WCO Secretariat Note
ROLE OF CUSTOMS IN FACILITATING AND SECURING THE CROSS-BORDER MOVEMENT OF SITUATIONALLY CRITICAL MEDICINES AND VACCINES
February 2021

I. Introduction and objective of the Secretariat Note
Since the World Health Organization (WHO) categorized the outbreak of the novel coronavirus disease (COVID-19) as a pandemic on 11 March 2020, the WHO has been working in collaboration with scientists, business and global health organizations to speed up the pandemic response.

In November 2020, the world witnessed the first announcements of COVID-19 vaccine candidates proving to be more than 90% effective based on first interim analysis of Phase 3 clinical trials results. By that time, vaccine distribution supply chain stakeholders had started their preparations for what is expected to be the world’s largest and fastest vaccine distribution operation ever.

Bearing in mind the challenges associated with the handling of time- and temperature-sensitive vaccines in large quantities, on 11 December 2020, the WCO Council unanimously adopted a Resolution on the Role of Customs in facilitating the cross-border movement of situationally critical medicines and vaccines (hereafter referred to as the Resolution).

The Resolution contains a preamble and two types of recommended measures – to be implemented by Member Customs administrations (12 measures) and to be implemented by the Secretariat (4 measures plus a measure regarding the monitoring of the implementation of the Resolution by the Permanent Technical Committee (PTC) and the Enforcement Committee (EC)). The Resolution is available on the WCO web-site in English, French, Arabic, Chinese, Portuguese, Russian and Spanish languages.

The objective of this document is to provide guidance with regard to the implementation by Members of the twelve measures outlined in the WCO Resolution on the Role of Customs in facilitating the cross-border movement of situationally critical medicines and vaccines, as well as provide information on WCO instruments and tools that can support the implementation of the Resolution.

The Secretariat Note has been prepared by the WCO Secretariat as an information document. It does not necessarily reflect the views or policies of the WCO or its membership.

The note is designed to be a living document that will be enhanced with more Members’ practices and further practical guidance as WCO Members gain experience and share information with the WCO Secretariat on the Customs clearance of COVID-19 vaccines, related supplies and equipment. The Secretariat Note was developed in response to Members’ needs and as a follow-up to discussions held with the Chairperson of the Permanent Technical Committee (PTC). The first edition of the Note will be presented to the 231st/232nd Sessions of the PTC in April 2021.
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II.1. Coordination with other government agencies and stakeholders (measures 10 and 6)

The Resolution contains two measures highlighting the importance of coordination with other government agencies and stakeholders, namely:

- Cooperate and coordinate with relevant government agencies, in particular health authorities, and supply chain stakeholders, so that facilities, security arrangements and border processes are ready for the large-scale and complex task ahead (measure 10);
- Ensure that inspections by other government agencies and inspections by Customs are coordinated and, if possible, carried out at the same time (measure 6).

II.1.a. Explanations with regard to the measures

Pharmaceutical products and medical equipment are highly regulated items. In the clearance process for these items, Customs usually enforces legislation on behalf of other government agencies, health authorities in particular. Therefore, proper dialogue and coordination with those agencies, both prior to and during the exportation, importation or transit of these items, is paramount for the simplification and facilitation of the clearance process.

The distribution of COVID-19 vaccines is further complicated by the fact that they require transportation and storage in a cold/ultra-cold chain (e.g. 2-8°C, -20°C, -75°C). This complex logistical process, involving rigorous stock management and temperature control, requires the availability/establishment of appropriate facilities and border processes. Moreover, vaccines are high-value goods, which, coupled with the imbalance between supply and demand, makes them vulnerable to attempted theft or diversion by criminal organizations seeking to make profit of the challenging situation brought by the COVID-19 pandemic. Hence the importance of governments putting in place appropriate security arrangements for the transportation and storage of COVID-19 vaccines.

Joint inspections by Customs and other government agencies allow significant cost savings for the importer or exporter, as well as speeding up of the clearance of the respective shipments. They are even more pertinent to the clearance of time- and temperature-sensitive items such as medicines and vaccines.

The coordination with health authorities and supply chain stakeholders is also of key importance for the implementation of measures 1, 2, 3 of the Resolution, as explained in section II.2 below, and of measures 4 and 12 of the Resolution, as explained in section II.4.

II.1.b. WCO instruments and tools that support the implementation of the measures

The WCO instruments and tools that can support the implementation of measures 6 and 10 of the Resolution are transitional standard 3.35 of the General Annex to the International Convention on the simplification and harmonization of Customs procedures, as amended, known as the Revised Kyoto Convention (RKC), the Guidelines to Chapter 3 Clearance and other Customs Formalities of the RKC General Annex, the SAFE Framework of Standards and in particular Pillar 3 thereof, the Coordinated Border Management (CBM) Compendium, and the 2011 WCO Resolution on the role of Customs in natural disaster relief.
II.1.c. Practical ways to implement the measures

Practical ways to implement measure 10 of the Resolution are to:

- Nominate contact points/enquiry points in Customs and other relevant government agencies to exchange information in a timely manner and respond to requests by supply chain stakeholders.
- Establish a task force with the participation of all relevant government agencies, including Customs, as well as relevant private sector representatives.
- Coordinate through the National Committee on Trade Facilitation (NCTF).
- Cooperate with health authorities and supply chain stakeholders to provide training to operational Customs staff.

II.1.d. Members’ case studies

Below are examples of Members’ good practices in this regard.

**Australian Border Force (ABF)**

In November 2020, the ABF established a whole of government senior-level committee and a working-level Joint Planning Group (JPG) that integrated the planning for border agencies accountable for the effective importation of essential COVID-19 goods to protect the Australian community, while ensuring border protection controls remain adequate to detect illicit variations of the vaccine. This cohesive planning mechanism has resulted in a coordinated effort across government to develop and implement specific border measures for COVID-19 vaccines.

The JPG undertook analysis of factors that facilitate or hinder the cross-border movement of essential goods without unnecessary interruption or delay. The JPG enabled the ABF and other government agencies to integrate Customs, biosecurity and health-related approvals – and overcome barriers to provide maximum facilitation to COVID-19 vaccines. Even before vaccines began arriving in Australia, Government agencies and industry collaborated on test runs involving placebo shipments sent by a vaccine manufacturer to enable stakeholders to refine the process.

Australia’s Therapeutic Goods Administration (TGA) and Department of Health lead industry engagement with pharmaceutical manufacturers and importers, with the ABF and the Department of Agriculture, Water and the Environment providing information on import requirements at the border. This close engagement between Government and industry is enabling a high level of coordination on delivery schedules, and general awareness of vaccine movements by all stakeholders.

Operational areas are currently participating in various training sessions facilitated by the WCO and Australia’s Department of Health in conjunction with COVID-19 vaccine manufacturers.

**National Customs Service of Costa Rica**

The Government of Costa Rica has long adopted measures for the treatment of relief shipments and import of urgent goods such as vaccines, with contacts established in different government entities, where coordination is done prior to the dispatch of COVID-19 vaccines, thus ensuring agile and timely treatment.

The shipment and transport of the vaccines to their place of storage is carried out immediately on arrival, the goods (COVID-19 vaccines) are accompanied by National Security.
New Zealand Customs Service

New Zealand Customs implemented and leads a Customs Centre of Excellence team to understand the current and future state of the importation and exportation of critical supplies deemed essential and a priority to support the COVID-19 operation within New Zealand.

Utilizing trade data New Zealand Customs made contact with all importers, exporters and manufacturers of critical supplies. Industry, government stakeholders and internal stakeholders were advised of the new centralized point of centre of excellence for critical supplies. This has given New Zealand Customs an awareness of all imports and exports of critical supplies as well as any known issues experienced by industry.

Keeping up with emerging trends in critical supplies remains a priority.

United States Customs and Border Protection (US CBP)

US CBP established a COVID-19 Cargo Resolution Team (CCRT).

Coordinated border management has been critical for the CCRT. The CCRT worked closely with Health and Human Services (HHS), Department of Defense (DOD), Federal Emergency Management Agency (FEMA) and offices across CBP to ensure the swift review and release of shipments as part of national initiatives. These include FEMA’s Project Airbridge and Operation Warp Speed with HHS and DOD.

Through the Pharmaceutical, Health and Chemical Center of Excellence and Expertise (PHC Center) Partnership Division, the team developed strong relationships with industry partners involved in the development of the vaccines, possible remedies, and the detection of counterfeits. The CCRT has been proactive in reaching out to vaccine developers and has ensured the prioritization of the release of these shipments to their final destination. Working with other government agencies, such as the FDA, the CCRT is able to resolve entry issues before the goods arrive.
II.2. Measures to prioritize and facilitate the clearance of situationally critical medicines and vaccines (measures 1, 2 and 3)

The Resolution contains three measures highlighting the importance of prioritizing and facilitating the clearance of situationally critical medicines and vaccines, namely:

- Carry out the clearance of situationally critical medicines and vaccines for export, transit and import as a matter of priority in appropriate facilities in order to prevent possible detrimental product temperature variations due to delays (measure 1);
- Provide mechanisms for identifying such medicine and vaccine shipments during import or export, such as on import or export documentation (measure 2);
- Provide for special procedures for authorized/recognized supply chain actors, including producers of COVID-19 vaccines (measure 3).

II.2.a. Explanations with regard to the measures

As indicated earlier, COVID-19 vaccines are time- and temperature-sensitive items. Due to the requirements for cold-chain transportation and storage, they can be categorized as perishable goods. In addition, the need for a speedy roll-out of the COVID-19 vaccine as the primary way to end the COVID-19 pandemic requires the prioritization of the clearance of COVID-19 vaccines and related medical supplies over the clearance of general cargo. Priority should also be given in the Customs clearance process to the medical supplies needed for the vaccines administrations, such as, but not limited to, vials, alcohol solutions, syringes, needles, etc., as well as to the raw materials and components used in the vaccines manufacturing process.

As indicated in the Secretariat Note on How to establish and utilize essential goods lists during a disaster, the prioritization of relief items, including the COVID-19 vaccines and related medical supplies, can be done based on the Harmonized System (HS) codes of the goods, or based on Customs Procedure Codes, or based on approved organizations importing the goods.

That is why it is important for Customs to have in place mechanisms for identifying the respective medicines, medical supplies and vaccines during import or export, such as on import or export documentation. The WCO, in cooperation with the WHO, issued a dedicated HS Classification Reference document to support Member Customs administrations and supply chain stakeholders in classifying vaccines and related supplies and equipment at the international level, i.e. 6 digits as per the HS. The related supplies and equipment include vials, syringes, needles, dry ice, freezers, among others. It is advisable that Customs administrations issue lists indicating the classification at a domestic level (7 or more digits) and make these lists available to the relevant government and private sector stakeholders.

Another Secretariat activity to support Members in this regard, as well as to assist them implement measure 12 of the Resolution, is the delivery of series of webinars with COVID-19 vaccines manufacturers. These webinars are restricted to Members only and provide information on the characteristics of the genuine vaccines and how they will be shipped.

The mechanisms for identifying the respective medicines, vaccines, related supplies and equipment can include the issuing by the Customs administration of the importing country of advance rulings for classification, origin or valuation.

Cooperation with relevant government authorities, vaccines manufacturers and supply chain stakeholders is of key importance so that Customs has at its disposal relevant and up-to-date information about the shipments of vaccines and related supplies.
The genuine COVID-19 vaccines will be distributed in a chain of authorized/recognized supply chain actors and it is important that special procedures are in place for those supply chain actors. These can be government agencies (Ministry of Health or similar), bona fide humanitarian actors, and economic operators accredited under an Authorized Economic Operator (AEO) programme or a Regulated Agent/Known Consignor programme or enjoying benefits under the RKC provision on authorized persons or the provision of the World Trade Organization Agreement on Trade Facilitation (WTO TFA) on authorized operators. The special procedures can include the possibility to lodge a simplified Goods declaration or of a provisional or incomplete goods declaration subject to completion of the declaration within a specified period, or the clearance of the goods at the declarant's premises or another place authorized by the Customs, or any other of the special procedures outlined in transitional standard 3.32 of the RKC General Annex, the SAFE Package or in Article 7.7 of the WTO TFA.

The following paragraphs provide further information on COVID-19 vaccine distribution stakeholders. The information is aimed at illustrating that the genuine COVID-19 vaccines will be distributed in a chain of authorized/recognized supply chain actors.

The manufactures of COVID-19 vaccines and related medical supplies are well-established pharmaceutical companies. In the first months of the COVID-19 vaccines roll-out, the vaccine manufacturers will be concluding contracts only with the governments of the beneficiary countries or with COVAX. The consignees of the shipments of vaccines are normally government agencies (Ministry of Health or similar government agency).

COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and WHO and is working in partnership with developed and developing country vaccine manufacturers, the United Nations International Children’s Emergency Fund (UNICEF), the World Bank, and others. It is the only global initiative that is working with governments and manufacturers to ensure COVID-19 vaccines are available worldwide to both higher-income and lower-income countries. There are two group of countries in COVAX – close to 100 self-financing countries and economies and 92 low- and middle-income countries eligible for donor funding.

UNICEF is coordinating and supporting the procurement, international freight and delivery of COVID-19 vaccines for the COVAX Facility, which is the procurement mechanism for COVAX. For the countries of Latin America and the Caribbean this coordination has been entrusted to the Pan-American Health Organization (PAHO).

II.2.b. WCO instruments and tools that support the implementation of the measures

The WCO instruments, tools and guidance material that can support the implementation of measures 1, 2 and 3 of the Resolution are transitional standard 3.32, standard 3.34, standard 9.9 of the RKC General Annex, Chapter 5 of Specific Annex J (SA J5) to the RKC, the Guidelines to Chapter 3 and Chapter 9 of the RKC General Annex, the Guidelines to RKC SA J5, the SAFE Framework of Standards, the Secretariat Note on How to establish and utilize essential goods lists during a disaster, the HS classification reference for vaccines and related supplies and equipment, and the Technical Guidelines for Advance Rulings for Classification, Origin and Valuation.
II.2.c. Practical ways to implement the measures

Practical ways to implement measures 1, 2 and 3 of the Resolution are to:

- Prioritize the clearance of situationally critical medicines and vaccines for export, transit and import based on HS code, on Customs Procedure Code or on approved organizations importing the goods.
- Issue lists of situationally critical medicines and vaccines indicating the classification at domestic level (7 or more digits), make the lists publicly available, preferably on the internet, and use them for prioritization purposes.
- Issue advance rulings for classification and/or origin of the situationally critical medicines and vaccines.
- An advanced way to identify the genuine vaccines and related supplies and facilitate their clearance is the use of advanced technologies such as artificial intelligence, data analytics and blockchain technology solutions.
- Apply the “green lanes”/priority lanes concept to the clearance of situationally critical medicines and vaccines.
- Provide for clearance outside the designated hours of business or away from Customs offices and the waiver of any charges in this respect.
- Provide for special procedures for authorized/recognized supply chain actors such as, but not limited to:
  - release of the goods on the provision of the minimum information necessary to identify the goods and permit the subsequent completion of the final goods declaration;
  - clearance of the goods at the declarant's premises or another place authorized by the Customs;
  - allowing a single goods declaration for all imports or exports in a given period where goods are imported or exported frequently by the same person;
  - allowing the lodgement of the goods declaration by means of an entry in the records of the authorized person to be supported subsequently by a supplementary goods declaration.
- Facilitate pre-arrival processing of documentation for COVID-19 vaccines.
- Provide for the separation of release from final determination of Customs duties, taxes, fees and charges.
- Provide facilities for the electronic payment of Customs duties, taxes, fees and charges.
- Provide for the deferring of the payment of Customs duties, taxes, fees and charges due with regard to the importation of situationally critical medicines and vaccines.

II.2.d. Members’ case studies

Below are examples of Members’ good practices in this regard.

**Australian Border Force (ABF)**

The ABF is aiming to clear the vaccines immediately without unnecessary interruption. For goods requiring a referral to specialists in the Therapeutic Goods Administration (TGA), the ABF is expecting to have cleared status within:
- 2 hours from time of referral for cold storage.
- 24 hours from time of referral for non-cold storage.
National Customs Service of Costa Rica

While Customs in Costa Rica prioritizes the importation of vaccines and coordinates efforts in advance for vaccines to be moved immediately to their destination, Customs is a supportive element and works with health entities to ensure that the importation of vaccines is managed in an agile manner, taking into account the COVID-19 cases forecast.

The exchange of information for the importation of COVID-19 vaccines is carried out by the health authorities with foreign suppliers and logistics providers. The health authorities coordinate this documentation with the Customs office prior to the arrival of the vaccines in the country, with the aim of making Customs clearance easier in an expedited procedure.

The Directorate-General of Customs implements measures aimed at the immediate exit and processing of vaccines, after the lifting of an administrative record.

United States Customs and Border Protection (US CBP)

US CBP established a COVID-19 Cargo Resolution Team (CCRT).

To streamline the process of triaging incoming inquiries, coordinating with affected Ports and Centers, and responding directly as appropriate, CBP created the COVID-19 Relief Imports Web Portal located on the CBP website. https://imports.cbp.gov. The web portal made it easy to find answers to COVID-19 FAQs on admissibility, cargo hold and facilitation, PPE and vaccine import guidance, classification, and duties. Through the web portal, the CCRT coordinates responses, prioritizes release, and provides timely guidance from all government agencies regarding the import of critical vaccines, vaccine supplies and PPE.

In order to avoid delays with these critical shipments, communication is key. The CCRT has relayed to the manufactures that all documentation related to these shipments must be forwarded prior to arrival and the CCRT must be aware of any shipments inbound to the United States. This enables the team to ensure all documentation is reviewed and the local port of entry is notified of its arrival. The CCRT has assembled a comprehensive list of personnel at all major ports of entry to ensure shipments are immediately released without delay.
II.3. Measures related to the Customs treatment and handling of specialized containers, devices and goods used for the distribution of situationally critical medicines and vaccines (measures 7, 8 and 11)

The Resolution contains three measures related to the Customs treatment and handling of specialized containers, devices and goods used for the distribution of situationally critical medicines and vaccines, namely:

- Implement measures such as those contained in the Customs Convention on Containers, 1972, with regard to the Customs treatment of containers (including specialized containers) used for the transportation of situationally critical medicines and vaccines (measure 7);
- Implement measures such as those contained in the Recommendation of the Customs Co-operation Council of June 2013 concerning Customs formalities in connection with the temporary admission of container security devices, with regard to the Customs treatment of devices (data loggers) affixed to containers used for the shipping of vaccines for the purpose of monitoring the status of the vaccines and/or for tracking purposes (measure 8);
- Ensure that Customs staff are prepared to handle specialized temperature-sensitive items, including those involving the use of dangerous goods (dry ice) for their transportation (measure 11).

II.3.a. Explanations with regard to the measures

The cross-border movement of medicines and vaccines is not something new to Customs. What is unprecedented is the scale of the COVID-19 vaccines distribution effort. In this context, and in view of the limitations associated to the number of specialized containers deployed in this logistics process, it is of paramount importance that Customs do not unnecessarily delay the re-deployment or re-utilization of such containers and the devices affixed to them.

The containers used in air transport are the so-called Unit Load Devices (ULD). The ULD classification includes two categories – Aircraft ULD and Non-aircraft Container. The Aircraft ULD category comprises two sub-categories – Aircraft Container and Combination of Aircraft Pallet and Aircraft Pallet Net. As per the ULD Regulations of the International Air Transport Association (IATA), an Aircraft ULD is a device for grouping and restraining cargo, mail and baggage for air transport. A key characteristic is that the Aircraft ULD is designed to be fully engaged with the aircraft Cargo Loading System and restrained by locks, stops, latches, guides, etc. on the aircraft floor. This is the main difference between Aircraft ULD and Non-aircraft Container. Per definition, a Non-aircraft Container is a reusable modular load unit, usually forkliftable and which may or may not be contoured, which does not directly interfere with the aircraft Cargo Loading System, to be loaded onto an aircraft pallet for transport.

Likewise, the Thermal Container classification includes two categories – Insulated Container and Temperature Controlled Container (TCC). Insulated containers do not have any temperature control function, but just insulation. The TCC category includes two sub-categories – Aircraft TCC and Non-aircraft TCC. Because of their high value (some with a replacement value of about Euro 50 000), leasing is the only business model for Aircraft TCC. Similarly to the Non-aircraft Container, the Non-aircraft TCC is not designed to be restrained by the aircraft Cargo Loading System, which does not mean that it is not suitable for air carriage.

Containers are also commonly referred to as instruments of international traffic.
The Customs Convention on Containers, 1972 (Container Convention) includes provision on the temporary admission of containers, whereas containers temporarily imported under the terms of the Convention shall be granted temporary admission without the production of Customs documents being required on their importation and re-exportation and without the furnishing of a form of security. The Convention specifies the conditions that should be met in this regard, including a definition for a “container”.

Similar provisions are included in the Convention on Temporary Admission (Istanbul Convention) and more specifically its Annex B.3 Annex concerning containers, pallets, packings, samples and other goods imported in connection with a commercial operation.

A notable difference in the provisions of the two conventions concerns the 1-cubic metre limitation included in the definition for a “container”. The Protocol of Signature of the Container Convention specifies that “the one-cubic-metre limitation of the internal volume … does not imply the application of more restrictive regulations to containers of a smaller volume, and the Contracting Parties shall endeavour to apply a temporary admission procedure to the latter similar to that which they apply to containers defined in the … Convention”. The Istanbul Convention does not contain a similar provision. However, Article 17 of the Istanbul Convention prescribes that “the provisions of this Convention set out the minimum facilities to be accorded. They do not prevent the application of greater facilities which Contracting Parties grant or may grant in future by unilateral provisions or by virtue of bilateral or multilateral agreements.” A similar flexibility is foreseen in Article 14 of the Container Convention.

Another instrument that regulates the Customs treatment of aircraft Unit Load Devices (ULDs) is the ICAO Convention on International Civil Aviation and more specifically Chapter 4 of its Annex 9 Facilitation.

With regard to the devices affixed to containers used for the shipping of vaccines for the purpose of monitoring the status of the vaccines and/or for tracking purposes it should be noted that these might be data loggers or connected devices affixed to the containers for tracking and tracing purposes.

In June 2013, the WCO Council adopted a Recommendation concerning Customs formalities in connection with the temporary admission of container security devices. The Recommendation contains a definition for a “Container Security Device (CSD)” and recommends that CSDs should not be subject to any individual Customs formalities in connection with the temporary admission of a container if they are accessories or equipment of that container. The Recommendation also includes provisions concerning the Customs formalities with regard to CSDs that are imported separately from a container and are intended to be re-exported being affixed to a container.

It should be noted that the connected devices may be affixed not just to the container, but to individual packages of vaccines in order to provide for door-to-door status monitoring, tracking and tracing thereof. The Customs formalities in such cases should be as facilitative as possible in order to not unnecessarily delay the distribution of the vaccines and the redeployment of the connected devices as well as the packages, when the latter are designed to be reused for subsequent distribution of additional vaccines.

The Customs treatment of containers and devices used for the transportation of situationally critical medicines and vaccines was discussed during the 18th Meeting of the Administrative Committee for the Container Convention on 28 January 2021.
With regard to the dry ice that is used for the transportation of the COVID-19 vaccines that require ultra-cold temperature environment, it should be noted that dry ice is solid carbon dioxide. It is used to maintain temperatures of as low as -78°C.

Safety precautions are critical when using dry ice in the transportation and storage of vaccines. Unlike conventional ice, dry ice does not melt into a liquid. Instead, dry ice sublimates, or in other words changes from a solid to a gas state, turning into carbon dioxide gas. Carbon dioxide is an oxygen-depleting gas that is both odorless and colorless. In poorly ventilated, confined spaces, such as cargo holds or cold-chain storage facilities, carbon dioxide can build up, creating a potentially serious health risk to flight crews and ground staff.

An environment in which oxygen levels fall below 19.5 percent is considered oxygen-deficient and should be treated as an immediate danger to health or life. When there is not enough oxygen in the air, persons working in the affected area may become disoriented, lose consciousness, or even suffocate due to the lack of sufficient oxygen.

If handled with unprotected skin, dry ice can cause burn-like injuries.

Some vaccine manufacturers may choose to use liquid nitrogen for the distribution of their vaccines. The potential health risks associated with nitrogen leaks are similar to those that may be caused by dry ice sublimation.

Vaccines may contain biological products or genetically modified (micro) organisms and as such may fall under the dangerous goods category (UN 3245).

II.3.b. WCO instruments and tools that support the implementation of the measures

The instruments, tools and guidance material that can support the implementation of measures 7, 8 and 11 of the Resolution are the Customs Convention on Containers, 1972, the Container Convention Handbook, Annex B.3 to the Istanbul Convention, the Istanbul Convention Handbook, the 2013 WCO Recommendation concerning Customs formalities in connection with the temporary admission of container security devices, and the Secretariat Note on How Customs can support the safe and secure storage of dangerous goods.

II.3.c. Practical ways to implement the measures

Practical ways to implement measures 7, 8 and 11 of the Resolution are to:

- Grant, even as a temporary measure, to the specialized containers used for the transportation of the COVID-19 vaccines, temporary admission without the production of Customs documents being required on their importation and re-exportation and without the furnishing of a form of financial security.
- Treat the data loggers and connected devices affixed to containers used for the shipping of vaccines for the purpose of monitoring the status of the vaccines and/or for tracking purposes as accessories to those containers and not subject them to any individual Customs formalities in connection with the temporary admission of a container.
- Provide information and training to operational Customs staff on how to handle specialized temperature-sensitive items, including those involving the use of dangerous goods (e.g. dry ice) for their transportation. For the purposes of organizing such training, the Customs administration may engage experts from the Ministry of Health, aviation authorities, vaccines manufacturers and other relevant supply chain stakeholders.
### II.3.d. Members’ case studies

Below are examples of Members’ good practices in this regard.

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<tr>
<th><strong>Australian Border Force (ABF)</strong></th>
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<tr>
<td>The ABF has developed a number of procedures that maps the importation pathway for COVID-19 vaccines to enhance ABF officers’ understanding of the processes and to remove ambiguity in the border clearance process. This includes information on the handling of vaccines requiring cold storage, noting the dangers of dry ice.</td>
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<th><strong>Customs and Monopolies Agency of Italy</strong></th>
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<td>A special section of the Customs intranet (accessible to the personnel only) provides all not confidential Customs and acts of Other Government Agencies (OGA) regarding the Administration of the emergency, but for many of them a special link into a special section of the public internet Customs site (<a href="https://www.adm.gov.it/portale/emergenza-covid-19">https://www.adm.gov.it/portale/emergenza-covid-19</a>) is provided as well. Both the intranet and internet website contain links to relevant documents of the WCO and the EU, i.e. DG TAXUD.</td>
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<th><strong>United States Customs and Border Protection (US CBP)</strong></th>
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<td>In March 2020, through the Integrated Trade Targeting Network (ITTN), CBP disseminated COVID-19 guidance related to the imports of personal protective equipment (PPE), unapproved test kits and other related products. In January 2021, through the ITTN, CBP disseminated updated COVID-19 related guidance to include critical information on imports of vaccines as well as the goods and devices used for the vaccines. Both guidance documents were a collaboration between CBP and the Food and Drug Administration (FDA) to provide critical information to the field to facilitate the movement of lawful products, while ensuring the safety and securing of the American people.</td>
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II.4. Measures related to the control of situationally critical medicines and vaccines (measures 4, 5 and 12)

The Resolution contains three measures related to the control of situationally critical medicines and vaccines, namely:

- Apply risk-based control and perform examinations on shipments declared as such medicines and vaccines only in exceptional circumstances, and only at the appropriate moment and place (measure 4);
- When an examination is deemed necessary, perform non-intrusive inspections to the extent possible (measure 5);
- Take appropriate measures to prevent organized criminal organizations from exploiting the situation, and to address the threat posed by illegal products in the cases of dangerous, sub-standard or counterfeit medicines and vaccines (measure 12).

II.4.a. Explanations with regard to the measures

As indicated earlier, the genuine COVID-19 vaccines will be moved across borders in a chain of authorized/recognized supply chain actors. Applying risk assessment and risk management to the clearance of the COVID-19 vaccines shipments is of key importance to facilitating the cross-border movement of the genuine vaccines, as well as to addressing the threat posed by counterfeit, sub-standard or dangerous medicines and vaccines.

Cooperation with relevant government authorities, in particular health authorities, and private sector stakeholders, such as vaccines manufacturers and logistics providers, is critical for obtaining information on the characteristics of the genuine vaccines and of their usual distribution supply chain.

When an examination is deemed necessary, Customs should consider performing non-intrusive inspections rather than physical inspections of the vaccines shipments in order to speed up the clearance process and prevent possible detrimental product temperature variations. When a physical inspection is deemed absolutely necessary, it should be performed in appropriate storage facilities with a view to maintaining the cold chain integrity.

As vaccines are high-value goods vulnerable to theft or diversion, risk assessment should be performed to determine vulnerabilities and threats, including insider and cyber threats in the Customs clearance process. Supply chain stakeholders (vaccine manufacturers, freight forwarders, carriers, Customs brokers, etc.) also need to perform such risk assessment with regard to insider and cyber threats in the manufacturing and logistics process. For the purposes of curbing the illicit trade in medicines and vaccines, the Secretariat has launched a dedicated IPR CENComm group for the exchange of enforcement sensitive information, has organized a series of webinars with COVID-19 vaccines manufacturers, has issued Counterfeit COVID-19 Vaccines open source alert, and is preparing the STOP II enforcement operation.

II.4.b. WCO instruments and tools that support the implementation of the measures

The WCO instruments and tools that can support the implementation of measures 4, 5 and 12 of the Resolution are standard 6.3, 6.4 and 6.5 of the RKC General Annex, SA J5 to the RKC, the Guidelines to Chapter 6 of the RKC General Annex, the Guidelines to RKC SA J5, the SAFE Framework of Standards, the Risk Management Compendium and specifically the part thereof dedicated to Customs risk management during a disaster, which is pending approval by the 41st
II.4.c. Practical ways to implement the measures

Practical ways to implement measures 4, 5 and 12 of the Resolution are to:

- Cooperate with relevant government authorities and supply chain stakeholders to obtain information on the characteristics of the genuine vaccines and medicines and of their usual distribution supply chain.
- Consider and implement the recommendations outlined in the document on Customs risk management during a pandemic.1
- Apply risk-based control to the clearance of situationally critical medicines and vaccines.
- Perform examination and sampling of situationally critical medicines and vaccines only in exceptional circumstances and at appropriate storage facilities.
- Use non-intrusive inspection techniques to the extent possible.
- Exchange relevant information to fight the trafficking of counterfeit vaccines and medical supplies through secure tools such as the IPR CENComm.
- Take part in global and/or regional enforcement operations targeting counterfeit, substandard or dangerous medicines and vaccines.
- Exercise extra vigilance and develop policies and procedures to mitigate the risks of insider threats to the security and integrity of the vaccine shipments.

II.4.d. Members’ case studies

Below is an example of a Member’s good practice in this regard.

<table>
<thead>
<tr>
<th><strong>Australian Border Force (ABF)</strong></th>
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<tbody>
<tr>
<td>The ABF undertakes a risk assessment process through the Joint Planning Group (JPG), which also oversees ongoing risk mitigation.</td>
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</table>

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1 Pending approval by the 41st Session of the EC
II.5. Role of Customs with regard to trade measures introduced by governments (measure 9)

The Resolution contains one measure related to the role of Customs with regard to trade measures introduced by governments, namely:

- Commit to working together to facilitate international trade and coordinate responses in ways that avoid unnecessary interference with international traffic and trade as it relates to COVID-19 medicines. Emergency measures aimed at protecting health should be targeted, proportionate, transparent, and temporary (measure 9).

II.5.a. Explanations with regard to the measure

Chapter 5 Relief consignments of RKC Specific Annex J prescribes that the clearance of relief consignments should be granted without regard to the country of origin, the country from which arrived or country of destination. It further specifies that any economic export prohibitions or restrictions and any export duties or taxes otherwise payable should be waived. On imports, relief consignments meeting certain criteria should be admitted free of import duties and taxes and free of economic import prohibitions or restrictions.

The importation of vaccines in many WCO members is subject to 0% duty rate and reduced rates for Value-Added Tax (VAT)/Goods and Services Tax (GST).

When Members opt to introduce export authorization requirements or any other trade restrictive measures taken for reasons of health or public order, these measures should be targeted, proportionate, transparent and temporary, in order to minimize any disruptions to cross-border trade in goods that are essential to combat the COVID-19 pandemic.

On 6 April 2020, the heads of WCO and WTO issued a Joint Statement on COVID-19 trade related measures, which is pertinent to the cross-border movement of the COVID-19 vaccines.

The WCO has referenced on its dedicated web-section the Market Access Map of the International Trade Centre (ITC) with the objective of providing up-to-date information on COVID-19 temporary trade measures introduced by Members.

II.5.b. WCO instruments and tools that support the implementation of the measure

The WCO instruments and tools that can support the implementation of measure 9 of the Resolution are SA J5 to the RKC and the Guidelines to RKC SA J5.

II.5.c. Practical ways to implement the measure

Practical ways to implement measure 9 of the Resolution are to:

- Advocate for the introduction of import support measures such as the waiving of any duties, taxes and fees on the importation of the COVID-19 vaccines.
- Advocate against the introduction of export restrictions with regard to the COVID-19 vaccines.
II.5.d. Members’ case studies

Below are examples of Members’ good practices in this regard.

**Australian Border Force (ABF)**

Vaccines will not incur any duty if using the correct HS code for human vaccines but are liable for Goods and Services Tax (GST).

**National Customs Service of Costa Rica**

In Costa Rica, vaccines are exempted by law from duties and taxes.

II.6. Other considerations

As indicated in the WTO report “Developing and delivering COVID-19 vaccines around the world”, management of waste related to COVID-19 vaccination requires special attention, due to the infectious nature of the virus. When COVID-19 vaccines are delivered in mass vaccination campaigns, the generation of healthcare waste will be amplified, due to the mandatory use of disposable and reusable materials and hazardous waste, such as personal protective equipment used by the vaccination teams.

Some medical waste could cross borders and the HS classification reference for vaccines and related supplies and equipment also includes clinical waste.

Trade in waste is regulated by different multilateral environmental agreements (MEAs), including the Basel Convention on the Control of Transboundary Movements of Hazardous Waste and their Disposal. Customs plays a key role in the implementation of these MEAs.

The Basel Convention is based on three pillars:

- The minimization of the generation of hazardous and other wastes;
- The requirement of ESM of hazardous wastes and other wastes; and
- The control of transboundary movements of hazardous wastes and other wastes.

To achieve its objectives, the Basel Convention has established a regulatory system based, inter alia, on the following:

- The requirement of prior informed consent (PIC) of a State of import and States of transit before a waste can be exported and, to this end, the establishment of a notification procedure;
- Restriction on exports to a country that is not a party to the Convention; and
- Consequences to be applied when an export or import has not complied with the provisions of the Convention.

Various WCO-coordinated enforcement activities (e.g. operations DEMETER) now also focus on medical waste generated due to COVID.

II.7. Other relevant information

The Annex to the Secretariat Note contains links to policy papers and guidance issued by partner international organizations and stakeholders, as well as a link to the section of the WCO web-site dedicated to COVID-19 vaccine distribution across borders.
Annex

Policy papers and guidance materials issued by partner international organizations and stakeholders

WHO web-page on COVID-19 vaccines - COVID-19 vaccines (who.int)

WHO Guidelines on the international packaging and shipping of vaccines - WHO | Guidelines on the international packaging and shipping of vaccines

WTO report “Developing and delivering COVID-19 vaccines around the world” - vaccine_report_e.pdf (wto.org)


IATA presentation on the characteristics of Unit Load Devices and the connected devices affixed to the containers for tracking and tracing purposes - http://www.wcoomd.org/~/media/meeting-documents/administrative-committee-for-the-customs-convention-on-containers-1972/18/item_vii_iata_uld_introduction_en_only_e.pdf?lang=en (log-in to the WCO Members’ web-site required)
