Part I : Guidance for Vaccine and pharmaceutical Logistics and Distribution

Part 2 : Safe transport of COVID-19 vaccines on commercial aircraft

Part I : Guidance for Vaccine and pharmaceutical Logistics and Distribution

1- **Purpose**: Set of considerations and awareness on large scale handling, transport and distribution of vaccines

2- **Reference:**

- IATA Guidance for Vaccine and Pharmaceutical, Edition 1 dated Nov. 16, 2020
- ICAO state letter No. AN 11/55-20/136

3- 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 of COVID-19 vaccines adapting infrastructure, processes and resources distribution 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. ECAA 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 they will be secured.

To ensure industry collaboration, stakeholders across the air cargo supply chain must move away from bilateral relationships and start to foster 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.

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5- 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.

3.1 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 minimize 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.

3.2 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 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;

3.3 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, adopts the best practices that are developed from the lessons learned.

Operational risks

- Scarcity of air cargo capacity; -
- Delayed / canceled 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.

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.

6- 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 efficient transport and efficiency 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.

- Capacity & Connectivity

The current diminished cargo capacity of the global air transport industry must be taken into consideration. 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.

- 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.

- 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.

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 development strategies on future use of temporary or mid-term temperature-controlled environments (eg 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.

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 ECAA, 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 ensure contained on ONE Source has been verified by IATA to help its accuracy.

- 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 ULD considerations:

- Performance and functionalities of aircraft unit load devices (ULDs), such as active / passive aircraft Temperature Controlled Containers (TCC) must be made available;
- The aircraft acceptability must be verified to ensure the aircraft ULDs are allowed to be loaded aboard the intended aircraft types;
- Training for parties who are not typically involved in ULD build-up procedures;
- Serviceability and air worthiness considerations will need to be met;
- Special handling instructions from the manufacturer of the aircraft ULD will need to be conveyed to all supply chain participants;
- Specific training for the use of Temperature Controlled Containers (TCC);
- Facilitate the transport of ULDs to's manufacturer facility for acclimatization and loading.

Non-aircraft Temperature Controlled Containers (TCC):
Non-aircraft TCC may also be used; However, considerations on the aircraft type and their suitability should be made as they will need to be loaded onto aircraft pallets, or otherwise secured to the aircraft structure in an aircraft-safe condition as per the aircraft Weight and Balance Manual. Heavier "box" type non-aircraft TCC may, due to their size and weight, require mechanical loading into the aircraft, which is not always available at all locations.

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);

- Other non-aircraft containers require either securing to an aircraft ULD (such as a pallet and net combination) or specific loading and securing to the aircraft structure;
- 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.

- 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 Organizations, 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 the convenience movement of the vaccine and life science products.

- 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 (eg, "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);
    - Common border procedures and simplification of import, export and transit documentation requirements to facilitate the release and clearance of goods;
    - Coordinated joint inspections of goods in temperature- controlled areas;
    - 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);
    - 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;
    - Granting the status of Instrument of International Traffic to the articles (incl. aircraft or non-aircraft containers) used for shipping the vaccines, pharmaceutical, life science and medical products whose aim is to address the COVID-19 pandemic, in order to guarantee the temporary admission and return of all concerned transport equipment with appropriate exemption from duties and guarantee requirements;
    - 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
    - The possible introduction of deferral (eg 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);

- **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 t 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 border cargo 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.

- **Security Environment**

Vaccines will be highly valuable commodities. Risk assessment should be performed to determine vulnerabilities and threats related to transport (safeguarding from tampering and theft). 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 Program (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).

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.

- **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 authorized for use by the appropriate national authorities of the States of origin, transit and destination must be classified as UN 3245, Genet modifiedically micro- organisms or Genetically modified organizations, 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 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):

- 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.
- 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 aluminum, plastic or steel drums or jerricans are not suitable.
    - Packagings such as wood, fiberboard or more likely expanded polystyrene boxes are suitable as These materials are gas permeable.
- 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).
- Where the dry ice is in packages, the outside of each package must:
    - 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
    - be labelled with a Class 9 hazard label.
- 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.
- 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.
- 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 aircraft particular 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.
- 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:
    - 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 (eg 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:

- 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 labeled in accordance with the Regulations and the details Required for the completion of the air waybill, or alternative documentation, are provided by the shippers.
- 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.
- 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 CO2 monitors that trigger alerts when the CO2 concentration exceeds the safe levels can be installed.
- In cases where aircraft TCC is used and in the possession of a third party (eg 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.

- **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.

- **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.

- **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.

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.

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 considered

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.

- **Sustainability**

As the world is scaling for a global transport and distribution of vaccines, medical supplies supporting the vaccines, life science and pharmaceutical products, it is important to consider moving towards a network of sustainable infrastructure especially in more low-income countries. Energy access can be challenging for temperature-controlled environments. Is there an opportunity for a more efficient, reliable and sustainable temperature-controlled management supply chain?

WHAT TO CONSIDER:

- Investing / subsidizing the deployment of renewable sources of energy in out-of-the-grid facilities;
- Examination on the energy requirements to keep vaccines deep-frozen.

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.

Part 2 : Safe transport of COVID-19 vaccines on commercial aircraft

Worldwide demand for COVID-19 vaccines will result in a significant increase in the volume of vaccines offered for air transport. The purpose of this guidance is to identify the specific areas related to the air transport of vaccines that may require action by the operator and ECAA to facilitate the safe air transport of vaccines.

It is understood that by complying with the requirements of ECAA dangerous good's regulations and the *Technical Instructions for the Safe Transport of Dangerous Goods by Air* (Doc 9284, Technical Instructions) operators will be able to safely accept, handle and transport these vaccines.

The transport of vaccines must comply with the detailed provisions of the Technical Instructions where the vaccines are classified as dangerous goods, or the vaccines are shipped with dry ice as a refrigerant, or data loggers and cargo tracking devices are included in packages or attached to packages or overpacks.

The UN Sub-Committee of Experts of the Transport of Dangerous Goods (57th session) confirmed that genetically modified micro-organisms based vaccines authorized for use (including clinical trials) are not subject to the UN model regulations for transport. As a result, ICAO is currently reviewing the applicability of the Technical Instructions to genetically modified vaccines and will be issuing advice through a State letter shortly. As such this issue has not been addressed in the following guidance.

Changes to the Technical Instructions (TIs) to remove some of the normal marking requirements for packages containing vaccines and lithium batteries contained in equipment are being considered by ICAO. If and when these changes are approved in ICAO, any hazards and risks associated with the change may need to be mitigated by other means. Further information will be provided below in the event of this change being approved.

Chapter 15 to Annex 6, Part I (applicable Nov 2020) requires a risk-based assessment, in addition to the prescriptive requirements in the Technical Instructions, for operators transporting items in the cargo compartment. The elements of the safety risk assessment set out in Chapter 15 to Annex 6, Part I have been used as the basis for reviewing the changes proposed to the existing requirements to determine what additional risk mitigations may need to be implemented.

The following key issues have been identified in relation to the carriage of COVID-19 vaccines

1. Data loggers and cargo tracking devices (batteries & quantities)

Data loggers and cargo tracking devices may be required to monitor the temperature and location of vaccines during transport. Most such devices are powered by lithium batteries and the packages need to be properly identified as such. The following table identifies the hazards associated with the data loggers and trackers transported, and the considerations for the operators risk assessments.

2. Data loggers and cargo tracking devices (EMI)

Inclusion of transmitting/receiving devices in packages for the purposes of tracking and data logging (e.g. of temperature) has the potential for electromagnetic interference with aircraft systems. The potential risk to the operations needs to be assessed.

3. Requirement for carriage of quantities of dry ice in excess of that previously specified by operator for the aircraft type

At present, many of the vaccines need to be transported in temperature controlled conditions. These conditions are specific to the vaccine itself. For example, some of the vaccines need to be kept at temperatures that require dry ice (carbon dioxide, solid) for cooling purposes. The volume of vaccine to be transported means that the quantity of dry ice proposed for carriage exceeds that previously specified for the aircraft type in the operator's manuals. A review of the risk assessment based on the considerations provided may be needed.

Guidance to support the operators risk assessment process

The following tables provide guidance for both the air operator and the ECAA to facilitate a common understanding of the requirements. It is structured around each element the operator is required to consider as part of its specific safety risk assessment and based on Guidance for Safe Operations Involving Aeroplane Cargo Compartments (Doc 10102). However, where the vaccine supply chain requires use of smaller aircraft without cargo compartments, this material can still be used as some guidance to develop the associated risk assessments for these types of operations. Different mitigation strategies may need to be developed depending upon the type of aircraft and operation considered.

Packages of vaccines may contain multiple elements such as:

- the vaccine component itself;
- data loggers and cargo tracking devices powered by lithium batteries, and that emit electromagnetic radiation that have the potential to interfere with aircraft systems; and
- dry ice.

For each identified element in the package, the following considerations will need to be addressed, to maintain safe operations.

The tables should not be considered as an exhaustive or limiting list and each operator is expected to tailor the tables as necessary for the individual case and context.

Specific guidance to conduct risk assessments with respect to operations that involve the transport of items in the cargo compartments of an aeroplane can be found in Doc. 10122. Further guidance on safety risk management can be found in Chapter 2.5 of the Safety Management Manual (4th edition).

a) **hazards associated with the properties of the items to be transported;**	
Hazard Description	***Information to support hazard assessment***
Increased quantities of data loggers and cargo tracking devices containing lithium batteries.	• Operator may not know the contents of the package – most vaccine packages will contain a data logger even if not marked as such • Lithium batteries can enter a thermal runaway and become a potential ignition source as a result of failure due to damage or internal quality issues. • Lithium batteries generally contain an electrolyte that can become a fuel source for a fire. • Capabilities of the aircraft fire suppression systems - see section d) could be exceeded Specific considerations: • Packages with data loggers and trackers powered by lithium button cells which meet the limits specified in the Technical Instructions, Section II of Packing Instruction 967 or Packing Instruction 970 are not required to bear the lithium battery mark. • Manufacturer testing (38.3 of *UN manual of tests and criteria*) still applies. • The number of lithium battery devices within the package should be taken into consideration.
b) capabilities of the operator	
	• Identification by the operator of the contents of the package may not be possible from inspection – there is a need to ensure operator has full knowledge of contents regardless of marking or labelling • Acceptance for transport should be only by operators with specific approval for carrying dangerous goods as cargo and with suitable training • Training and procedures are required to ensure damaged items are not accepted for transport, regardless of whether the label indicates lithium battery contents or not
c) operational considerations;	
	• Operators need to ensure they are provided with the information regarding the content of the packaging and can take measures to ensure the type and quantity is consistent with the capabilities of the aircraft cargo compartment (see section d) and the procedures of the operator • Loading of packages must not exceed maximum quantities identified by the operator for the carriage of lithium batteries in the cargo compartment
d) capabilities of the aircraft and its systems;	
	• Size, type and quantities of batteries needs to be assessed to ensure the capabilities of the cargo compartment, and in particular of its fire protection or suppression system, are not exceeded
e) containment characteristics of unit load devices;	
	• None

f) packing and packaging;	
	• Compliance with packing requirements detailed in the Technical Instructions is still essential even where marking of the contents (lithium batteries) may not be mandated • Design of package needs to minimize the risk of damage to the contained lithium cells
g) safety of the supply chain for items to be transported;	
	• None
h) quantity and distribution of dangerous goods items to be transported	
	• Operators should consider the risks of loading these shipments with other flammable dangerous goods.

a) **hazards associated with the properties of the items to be transported;**	
Hazard Description	***Information to support hazard assessment***
Data loggers and cargo tracking devices used in monitoring the transport of the vaccine	• Operator may not know the contents of the package • Specific details regarding acceptable transmissions not known by the operator • Potential for the electromagnetic radiation from such devices to interfere with the aircraft systems
b) capabilities of the operator	
	• Identification by the operator of the contents of the package may not be possible from inspection – there is a need to ensure operator has full knowledge of contents regardless of marking or labelling • Operator approves the carriage of data loggers and cargo tracking devices based on information from the device manufacturer confirming compliance with applicable standards and airframe manufacturer regarding the Portable Electronic Device (PED) tolerance of the aircraft.
c) operational considerations;	
	• Portable Electronic Devices that have a transmitting function should meet the requirements of the State of Design such ○ FAA AC 91.21-1D and EASA AMC1 CAT.GEN.MPA.140. ○ EASA published Guidelines for Use of Cargo Tracking Devices in relation to the COVID-19 pandemic ○ Get Approval from ECAA according to ECAR 91.21
d) capabilities of the aircraft and its systems;	
	• aircraft systems susceptibility to electromagnetic interference; the relevant information and documents from the aircraft OEM and/or Operator should be considered; • Additional guidance specific to each aircraft type and model (if any), should be obtained from the aircraft manufacturer.
e) containment characteristics of unit load devices;	
	• None
f) packing and packaging;	
	• None

g)	**safety of the supply chain for items to be transported;**
	• None
h)	**quantity and distribution of dangerous goods items to be transported**
	• See c) & d) • Type and quantity of data loggers and cargo tracking devices may be limited • Loading on the aircraft may be subject to specific restrictions in terms of location

a)	**hazards associated with the properties of the items to be transported;**
Hazard Description	***Information to support hazard assessment***
Carriage of large quantities of dry ice (CO_2, solid)	• The sublimation of dry ice may result in significant concentrations of gaseous CO2 in aircraft • Gaseous CO2 will replace oxygen in aircraft compartments and may interfere with the breathing abilities of the occupants • High concentrations of CO2 can lead to unrecognized degradation of cognitive functioning and asphyxiation. It causes suffocation by displacing and diluting the amount of oxygen in the air, leading to hypoxia (lack of oxygen) and is toxic to brain functioning
b)	**capabilities of the operator**
	• Operators must ensure that their dangerous goods training programme, operational procedures and safety management system address the requirements applicable to transport of dry-ice (including the acceptance, handling, loading and carriage of cargo containing dry ice) during both ground and flight operations. • Pilot and crew training on specific conditions and procedures can improve pilot decision-making in the event of a CO2 detector alert or other system abnormalities • Training for loading and unloading precautions for ground/service crews
c)	**operational considerations;**
	• The operators' determination of the maximum amount of dry ice it will allow in a cargo compartment based on the aircraft manufacturer's recommendations, operational considerations for the air conditioning system, and the sublimation rate • An accurate determination of the dry ice sublimation rate is necessary to determine the quantity of dry ice that may be safely transported ○ Sublimation rate can be affected by ambient compartment temperature and pressure, amount of insulation surrounding the dry ice, type of container, amount of surface area of the dry ice, and the temperature of the cargo being cooled by the dry ice • As the dry ice sublimates, a loss of weight occurs that may affect the aircraft center of gravity • CO2 sensors installed or carried in the aircraft to recognize hazardous concentrations of CO2 and to implement effective risk controls • Aircraft ventilation during normal procedures, to include engine start, less than all engine taxi, aircraft de-icing, and with MEL deferred items • Aircraft ventilation during abnormal and emergency procedures to include abnormal and emergency operations and flight during air system component failure.
d)	**capabilities of the aircraft and its systems;**

	• The environmental control system on the aircraft must be suitable for the quantity of dry ice intended to be carried, including flow mode, air recirculation control, MEL deferred items, and possible malfunctions en-route. • Additional guidance specific to each aircraft types and models, if any, should be obtained from the aircraft manufacturer.
e)	**containment characteristics of unit load devices;**
	• None.
f)	**packing and packaging;**
	• Compliance with packing requirements detailed in the Technical Instructions
g)	**safety of the supply chain for items to be transported;**
	• None
h)	**quantity and distribution of dangerous goods items to be transported**
	• As determined by the operators' safety risk assessment taking into considerations of items a) to g)