ICAO EURNAT RD BRIEF

#1 Preparation to the vaccine delivery by air

I would like to take the opportunity of this first edition for 2021, to wish for you and your family a better, happier, and healthy year ahead.

The year 2020 proved to be a very challenging one for all of us in aviation. As we now enter into 2021 we hope that this year will bring a final resolution to the COVID-19 problem and speed up recovery of the aviation sector.

These hopes are linked to the fact that more and more vaccines are being developed and distributed. With a critical mass of people vaccinated, the world is expected to receive a sustainable protection against COVID-19.

Air cargo has been playing a key role in the distribution of pharmaceuticals including vaccines in normal times through well-established global procedures. This capability is crucial to ensure quick, efficient transportation and distribution of COVID-19 vaccines. However, a high amount of vaccines that need to be transported as well as a requirement for some vaccines to be stored at temperatures of minus 70 degrees Celsius, create a new challenge which can only be met with careful planning and coordination, led by governments and supported by industry stakeholders.

This RD Brief will provide information on preparatory steps that might be needed globally and in the European and North Atlantic Regions to address those challenges and ensure safe, secure, environmentally friendly and efficient transportation of vaccines by air.

Enjoy the reading,

Silvia Gehrer

Preparatory steps for vaccine delivery

Transportation of vaccine is not a new task for aviation that managed to handle and transport them in line with international regulatory requirements, at controlled temperatures and without delay to ensure the quality of the product. Having said that, the scale of the forecasted transportations could be quite new. While there are still many unknowns (number of doses, temperature sensitivities, manufacturing locations, etc.), it is clear that the scale of activity will be vast. Some experts talk about delivering billions of doses of vaccines to the entire world.

In order to cope with this demand for global distribution of COVID-19 vaccines adapting infrastructure, processes and resources will be critical to be able to respond effectively to the huge global logistical challenges. Governments, supply chain partners, humanitarian organizations and pharmaceutical manufacturers must prepare themselves collaboratively 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.
It is clear that this in itself would require and boost developments in different functional areas of aviation to include, but not limited to, the areas of:

- Facilitation
- Cargo security
- Cargo safety
- Air Navigation Capacity and Efficiency
- Economics

As the transportation of vaccines to end consumers accelerates in the coming weeks and months, new challenges will arise. Amongst these is the potential need for certification of an individual that has been vaccinated. This challenge has particular relevance to aviation given the consideration of an individual's vaccination status as part of the multi-layer approach to the mitigation of risks associated with international travel advocated by ICAO.

Facilitation related issues

To allow for an efficient and seamless transport of COVID-19 vaccines from the production site to the receiver proper coordination and collaboration amongst all involved entities, governments and industry stakeholders, is key. Appropriate collaboration throughout the supply chain is needed to ensure that facilities, overflight, transit/ transfer and border processes are in place for the transportation of vaccines by air and other modes of transport.

ICAO Annex 9, Facilitation, provides for a set of standards which offer the frame to achieve facilitation throughout the supply chain.

A National Air Transport Facilitation Programme (NATFP) and the existence of National Air Transport Facilitation Committees (NATFC) and Airport Facilitation Committees or similar coordination bodies may help to achieve effective collaboration between civil aviation authorities, airports, public health authorities, customs and the air cargo community to facilitate appropriate handling of vaccines at all stages of the journey as well as speedy customs clearance.

Pre-authorization of air-cargo operators to fly additional services without any restrictions, continued engagement with State authorities to ensure awareness of needs as well as proactive deployment of appropriate national structures for cooperation and facilitation of movements of vaccines and associated medical equipment through air and between air and other transport modes will be key to achieving a successful result of this enormous logistical challenge in distributing COVID-19 vaccines in a timely safe and secure manner in the EUR/NAT Regions and around the globe.

Furthermore, helpful facilitation measures would be the use of digital information sharing, advance cargo information, a single entry window for vaccine shipment clearance and smart border processes, digitized passenger locator forms for cargo crew and health declaration forms as well as the avoidance of quarantine requirements. Properly used, these measures will support the smooth transport of COVID 19 vaccines in the EUR/NAT regions and globally.

Security related issues

To assure that COVID-19 vaccines flown as air cargo are safeguarded against acts of unlawful interference, Chapter 4.6 of Annex 17 – Security requires that all air cargo and mail shipments be secured and protected from unauthorized interference before being loaded on board a commercial aircraft. Implementation of aviation security procedures for the secure transport of vaccines includes: screening where it is practicable; implementing secure supply chain procedures; and by applying exemptions from screening for biomedical materials (BIOM).

Other Annex 17 standards and recommended practices may further help ensuring the security of COVID-19 vaccine shipments in a wider context, such as effective risk assessment, landside security measures and requirements relating to cybersecurity.

Chapter 13 of the ICAO Aviation Security Manual (Doc 8973- restricted) provides guidance on HOW states should establish the security of air cargo, either via a secure supply chain process implemented and overseen by the appropriate authority, by screening or alternative measures which can be applied to secure special categories of air cargo and mail such as the vaccines (e.g. verification of accompanying airway bills, visual inspections for any signs of tampering etc.).

To efficiently link the need for securing the vaccine consignments appropriately and the need for facilitating the transport, States should support manufacturers and other involved entities in the process to become known consignors. Alternatively, States may consider granting temporary exemptions from security screening of COVID-19 vaccine shipments using the State's risk assessment process and ensure at all times that the vaccine shipments are protected and accessible only to authorized staff.

Transfer (changing of aircraft) and Transit (departing on the same aircraft it arrived in) vaccine consignments may not need to be re-screened provided that such cargo is subjected to appropriate security controls and protected thereafter at all times before being loaded on the departing aircraft (transfer) or be clearly indicated on the accompanying airway bills (transit). Each consignment should have a security status indicating the security controls/exemptions applied from the up-station airport to accompany the shipment.

Furthermore, COVID-19 vaccines are considered high-value shipments. Where required by other national authorities, a State's appropriate authority should facilitate the implementation of measures aimed to protecting such shipments from non-aviation security-related threats (e.g. criminal threats). It is of utmost importance that all involved authorities and stakeholders coordinate and cooperate with each other using either the NATFC, the National Security Committee or similar coordination bodies as mentioned before. The need to protect COVID-19 vaccine shipments from being misused for acts of unlawful interference, the need to protect the shipment's high value and the need for facilitating the delivery process seem to be difficult to marry and require the highest level of cooperation to organize successful distribution of the vaccine in the EUR/NAT Regions and globally.

Safety related issues

It is understood that by complying with the requirements of Annexes 6, 18, 19 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.
Some COVID-19 vaccines may need to be maintained at sub-zero temperatures during transport, and some may even require a temperature-controlled environment of below -70°C. The cooling can reliably be ensured by the use of dry ice (frozen CO2). However, dry ice is classified as a dangerous good. The use of dry ice in large quantities on board an aircraft may increase hazard particularly when transported on the main (passenger/cargo) deck of a large aeroplane.

On 31 December 2020, The ICAO Council approved two amendments to the Technical Instructions to facilitate the transport of COVID-19 vaccines. One makes COVID-19 vaccines containing genetically modified organisms (GMOs) or genetically modified micro-organisms (GMMOs), including those in clinical trials, not subject to the Technical Instructions. The second removes a requirement for a lithium battery mark on packages containing COVID-19 vaccines accompanied by data loggers and/or data tracking devices. The amendments are contained in Addendum No. 1 to the 2021-2022 Edition of the Technical Instructions, applicable 1 January 2021.

Chapter 15 to Annex 6, Part I (applicable Nov 2020) requires operators to conduct a specific safety risk assessment, in addition to the prescriptive requirements in the Technical Instructions, for transporting items in the cargo compartment. The elements of the safety risk assessment set out in Chapter 15 to Annex 6, Part I were taken into account when considering the amendments to the Technical Instructions. Operators should consider whether additional risk mitigations are needed based on their unique operations.

More guidance from ICAO on the topic is available via link:
https://www.icao.int/safety/OPS/OPS-Normal/Pages/Vaccines-Transport.aspx
Additional guidance is available from EASA, FAA, IATA, and aircraft manufacturers.

Air Navigation Capacity and Efficiency related issues

Following the publication of the IATA Guidance for Vaccine and Pharmaceutical Logistics and Distribution in December 2020, where it was noted that the routine transport of the COVID-19 vaccine is really business as usual several aviation stakeholders started the discussions on specific aspects of the COVID-19 vaccine delivery (e.g. ensuring arrival before a curfew at the one destination that can uplift and distribute the vaccine in a region, or avoiding delays which would have a direct impact on connecting flights when the vaccine shipment will be distributed onto several flights at a hub airport towards different destinations) which could require special or priority handling.

As a result of the discussions between IATA and several Air Traffic Flow Management (ATFM) Centres (FAA Command Centre in the United States, EUROCONTROL Network Manager and NAV CANADA National Operations Center) a procedure was developed that introduces a coordinated Air Traffic Management approach for specific flights transporting COVID-19 vaccines which may require special handling and/or priority. The process/procedure does not apply to all flights carrying COVID-19 vaccines as it pertains only to critical flights where, in certain circumstances, it is recognized that delays may put the vaccines at risk. Flight operators are responsible for determining which flights carrying COVID-19 vaccines are critical.

The procedure allows aircraft operators to insert “STS/ATFMX” and “RMK/VACCINE” in Item 18 of the ICAO Flight Plan so that any flight they have determined as a critical flight due to COVID-19 vaccine transport can be identified to Air Navigation Service Providers. This will assist the ANSPs in maintaining an appropriate level of awareness of these critical COVID-19 vaccine distribution flights which may need special air traffic and/or priority handling.

The procedure will be implemented on 28 January 2021 in the United States, Canada and in all EUROCONTROL Member States. The ICAO EUR/NAT Office has issued a State Letter which invited the States in the EUR Region that are operating an Air Traffic Flow Management Centre to also consider the implementation of this harmonized process/procedure.

Economic considerations

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.

ICAO has recently issued Guidance on economic and financial measures to mitigate the impact of the coronavirus outbreak on aviation:
https://www.icao.int/sustainability/Documents/COVID-19_Economic_and_Financial_Measures/ICAO_Guidance_on_Economic_and_Financial_Measures.pdf

One of the options that a State can consider is to revise or supplement existing air services agreements by concluding a “mini-deal” with bilateral or regional partner States. The

amendments to these agreements can include expanded opportunities of fifth and seventh freedom operations, especially for all-cargo services, temporary arrangements to grant additional air service rights in response to the urgent needs, as well as relaxation of airline designation and authorization (nationality) clauses.

One example is the Latin America Civil Aviation Commission (LACAC) MOU allowing temporary seventh freedom all-cargo operations. This MOU will allow airlines of the signatory 'States to exercise the seventh freedom traffic rights for all-cargo services, both scheduled and non-scheduled, reciprocally with equal opportunities and without restrictions or limitations on routes and capacity'. The agreement will remain in effect for one year, until 31 December 2021, and can be extended for a further year, at the discretion of LACAC States.

Besides its immediate impact in terms of pandemic response and recovery, ICAO encourages other countries to view it as a significant step in advancing the ICAO Long-Term Vision for International Air Transport Liberalization.

Useful links

ICAO website for safe transport of COVID-19 vaccines on commercial aircraft:
https://www.icao.int/safety/OPS/OPS-Normal/Pages/Vaccines-Transport.aspx

ICAO Guidance on economic and financial measures to mitigate the impact of the coronavirus outbreak on aviation:
https://www.icao.int/sustainability/Documents/COVID-19_Economic_and_Financial_Measures/ICAO_Guidance_on_Economic_and_Financial_Measures.pdf

ICAO Long-Term Vision for International Air Transport Liberalization
https://www.icao.int/sustainability/Pages/economic-policy.aspx

IATA guidance for vaccine and pharmaceutical logistics and distribution:
https://www.iata.org/en/programs/cargo/pharma/vaccine-transport/

EASA guidelines in relation to the COVID-19 pandemic:
https://www.easa.europa.eu/document-library/general-publications/transportation-vaccines-using-dry-ice
https://www.easa.europa.eu/newsroom-and-events/news/exemptions-allowing-third-country-operators-tcos-transportation-cargo

FAA guidance on vaccine transport:
https://www.faa.gov/coronavirus/vaccine_transport/

Upcoming EUR/NAT events

To facilitate preparation for vaccine transportation particularly in the Eastern part of ICAO EUR Region, the ICAO EUR/NAT Office and Interstate Aviation Committee (IAC) are organizing a joint webinar “Preparation and implementation of a plan for COVID-19 vaccines delivery by air” to be held on 01 and 02 February 2021 within the framework of the ICAO-IAC Project «Improvement of flight safety and airworthiness in the IAC States».

The webinar is primarily targeted for Russian speaking States, but invitations can be extended to other interested Regulators. Please contact the ICAO EUR/NAT Office for more details at icaoeurnat@paris.icao.int

Editors and the EUR/NAT Team

This edition was developed by the Officers of the ICAO EUR/NAT office and ICAO Headquarter

The next EUR/NAT Brief will be issued on 2 March 2021

International Civil Aviation Organisation European and North Atlantic Office (ICAO EUR/NAT)

3 bis villa Émile Bergerat, 92200 Neuilly-sur-Seine
Cedex, France

Phone: +33 1 46 41 85 85
Email: icaoeurnat@paris.icao.int
Website: www.icao.int/EURNAT