin due to regulatory constraints or risks to the operation. Therefore, all supply chain partners must familiarize themselves with the overall requirements to safely transport vaccine shipments before looking to accept or handle such consignments, especially where cabin loading of cargo is considered.

Manufacturers of vaccines must consider the classification of the vaccine, particularly where regulatory approval from the appropriate national authority of the State(s) of origin, transit or destination has not been issued, or is still pending.

- where the vaccine contains live pathogens but has not received regulatory approval from all applicable States through which it will be transported it should be classified as UN 2814, **Infectious substance, affecting humans** or UN 3373, **Biological substance, Category B**, as appropriate;

- vaccines containing genetically modified micro-organisms (GMMOs) or genetically modified organisms (GMOs) that have not been authorised for use by the appropriate national authorities of the States of origin, transit and destination must be classified as UN 3245, **Genetically modified micro-organisms** or **Genetically modified organisms**, as appropriate.

The challenges are really about preparation and planning as well as vaccine manufacturers providing information as early as possible to airlines and other supply chain partners to understand which temperature-controlled environment will be needed when transporting vaccines. Potentially the temperature required may range from deep frozen at -80°C to +2°C - +8°C. The temperature requirements will also impact on the type of packaging solution that will be used and any special handling requirements.

Where dry ice is required to maintain the vaccine in a frozen state consideration must be given to:
- the quantity of dry ice that will be offered for each flight;
- training requirements for personnel who will prepare the shipments;
- the prohibition on the carriage of dry ice when cargo is loaded in the passenger cabin;
- how the shipments will be offered for air transport, e.g. individual packages, overpacks or in aircraft unit load devices.

These factors may limit the quantity of vaccine that can be transported per flight and the time and effort required by the airline or their ground service provider to accept the shipments.

Most pharmaceutical shipments require the use of data loggers / cargo tracking devices that are inside packages, attached to packages or may be inside the ULD, or pre-installed in the TCC by manufacturers, to record and verify that the contents have at all times been maintained within the required temperature range. The types of data loggers vary as does their power source, however where the data loggers have a transmitting function (GSM / GPS) and/or are powered by lithium batteries then the regulatory requirements that apply to the transport of lithium battery-powered equipment and the transport of active portable electronic device (PED) must be addressed.

WHAT TO CONSIDER:

For shipping dry ice as refrigerant for general cargo, the shipper must also be dangerous goods qualified (i.e. trained and assessed), and the packing requirements must meet the applicable requirements of the IATA Dangerous Goods Regulations (DGR).

Shippers are advised to coordinate with the airlines in advance for shipping dangerous goods (as well as pharmaceutical products).

For the shipper (consignor):

1. Dry ice (Carbon dioxide, solid) is regulated by the Dangerous Goods Regulations (DGR) even when used as a refrigerant for non-dangerous goods. Shippers must be dangerous goods qualified (i.e. trained and assessed) according to the training requirements in the Regulations and follow the packing requirements laid out in Packing Instruction 954.

2. Dry ice must only be in packagings that allows the release of the carbon dioxide gas that is generated as the dry ice sublimates.
   ⇨ Packagings such as aluminium, plastic or steel drums or jerricans are **not suitable**.
   ⇨ Packagings such as wood, fibreboard or more likely expanded polystyrene boxes **are suitable** as these materials are gas permeable.

3. Dry ice can be placed directly into the appropriate packagings or in the dry ice bunker of the ULD or loose in the ULD. Completed packages can be packed with the dry ice into a larger box to form an overpack. Alternatively, the packages can be packed into a ULD with the dry ice provided that the airline agrees. In that respect, it is not just the dry ice inside a package that can be packed into an aircraft ULD but the dry ice itself can also be in loose in the ULD. It must be emphasized that "overpack" does not exist for general cargo, and acceptance staff will consider the "overpack" of general cargo as a single package (piece).

4. Where the dry ice is in packages, the outside of each package must:
   a. be marked with the name and address of the shipper (consignor) and consignee, "UN 1845", "Carbon dioxide, solid" or "Dry ice" and the net weight of dry ice in each package; and
   b. be labelled with a Class 9 hazard label.

5. If the individual packages are packed with the dry ice into an overpack then the information in 4 a. and b. must be on the outside of the overpack. Where very large numbers of packages each containing dry ice

are to be offered for transport, it is recommended that the shipper group packages into an overpack as this will facilitate handling and reduce the time and effort required by the airline or their ground service provider to perform the dangerous goods acceptance check.

6. There is no requirement for a Shipper's Declaration for Dangerous Goods where the dry ice is used as a refrigerant for non-dangerous goods. However, there must be information on the air waybill, or if there is no air waybill on another document, that shows: "UN 1845", "Carbon dioxide, solid" or "Dry ice", the number of packages and the weight of dry ice in each package.

7. Shippers shall always make advance arrangement with the freight forwarder or directly with the airline for the transport of shipments containing dry ice to ensure that the total weight of dry ice being offered in the consignment does not exceed the limit for the particular aircraft type. Shippers must ensure that all requirements in the DGR have been followed before tendering the shipment because a shipment rejection can possibly result in a delay and potentially miss the booked flight.

8. In cases where aircraft TCC is used and in the possession of shipper, shipper is responsible for ensuring the aircraft TCC is only handled by appropriately trained and qualified personnel and the serviceability of ULD is maintained.

Where lithium battery-powered data loggers / cargo tracking devices are planned to be used or have been installed in the TCC by manufacturers, the shipper must ensure that the applicable provisions in the DGR are complied with. These include:
-   Obtaining a copy of the lithium battery test summary from the manufacturer / supplier of the lithium batteries or the manufacturer / supplier of the device. This test summary must confirm that the lithium cell or battery type has passed all applicable tests in Subsection 38.3 of the UN Manual of Tests and Criteria;
-   Packing requirements laid out in Section II of Packing Instruction 967 or Packing Instruction 970 in the DGR, as applicable;
-   Unless the data logger / cargo tracking device only contains a button cell, then where there are:
    o   more than two packages in the consignment that contain a data logger / cargo tracking device in each package, or
    o   multiple data loggers / tracking devices in a package (e.g. more than four devices powered by lithium cells or more than two devices powered by lithium batteries)
    then each package must bear the lithium battery mark with "UN 3481" or "UN 3091" as applicable, and there must be a compliance statement on the air waybill, when an air waybill is used;
-   All employees preparing or offering shipments must receive adequate instruction on the provisions set out in the aforementioned packing instructions. This adequate instruction must be commensurate with the functions for which they are responsible.

Some data loggers / cargo tracking devices may not be powered by lithium batteries but other battery types, such as dry batteries or nickel-metal hydride batteries that are not restricted by the DGR when the conditions as shown in the corresponding special provision in the DGR are met (e.g. Special Provision A123 for dry battery and Special Provision A199). More information can be found on the IATA Dangerous Goods Website.

Where the data loggers / cargo tracking devices are a type with transmitting functions, the shipper must ensure that:
-   They confirm with the manufacturer / supplier of the device that the device has passed all applicable tests to ensure that it does not pose a hazard to aircraft systems due to emission of electromagnetic radiation;
-   The device is fitted with two independent means of shutting down all transmitting functions when airborne;
-   The device has been approved by the airline on which the cargo will be transported.

For acceptance, handling and loading as a freight forwarder:

1. The staff processing the shipments should inspect the packages, when visible, to ensure that the packagings used are designed and constructed to permit the release of carbon dioxide gas, the packages or overpacks are marked and labelled in accordance with the Regulations and the details required for the completion of the air waybill, or alternative documentation, are provided by the shippers.

2. There must be coordination with the airline that will transport the consignment with dry ice to confirm that the quantity of dry ice is within the limits set by the airline specified for the particular aircraft type(s) over the route from origin to destination.

3. Where the consignment with the dry ice is to be stored in a freezer / cool room, there should be procedures to ensure that employees are aware of the risks associated with dry ice. The carbon dioxide gas generated as dry ice sublimates displaces the air in a confined space, such as a freezer or cool room. This may create an oxygen deficient atmosphere that can asphyxiate persons. It is recommended to placard the freezer / cool room that is stored with these shipments to identify the presence of dry ice and that people should not enter the room unattended. Additional CO_2 monitors that trigger alerts when the CO_2 concentration exceeds the safe levels can be installed.

4. In cases where aircraft TCC is used and in the possession of a third party (e.g. shipper, or freight forwarder), that party is responsible for ensuring the aircraft TCC is only handled by appropriately trained and qualified personnel and the serviceability of ULD is maintained.

3.6. Risk Management

Companies that implemented quality-driven strategy programs such as the IATA Center of Excellence for Independent Validators in Pharmaceutical Logistics (CEIV Pharma) program are well placed to mitigate the impact of logistical constraints in their strategies, as they are already aware of:

- the operational challenges;
- the standards and requirements to be followed;
- the necessity to have trained and knowledgeable staff;
- the requirement to have dedicated equipment as well as infrastructure;
- the importance of reviewing and if necessary, adjusting robust risk assessments.

Being part of such programs will be a significant advantage in building confidence and trust, in a collaborative environment where the integrity of such sensitive products is maintained throughout the handling and transport journey until it reaches its end customer. This provides manufacturers and logistics providers the possibility to identify the level of competency as well as operational and technical preparedness at airports.

WHAT TO CONSIDER:

Standards and Training
Non-standardized processes have a detrimental impact. Global standards must be implemented, reviewed and maintained through robust audit and training processes.

Risk-based Approach
Establish contingency and emergency plans as well as the most direct communication for rapid response to issues arising along the supply chain.

3.7. Digital Environment

Enhancing patient safety and quality of care can be achieved by connecting logistic networks, increasing the level of supply chain digitalization, as well as increased end-to-end visibility and transparency of existing capacity and facilities. Digitalization will be the enabler for more robust resilient and smarter supply chains across various modes of transport by using the captured data for analysis and information sharing. These, in turn, could lead to more effective planning for future pandemics and other emergencies, as well as for infrastructure, policies, and regulations.

3.7.1 Track and Trace solutions

To ensure the security and integrity of the data and the products are maintained throughout the supply chain track and trace solutions can be implemented either in real time or at destination. These are for temperature and/or humidity monitoring or localisations for security reasons.

3.7.2 Transport & logistics transparency and visibility

To ensure maximized usage of both the logistics capacity as well as the vaccines themselves, stakeholders should make data available on the shipments, planned and executed transport parameters, disruptions and alternative plans. IATA's ONE Record data sharing standards prescribe a method for such direct data access securely using a common language for data exchange.

3.7.3 Global distribution planning and oversight

Governments and pharma suppliers should consider sharing data on the global distribution planning and oversight to ensure that logistics resources are maximised, ideally fairly, but at least with common knowledge.

WHAT TO CONSIDER:

Temperature Monitoring
Monitoring activities by means of validated temperature monitoring devices are necessary to ensure that the process is under control at each critical step in the supply chain, to minimize the time out of refrigeration (ToR) and to avoid temperature excursions. Product will be sensitive to moving out of the mandated temperature ranges so temperature monitors will be critical in validating the quality of the final product.

End-to-end visibility and data sharing
Collaborate in establishing effective technologies allowing parties to be accurately informed about the status and the movement of their air cargo. This can be achieved through proactive data sharing, facilitating transparent, reliable and direct access to such data to all relevant stakeholders.

△ 3.8. Sustainability and CO$_2$ Emissions

△ 3.8.1 Sustainability considerations

As the world is preparing to roll out the global transport and distribution of vaccines, medical supplies supporting the vaccines, life science and pharmaceutical products, it is important to consider establishing a sustainable infrastructure network. This is especially critical in low-income countries, where energy access can be challenging for temperature-controlled environments. GAVI estimates that only 10% of healthcare facilities in GAVI-eligible countries have adequate cold chain equipment, and many rely on polluting diesel generators for electricity[6].

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[6] **https://www.seforall.org/news/sustainable-cold-chains-needed-for-equitable-covid-19-vaccine-distribution**

Where significant investment will be necessary to expand the cold chain, sustainable, long-term solutions should be selected (e.g. off-grid[7], solar-powered mobile cold-rooms[8] can be an efficient and lasting solution for remote areas.). Building effective and resilient cold chains in low-income countries will also reduce food and medicine waste, ease new health and vaccination campaigns, and enable economic growth. These actions will lead to a successful response to the pandemic and contribute to green recovery worldwide.

△ | **WHAT TO CONSIDER:**

- Invest / subsidize the deployment of renewable sources of energy in out-of-the-grid facilities;
- Analyse the energy requirements to keep vaccines deep-frozen;
- Select efficient, clean cooling technologies and approaches during the planning and procurement processes as much as possible;
- Examine how to minimize energy waste and emissions of refrigerant gases;
- Calculate the waste produced by vaccine transportation and analyze reduction, recycling, and safe disposal options.

□ 3.8.2 CO_2 Emissions

The CO_2 emissions generated as a result of flight operations itself is also worth considering. The global vaccine distribution is undoubtedly a large-scale operation which means even relatively small efficiency gains can result in absolute CO_2 savings that are substantial. Many measures to enhance operational efficiency, in particular fleet optimization, may already be implemented as part of an ongoing effort to save fuel and reduce CO_2. Beyond this, it may be advantageous to explore carbon offsetting as a means to compensate in part or fully for the CO_2 produced.

WHAT TO CONSIDER:

- Estimating the CO2 footprint of vaccine distribution flights with best available data, e.g. attributable fuel consumption and/or payload data;
- Sourcing good quality carbon credits in projects that are meaningful to your organization's Corporate Social Responsibility (CSR) objectives.

3.9. Multimodal

Ground based distribution networks will have to be capable of guaranteeing temperature integrity at destination as well as on the last mile delivery.

WHAT TO CONSIDER:

- Collaborate and use existing road distribution channels;
- Ensure appropriate and availabilities of Road Feeder Services (RFS);
- Guidance for ground transport of ULD (aircraft TCC) including loading/ unloading;
- Align transport of vaccines and the associated medical consumables (syringes, vials, needles, PPE, etc); via different modes to prioritize air cargo for short shelf life and temperature sensitive vaccines;
- Freight forwarder qualification and capability (training, facilities, equipment, etc.);
- Quality management program in place (Master Operating Plan, track & trace, real-time monitoring);
- Collaboration on ground, for first and last mile.

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[7] **https://www.sun-connect-news.org/de/articles/technology/details/taking-cold-chains-off-grid-how-solar-powered-cold-rooms-could-dramatically-reduce-food-waste-in-su/**
[8] **https://www.fastcompany.com/90574433/solar-fridges-and-powdered-vaccine-how-to-get-a-covid-19-vaccine-to-the-developing-world**

4. Summary of the Considerations

CHAPTER / SECTION	CONSIDERATIONS	YES	NO	N/A
3	**Industry Preparedness**			
3.1	**Capacity & Connectivity**			
	- Government interface			
	- Airlines to ensure prioritization of shipments			
	- Capacity expansion with COVID-19 testing roll-out			
	- Facilitating freighter charter			
	- Interline operations and multilateral interline agreements			
3.2	**Operational Environment**			
	Capabilities & Infrastructure			
	- Estimate and evaluate the capacity of handling and storage facilities			
	- Assess the risks of temporary storage areas such as temperature-controlled rooms / freezers that are used to hold vaccines where dry ice is present as a refrigerant			
	- Assess the risks of ramp operations when loading and unloading vaccines where dry ice is present as a refrigerant.			
	- Assessment of airline's capabilities			
	- Optimizing operational efficiencies			
	- Compliance with standards			
	Equipment			
	- Planning on available ULDs and their distribution to the origin and final return logistics			
	- Assessment of the type of aircraft or non-aircraft containers			
	- Compliance with the Dangerous Goods Regulations (DGR)			
	- Return ULDs logistics			
3.3	**Border Management**			
	Facilitation procedures			
	- Implement collaboration between border agencies and private sector partners			
	- Implementation by border agencies of a series of trade facilitation measures			
	Smart Coordinated Borders			
	- Coordination to fight illicit trade of counterfeit medical supplies			
	- Emergency border contacts list for humanitarian goods			
3.4	**Security Environment**			
	- Appropriate security screening facilities			
	- Usage of Known Consignor and Regulated Agent programs			
	- On/Off airport secure facilities			
	- Security measures in place of all distribution and final disbursement facilities			
	- Update Air Cargo Service and Systems			
	- Consult solutions on the capacity to sustain cyber-attacks			
	- Review Business Continuity Plan to face such malicious events			

☐		- Consult with regional regulator authorities on government and private intelligence sharing working groups for a better understanding and monitoring of the threat landscape			
	3.5	**Safety Environment**			
		- Shipper must be dangerous goods qualified			
		- The use of dry ice and lithium batteries must in compliance with the Dangerous Goods Regulations (DGR)			
		- Appropriately trained and qualified handling personnel in dangerous goods and in aircraft TCC handling			
		- Coordination with the airline that will transport the consignment with dry ice must be ensured			
		- Procedures to ensure that employees are aware of the risks associated with dry ice when stored in a freezer / cool room			
	3.6	**Risk Management**			
		- Standards and Training compliance			
		- Establish contingency and emergency plans in a risk-based approach			
	3.7	**Digital Environment**			
		- Implement monitoring activities using validated temperature monitoring devices			
		- Establish end-to-end visibility technologies			
		- Implement data sharing			
	3.8	**Sustainability**			
		- Investing / subsidizing the deployment of renewable sources of energy in out-of-the-grid facilities			
△		- Analyse the energy requirements to keep vaccines deep-frozen			
☐		- Select efficient, clean cooling technologies and approaches			
☐		- Minimize energy waste and emissions of refrigerant gases			
☐		- Calculate and analyse the waste produced by vaccine transportation			
☐		- Estimating the CO_2 footprint of vaccine distribution flights			
☐		- Sourcing good quality carbon credits in organization's projects			
	3.9	**Multimodal**			
		- Collaboration on the use of existing road distribution channels			
		- Ensure appropriate and availabilities of Road Feeder Services (RFS)			
		- Align transport prioritization in the different mode of transport on			
		- Ensure freight forwarder qualifications and capability			
		- Collaboration on ground transportation			
		- Establish quality management programs			

5. References

The following list is not exhaustive and is aimed at providing the appropriate references.

Organizations / Topic	Description
☐ IATA Regulations, Manuals and Standards	Dangerous Goods Regulations (DGR) Temperature Control Regulations (TCR) Cargo Operations Manuals (Cargo Handling Manual (ICHM), ULD Regulations (ULDR), Ground Operations Manual (IGOM) and Airport Handling Manual (AHM)) Security Management System Manual, Edition 4 Digital Cargo (ONE Record)
IATA Guidance Material	Transport of Cargo in Passenger Cabin Battery Powered Cargo Tracking Devices / Data Loggers
IATA Services	IATA Training CEIV Pharma ONE Source Platform
ICAO	CART Take-Off Guidance – Cargo Module Implementing a Public Health Corridor to Protect Flight Crew During the COVID-19 Pandemic (Cargo, Maintenance, Ferry, and Delivery Flight Operations Operations) Facilitating passenger flights, including repatriation flights, using public health corridors during the COVID-19 pandemic Technical Instructions for the Safe Transport of Dangerous Goods by Air
☐ EASA	Guidelines for the Use of Cargo Tracking Devices in relation to the COVID-19 pandemic
WHO	Distribution of essential medicines and health products Immunization supply chain and logistics Effective Vaccine Management (EVM) Initiative Guidelines on the international packing and shipping of vaccines Estimating the capacity of storage facilities
WCO	WCO – WHO cooperation - HS classification reference for COVID-19 medical supplies 3.01 Edition COVID-19 – WCO-WHO Cooperation - List of priority medicines for customs during COVID-19 pandemic International Convention on the Simplification and Harmonization of Customs Procedures, as amended (Revised Kyoto Convention)

☐		Guidelines to Specific Annex J Chapter 5 (relief consignments) of the Revised Kyoto Convention
		List of national legislation of countries that adopted temporary import support (lowering or waiving of direct and indirect duties and taxes) on certain categories of critical medical supplies in response to COVID-19
		What Customs can do to mitigate the effects of the COVID-19 pandemic
		WCO Resolution on the Role of Customs in Facilitating the Cross-Border Movement of Situationally Critical Medicines and Vaccines
	WTO	COVID-19 Trade Facilitation Resource Repository
		Trade in Medical Goods in the Context of Tackling COVID-19
		The Treatment of Medical Products in Regional Trade Agreements
		How WTO Members Have Used Trade Measures to Expedite Access To COVID-19 Critical Medical Goods and Services
☐	Pharma.aero	Shining light on COVID-19 vaccines transport requirements and global airfreight readiness
	Industry Awareness Information	Transport of Vaccines by Air
		Distributing the COVID Vaccine: The Greatest Logistics Challenge Ever
☐	Sustainability sources of information	Why optimized cold-chains could save a billion COVID vaccines
		What would it take to deploy COVID-19 vaccines through sustainable cold chains?
		Sustainable cold chains needed for equitable COVID-19 vaccine distribution
		A Possible Covid Vaccine Means It's Time to Fix Cold Chains
		Taking Cold Chains Off-Grid: How Solar Powered Cold Rooms Could Dramatically Reduce Food Waste in Sub-Saharan Africa
		Solar fridges and powdered vaccines: How to get a COVID-19 vaccine to the developing world
☐	Security source of information	Report on Cyber Actors Targeting the COVID-19 Vaccine Supply Chain
		INTERPOL warns of organized crime threat to COVID-19 vaccines
		AVIATION ISAC - International cyber-threat sharing organization providing aviation-specific threat information to the aviation community

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