Role of Customs in facilitating and securing the cross-border movement of situationally critical medicines and vaccines

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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 trial results. By that time, vaccine distribution supply chain stakeholders had started their preparations for 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, and on Members’ good practices.

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 has been developed following a collaborative approach with Members, relevant international organizations, the pharmaceutical industry and other private sector entities and is designed to be a living document that will be enhanced with more Members’ practices and further practical guidance as WCO Members and the industry gain experience and share information with the WCO Secretariat on the Customs clearance of COVID-19 vaccines, related supplies, inputs and equipment. The first edition of 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 second edition has been enhanced based on the practices submitted by WCO Members as of 27 May 2021, the discussions held in the 231st/232nd Sessions of the PTC in April-May 2021 and the collaboration with relevant international organizations and the industry.
Measures to facilitate and secure the cross-border movement of situationally critical medicines and vaccines

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).

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, and of measures 4 and 12 of the Resolution, as explained below.

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, the WCO Guidelines on Disaster Management and Supply Chain Continuity that were endorsed by the PTC in May 2021 and the 2011 WCO Resolution on the role of Customs in natural disaster relief.
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).
- Engage with all relevant government agencies and supply chain stakeholders to develop Standard Operating Procedures for the exportation and importation of situationally critical medicines, vaccines and related supplies, inputs and equipment.
- Perform all border clearance procedures through a Single Window facility.
- Cooperate with health authorities and supply chain stakeholders to provide training to operational Customs staff.

d. **Members’ case studies**

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

**Customs Administration of Argentina**

The Directorate of Ezeiza Customs is comprised of 4 international airports: Ministro Pistorini International Airport in Ezeiza, San Fernando International Airport, El Palomar Airport and Aeroparque Jorge Newbery. So far, Ezeiza Customs has been the only Customs office through which COVID-19 vaccine imports have been processed, due to its importance in terms of air transport management. Since the beginning of the pandemic, the Ezeiza Customs has been working in a synchronized and proactive manner with governmental agencies, the National Health Authority (Ministry of Health) and with the Sanitary Inspection and Registration Authority (ANMAT), regarding the import authorization prior to the arrival of goods, medicines and vaccines against COVID-19, through a fluid, dynamic and direct communication channel, in order to minimize verification times and Customs clearance.
**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.

**Belgian Customs Administration**

Belgian Customs has procedures in place with the Federal Agency for Medicines and Health Products. A taskforce is installed to monitor closely and act accordingly on indicated risks and problems. Furthermore, there is regular contact with the private sector through the private sector consultative body that is called the National Forum.

**The National Customs of Bolivia**

The National Customs of Bolivia is facilitating the entry of medicines, medical supplies and vaccines, in coordination with government agencies such as the National Drug Agency (AGEMED) and the Ministry of Health, with adequate facilities and Customs personnel who are prepared for the Customs clearance of said merchandise.
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.

Customs Administration of Guatemala

The Ministry of Health and the Superintendency of Tax Administration (Guatemalan Customs Administration) hold working meetings that have allowed coordinated inter-institutional work, with excellent results.

https://lahora.gt/mspaysat-preven-disminucion-en-tiempo-de-ingreso-de-vacunas-COVID-19/

India Customs

The national authorities responsible for the checking and clearing the COVID-19 vaccines shipments for exportation and importation are the Central Board of Indirect Taxes and Customs (CBIC) and the Central Drugs Standard Control Organisation (CDSCO). Both authorities are part of the Government of India and work hand-in-hand for safe and secure handling of COVID-19 vaccines and medicines. The Indian Customs Administration has established a Single Window which enables electronic communication between Customs and other Partner Government Agencies like the CDSCO.

At the national level, Joint Secretary (Customs) has been nominated as nodal officer for expeditious clearance of COVID-19 related imports. At the local level, nodal officers at the ports are nominated to co-ordinate the Customs clearance and their contact details have been published on the website of the Indian Customs Administration. A dedicated Helpdesk comprising of a toll-free helpline and an email address has been set up.
Directorate General of Customs and Excise of the Republic of Indonesia

Indonesia Customs, Indonesia National Single Window Agency, National Agency on Drugs and Food Control, and Ministry of Health have initiated and implemented Standard Operating Procedures (SOPs) on Procedures for Vaccine Imports for COVID-19 Counter-Measures Purposes. These newly implemented SOPs and regulations have been disseminated in an appropriate manner towards field Customs officer through internal focus discussions as well as field coordination.

The inter-agency cooperation enhances the simplification of import permit services and the implementation of risk management during the clearance process for vaccines. The simplification is provided in the form of Single Submission in an integrated import permit application through the application system provided by the Indonesia National Single Window Agency. However, document examination and physical inspection, as well as the clearance process, are undertaken only by the Indonesia Customs Agency.

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.

Customs Administration of Peru

Once the Peruvian State was aware of the procurement of vaccines against COVID-19, the Customs Administration led a technical team that involved all public and private actors that have some type of participation in the process of the importation of vaccines, including the carrier, supplier, importer, health authorities, airport terminal operator, etc., which also allowed us to receive some concerns from the first source and enabled a series of means allowing the process to be fluent.

Saudi Customs

There is a prior arrangement and coordination among the responsible government authorities (General Customs Authority and the Food and Drug Authority) and the relevant stakeholders (shipping agent, Customs broker, importer) with regard to the release of COVID-19 shipments. There are working groups on WhatsApp to coordinate and fulfill all the clearance requirements before the arrival of the shipments.
Singapore Customs

Singapore has set up a joint taskforce, comprising border agencies, relevant regulatory bodies and private stakeholders to facilitate the import and distribution of COVID-19 vaccines.

Singapore’s border agencies and the health authority work closely to facilitate the import and clearance of the COVID-19 vaccines. The shipments are processed pre-arrival in Singapore through our National Single Window, which connects all the relevant competent authorities.

South African Revenue Service (SARS)

SARS forms part of the National Joint Operational and Intelligence Structure (NatJOINTS) which is amongst other, coordinating government’s daily response to COVID-19. The committee continuously monitors the movement of vaccines and the collaboration with relevant stakeholders to develop and execute needed plans intended to facilitate safe, secure, and efficient vaccine delivery.

A task team comprising various stakeholders was set up to deal with all issues pertaining to the importation of the first batch. Details of the shipment were kept confidential for security reasons. All stakeholders had to look at legal implications concerning their respective areas, i.e. dangerous goods that might be classifiable as such in aviation security were dealt with by South African Civil Aviation Authority which was part of the task team. All information was made available to supply chain stakeholders via various association representatives.

A task team developed Standard Operating Procedures to be followed in handling the COVID-19 vaccine.

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.
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).

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. In order to support the global efforts to scale up the manufacturing of COVID-19 vaccines, special attention and priority in Customs clearance should also be given to the raw materials and components used in the vaccine 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, vaccines, and vaccine manufacturing inputs and components 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, including vaccine manufacturing inputs and components.

The genuine COVID-19 vaccines are being 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 groups 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).

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.
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, vaccines and related supplies, inputs and equipment 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, vaccines and related supplies, inputs and equipment 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, vaccines and related supplies, inputs and equipment.
- 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 and related supplies, inputs and equipment.
- Apply digitalized export and import Customs procedures, and accept electronic Customs data and digital copies of documents.
- Provide for the separation of release from final determination 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, vaccines and related supplies, inputs and equipment.
- Make all relevant information publicly available in an easily accessible manner.
d. Members’ case studies

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

**Customs Administration of Argentina**

Since the beginning of the pandemic, Ezeiza Customs has considered necessary to apply the "priority criteria" of the import/export shipments of medicines, vaccines and supplies, considered critical and essential, above the rest of the goods.

Having identified health agencies, as well as the Customs brokers, who carry out the import/export procedures of this type of goods ("critical and essential"), Customs worked with advanced cargo information. It was also known by all the actors of the supply chain that this "priority criteria" was adopted by this Customs for this type of goods.

**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.
Belgian Customs Administration

The Belgian administration, in response to an Italian proposal for new TARIC-level codes for protective masks, proposed a number of new codes including codes for both COVID-19 vaccines and diagnostic materials/test kits. Aside from contributing to the discussion at TARIC-level, this resulted in the adoption of:

- CN-code 3002 20 10 00 – Vaccines against SARS-related coronaviruses (SARS-CoV species) (and its counterpart code 3002 90 00 – Other)
- TARIC-code 3002 13 00 10 – Diagnostic reagents of a kind used in the diagnosis of SARS-CoV virus species infections (and its counterpart 3002 13 00 90 – Other)
- TARIC-code 3002 14 00 10 – Diagnostic reagents of a kind used in the diagnosis of SARS-CoV virus species infections (and its counterpart 3002 14 00 90 – Other)
- TARIC-code 3002 15 00 10 – SARS-CoV virus species diagnostic reagents, whether or not put up in the form of kits (and its counterpart 3002 15 00 90 – Other)

Since there was a perceived need to differentiate, if necessary, between vaccines for COVID-19 in particular and possible later diseases caused by ‘SARS-related coronaviruses’, existing national codes were used until 31 December 2020 for this purpose:

- 3002 2000 00 – 1065: for Vaccines against COVID-19
- 3002 2000 00 – 1066: for other vaccines against SARS-related coronaviruses

This was communicated to Customs agents in the field by means of an internal service note.

The need to use the national additional codes for COVID-19 vaccines was communicated externally on the public website of the Belgian Customs and Excise Administration. Additionally, the communication was done at the “National Forum”, a platform for discussion between the private sector and the Belgian Customs and Excise Administration. These communications referred to the site “TARBEL”, a public site where all information regarding commodity codes (including the national additional codes), tariff- and non-tariff measures, and more can be consulted:

English version: https://eservices.minfin.fgov.be/extTariffBrowser/Browser?lang=EN&date=20210126

As the national codes were no longer necessary with the arrival of the new CN-level codes, these notifications were updated. French: https://finances.belgium.be/fr/douanes_accises/entreprises/corona-informations-et-mesures/importation/codes-nationaux

We have contacted all large concerned operators (mostly producers). Green lane in place for one supply chain actor (producer). Negotiations ongoing with two other companies. Others are aware they can contact our Marketing Department to negotiate facilitations. General principles about Customs rules are decided on European Union level. A European Commission’s Decision IAW EU Regulation provides Member States of the EU possibilities for relief from import of duties and VAT exemption on importation granted for goods (materials, medicines and goods as listed) needed to combat the effects of the COVID-19 outbreak. Uniform simplified operational procedures have been implemented in accordance with this Commission Decision.
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.

Customs Administration of the Dominican Republic

By means of a circular of 11 February 2021, the personnel of the Customs offices was instructed to expedite and treat with priority the vaccines against COVID-19, without charging tariffs, taxes and Customs service fees.

The European Union and its Member States

As from 1 January 2021, the EU introduced a specific code for “Vaccines against SARS-related coronaviruses (SARS-CoV species)” in its nomenclature in order to easily identify them and facilitate the movement of such goods. The classification code for the goods concerned is CN code 3002 20 10.

Customs Administration of Guatemala

The Guatemalan Customs Administration issued Guidance for the entry of vaccines, which has been made publicly available and can be consulted in the annex to the information submitted by Guatemala to the WCO Secretariat. The guidance document was also published in the Aduana Moderna Newsletter, along with communication notes coordinated with the Ministry of Health of Guatemala.

The import shipments of COVID-19 vaccines are being released within 22 minutes.

Guyana Revenue Authority

The regulatory agencies formed a national task force and as such, there is coordination of activities concerning the clearance of COVID-19 vaccines.
India Customs
The Customs clearance procedure is completed within half an hour on import of COVID-19 vaccines.

Directorate General of Customs and Excise of the Republic of Indonesia

Any relevant technical information concerning the clearance process of COVID-19 vaccines and all related-vaccine items, including the newly implemented single-entry tax and import duty exemption system for vaccine importation to Indonesia have been disseminated in an appropriate manner towards the relevant supply chain stakeholders through limited-access focus group dissemination. Meanwhile, the general information concerning clearance process, facilitation, and recent updates have been made publicly available in the Indonesia Customs official website, social media and electronic media, as well as related government agencies official website and the national media.

In anticipating time-consuming clearance process, the vaccines importation to Indonesia has been carried out by implementing Immediate-Release facility. The Immediate-Release facility enables the vaccines and vaccine-related items to be released by only submitting complementary document, accompanied with required import permits and guarantee or submission of the Minister of Finance (MoF) Decree for taxation and import duties exemption purposes.

The Import Declaration can be submitted later in within 3 (three) working days post goods-release, which further be used for tariff and Customs value assessment process.

For time efficiency, prior to the vaccines arrival period, Indonesia Customs, relevant government agencies and importers actively conduct coordination, consultations and confirmations in order to ensure the import formalities compliance. Thus unexpected constraints during the clearance process can be avoided.

The time required for the release of import COVID-19 vaccines shipments through the Immediate Release facility is approximately 2 hours (excluding pre-clearance and post-clearance) provided all required documents have been completed.

Administration of Customs and Indirect Taxes of Morocco

Close collaboration has been established between the Moroccan Customs Administration and those in charge at the Ministry of Health, which is responsible for the checking and clearance of COVID-19 vaccines consignments at importation. The health authorities inspect the vaccines received and duly inform Customs, which releases the goods immediately based on the accompanying documents (AWB). The health authorities undertake to regularize the import operations post-facto, by presenting the prescribed Customs declarations and paying the duties and taxes payable.
Customs Administration of Peru

The interaction with the different actors has made it possible to provide recommendations that have been materialized in the destination for importation of the vaccines under the modality of advance processing, a situation that allowed us to have information before the arrival of the goods, which facilitates its follow-up. Likewise, the clearance of vaccines has been monitored in order to provide not only speed, but also regulatory support for a correct destination, which facilitates and accelerates entry mechanisms.

The time required for the release of the COVID-19 vaccines shipments imported into Peru was approximately 15 minutes from the time of arrival of the plane.

Saudi Customs

The shipments of the COVID-19 vaccine have been given high priority by coordination with clearance authorities and other government entities to synchronize the clearance simultaneously, as they have been cleared immediately after the approval of the result of the Food and Drug Authority within 15 minutes.

South African Revenue Service (SARS)

As of 12 February 2021, tariff heading 3002.20.00.1 (Vaccines for human medicine) has been substituted with heading 3002.20.11.7 (Against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and its variants).

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.
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 Cooperation 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).

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.

The components of some vaccines may be biological products or genetically modified (micro) organisms and as such may fall under the dangerous goods category (UN 3245).
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.

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.
d. **Members’ case studies**

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

**Australian Border Force (ABF)**

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.

**Belgian Customs Administration**

The working method: "COVID-19: personal protective equipment, test materials, vaccines for influenza and COVID-19" was written and made available to the Customs officers concerned. It aims to clearly define the procedure for importing and exporting these goods and to centralize all information for control.

In general, Customs officers do not manipulate the goods in the verification procedure (i.e. handle dry ice). The declarant is asked to do the necessary manipulations under supervision of the Customs officer and in the premises that allow the goods to be verified.

**The National Customs of Bolivia**

The National Customs of Bolivia has trained the officials of the different Customs offices on current regulations and operational aspects that they must consider in the clearance for the importation of vaccines, diagnostic tests, medicines, medical devices, supplies, reagents and medical equipment. It has also issued the Instructions AN-GEGPC-I-006/2021 of 27 January 2021 for the importation of vaccines and others.

**India Customs**

The Central Board of Indirect Taxes and Customs (CBIC) has clarified the procedure for temporary import of reusable temperature-controlled containers vide Board Circular No. 51/2021 dated 20.11.2020.

The Indian Customs Administration has been conducting various online sessions and webinars through its academic wing to impart information about COVID-19 related items.
**Directorate General of Customs and Excise of the Republic of Indonesia**

Customs inspection officers have been equipped with general goods inspection skills including inspection skills towards goods with certain characteristics and/or goods with special handling needs (i.e. light, time-temperature sensitive items). The training has been provided in cooperation with Indonesia Customs Training Center and Financial Education and Training Agency of the Ministry of Finance of the Republic of Indonesia.

**Customs and Monopolies Agency of Italy**

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 (https://www.adm.gov.it/portale/emergenza-covid-19) 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.

**Germany – Central Customs Authority**

Customs officers are made aware that, if the vaccines have to be handled, handling is carried out only after consultation with the declarant or his/her representative. This ensures that the vaccines are handled with due care and that the vaccines are not damaged or rendered unusable during a control.

**Customs Administration of Guatemala**

A sensitization and awareness-raising process has been carried out with the personnel of the Guatemalan Customs Administration, especially with the field personnel who work in the Guatemalan Airport Customs who are directly interacting with the entry of vaccines against COVID-19.

Training processes have been carried out with the support of the Ministry of Health, the airport Customs warehouse and the private sector, which has allowed for good results in the importation of vaccines.

**Customs Administration of Peru**

On the occasion of the several working meetings held before the arrival of the vaccines with the different actors, it was possible to collect information related to the way in which they are being transported, which has facilitated feedback to the field officials with the details for a non-intrusive action. This has also allowed the Customs administration to better manage and facilitate questions related to the temporary entry of Envirotainers or the entry authorization of data loggers, situations that are relevant for the entry of vaccines.
Singapore Customs

Singapore’s border agencies receive guidance from the health authority on their control regime for the COVID-19 vaccines, which enables the identification of COVID-19 vaccines shipments based on product code, product description and the product interim authorisation reference number declared in the permit declarations. Singapore’s border agencies also receive guidance from the health authorities on the properties of the COVID-19 vaccines, and officers are trained on the appropriate steps to maintain the integrity of the vaccines during the Customs clearance process.

United States Customs and Border Protection (US CBP)

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.
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).

a. Explanations with regard to the measures

As indicated earlier, the genuine COVID-19 vaccines are being 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 launched a dedicated IPR CENComm group for the exchange of enforcement sensitive information. Recently the tool was improved with a pre-arrival information template for legitimate shipments of COVID-19 vaccines, a mobile shortcut and a rightholders’ corner. Traditionally, CENComm has been used primarily to exchange information on seizures of counterfeit and other illicit products, but this new template brings a different and innovative dimension to the use of the CENComm platform. The template is to be used initially by COVID-19 vaccine exporting Members, and any transit Members, to enter information regarding any planned vaccine shipments. Member administrations in the destination countries will then have prior knowledge of the shipments’ arrival based on the information entered in the said template. This will allow for quicker risk management, which in turn will facilitate even faster Customs clearance.

The Secretariat also organized a series of webinars with COVID-19 vaccines manufacturers, issued Counterfeit COVID-19 Vaccines open source alerts, and launched the STOP II enforcement operation with 144 WCO Members administrations, International Organizations (WHO, Interpol, OLAF, Europol, UNODC) and the private sector.

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 JS to the RKC, the Guidelines to Chapter 6 of the RKC General Annex, the Guidelines to RKC SA JS, the SAFE Framework of Standards, the Risk Management Compendium and specifically the part thereof dedicated to Customs risk management during a pandemic, which was approved by the 41st Session of the EC, the Guidelines for the procurement and deployment of scanning/Nil equipment, and the IPR CENComm tool.
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.
- 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, sub-standard 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.

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**d. Members’ case studies**

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

**Customs Administration of Argentina**

Regarding imports inspections/verification, and being aware that Ezeiza Customs is specialized for this type of goods, among others, the staff has long experience and is used to verifying them, taking special care in the cases of sensitive goods, as well as considerations such as "cold chain", the handling of dry ice, and the aptitude for the use of X-ray systems (scanners) depending on their characteristics. If necessary, due to the storage conditions in extreme cold temperatures (more than -70°C), as well as their packaging in special "containers", the verification procedures are coordinated to be carried out at the premises of the Importer or Exporter, facilitating the release processes.

**Australian Border Force (ABF)**

The ABF undertakes a risk assessment process through the Joint Planning Group (JPG), which also oversees ongoing risk mitigation.
Belgian Customs Administration

There already is a green lane in place for a large producer of COVID-19 vaccines (probably more to come). We apply a zero selection procedure, based on the combination of trusted VAT numbers and goods codes for COVID-19 vaccines mentioned in declarations. In order to make sure there is no misuse of our green lane (mostly in the field of identity theft, so the trusted VAT numbers are not used by another party) we have set up a real-time datamining procedure which performs checks on certain parameters (like weight) to see whether the shipment fits into the regular flows of the trusted trader. In case of doubt, initiate documentary control.

In the unlikely event a verification is deemed necessary within our green lane system, it will be a documentary control.

As the Central Coordinating Unit for Mutual Assistance in Customs Matters we handle all requests from the European Anti-fraud Office (OLAF), EU Member States and third countries, including requests related to pharmaceutical products/vaccines and personal protective equipment (PPE).

Through our long-standing participation in the multidisciplinary Pharma and Food Crime Platform (PFCP) we exchange information and collaborate with other competent authorities in Belgium, most notably with the Federal Judicial Police/FUPHEC (Federal Unit Public Health and Environmental Crime) and the Federal Agency for Medicines and Health Products.

We were responsible for coordinating Operation STOP (I) in Belgium.

Together with FUPHEC we participated in Europol Operation SHIELD (spring/summer 2020), targeting falsified and misused medicines in general and COVID-19 related crime in particular. Through Europol SIENA, we exchange information with the EU law enforcement community. We participate in Operation STOP II in order to protect the public against counterfeit/illicit medicines and other medical supplies and equipment linked to COVID-19. This Operation will also take into account vaccines being circulated in connection with the COVID-19 pandemic in order to protect people against fake vaccines. Our services will conduct risk based controls on all borders with third countries with an emphasis on air and sea cargo.

The European Union and its Member States

The EU has issued guidelines on the treatment of COVID-19 goods setting up the common risk criteria and standards agreed to cover the crisis. An addendum specifically covering vaccines was provided in January 2021 in order to allow for the facilitation of movements of legitimate consignments whilst addressing the risk of unsafe and non-compliant products. Member States also share risk information on a daily basis in the Customs risk management system to enable a common treatment of risks at any point of the EU border.

The European Commission distributed a note via the Prohibitions and Restrictions Customs Control Strategy (PARCS) meeting expert group, the Customs expert group controls and risk management and the members of the expert group on IPR. (NB: This note includes some information relating to Customs risk management and is only destined for EU Member States and is not publically available due to its sensitivity).
**India Customs**

The Indian Customs Administration has deployed a Risk Management System (RMS), which is an automated system to apply principles of risk-based selectivity for carrying out inspection and testing by the concerned government agencies such as the Central Drugs Standard Control Organisation (CDSCO). The risk criteria of CDSCO are integrated with India Customs RMS.

**South African Revenue Service (SARS)**

With regard to the COVID-19 vaccines distribution efforts, SARS seeks, through robust risk management mechanisms, to facilitate the delivery of original vaccines to the end user, whilst minimising the risk of distribution of unsafe and counterfeited medical products.
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).

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.

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.

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.
d. Members’ case studies

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

**Customs Administration of Argentina**

The importation of COVID 19 vaccines is subject to tariff exemptions.

**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).

**State Customs Committee (SCC) of the Republic of Azerbaijan**

The import of COVID-19 vaccines and their syringes into Azerbaijan is allowed free of duties and taxes for a period of 2 years staring from 1 January 2021 in accordance with the Decision of the Cabinet of Ministers of the Republic of Azerbaijan and relevant changes to the Tax Code of the Republic of Azerbaijan.

**National Customs Service of Costa Rica**

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

**The European Union and its Member States**

The Council Directive (EU) 2020/2020, adopted on 7 December 2020 allows Member States to apply a reduced VAT rate to the supply of COVID 19 in vitro diagnostic medical devices (and services closely linked thereto) or to grant an exemption with deductibility of VAT paid at the preceding stage (zero rate) in respect of the supply of COVID 19 vaccines and in vitro diagnostic medical devices (and services closely linked thereto). This measure is still very limited in scope of application and also of temporary nature.
India Customs
The Government of India has exempted Basic Customs Duty and Health Cess for import of COVID-19 vaccines for a period of 3 months.

Directorate General of Customs and Excise of the Republic of Indonesia
The Indonesian government through the Directorate General of Customs and Excise has provided taxation and import duty exemption facilities for the importation of Covid-19 vaccines, vaccine raw materials, and equipment needed for vaccine production and handling.

Customs Administration of Spain
Spain has issued “Real Decreto-ley 35/2020, de 22 diciembre, de medidas urgentes de apoyo al sector turístico, la hostelería y el comercio y en materia tributaria” which establishes a 0% VAT rate to the imports of COVID-19 vaccines and to the transportation, lodging and distribution services related to these imports. The measure will be in place until 31 December 2022. [https://www.boe.es/buscar/act.php?id=BOE-A-2020-16823](https://www.boe.es/buscar/act.php?id=BOE-A-2020-16823)

Saudi Customs
All COVID-19 vaccines are exempt from Customs duties and taxes.

Singapore Customs
COVID-19 vaccines imported by Singapore’s Health Ministry for official use are exempted from Goods and Services Tax (GST).

South African Revenue Service (SARS)
COVID-19 vaccines fall in the category of “goods imported for the relief of distress of persons in cases of famine or national disaster...” this automatically qualifies it for the waiver of taxes especially that COVID-19 has been declared national disaster.
- As of 12 February 2021, tariff heading 3002.20.00.1 (Vaccines for human medicine) has been substituted with heading 3002.20.11.7 (Against Severe Acute Respiratory Syndrome Coronavirus 2 (SARSCoV-2) and its variants). The current provisions provide for the importation of vaccines at a ‘Free’ rate of duty.
- There is a value-added tax (VAT) exemption on the importation of vaccines classifiable under tariff heading 3002.20.11.7, for use in the vaccination of persons against the Severe Acute Respiratory Syndrome Coronavirus 2 or SARS-CoV-2 for the treatment of COVID-19.
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 environmentally sound management (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.

Other relevant information

Annex I to the Secretariat Note contains Operational Guidelines for the facilitation of situationally critical medicines and vaccines sponsored by the Australian Border Force and the Nigeria Customs Service. The Operational Guidelines draw on Australia’s operational experiences in facilitating vaccine movements and recommend specific actions from pre-border clearance, through to post-border compliance activities. The document also considers how to deal with illicit and counterfeit vaccines. In its 231st/232nd Sessions, the PTC supported the inclusion of the Operational Guidelines in the 2nd edition of the Secretariat Note on the Role of Customs in facilitating and securing the cross-border movement of situationally critical medicines and vaccines. The Operational Guidelines are annexed without changes.

Annex II 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 I

Operational Guidelines for the Facilitation of Situationally Critical Medicines and Vaccines

COVID-19 Vaccine Facilitation

In December 2020, the WCO Council took steps to address the fragmented international responses to the disruptions to trade and travel caused by COVID-19. This document can assist national administrations to operationalise the WCO Secretariat Note on the Role of Customs in Facilitating and Securing the Cross-Border Movement of Situationally Critical Medicines and Vaccines to facilitate the safe and secure movement of vaccines.
Coordinated Border Management

Early stages

Establish a Coordination Group

Cross-border movement of medicines and vaccines may be situationally critical during large-scale public health events – such as the COVID-19 pandemic – or due to natural disasters. For customs agencies, the ultimate goal should be the rapid facilitation of legitimate shipments while ensuring proper controls are in place to protect the community from illicit or substandard shipments. Early establishment of a coordination group is critical to ensuring a coordinated effort across Government agencies to develop and implement specific border measures.

There are multiple possible ways to achieve this coordination. For example, there may be a central disaster management body responsible for establishing such mechanisms, or it may be up to customs and other agencies to initiate such a mechanism.

Within these frameworks, it is likely that different Government agencies will have the national competence for border management, approvals of therapeutic goods (medicines and vaccines), and distribution of medicines and vaccines. The initial stages of the work of the coordination group should identify and integrate border agencies accountable for the effective importation of essential COVID-19 goods, while ensuring border protection controls remain adequate to detect illicit versions of the vaccine. It is essential to identify all stakeholder agencies and to share information and requirements.

Strategic communication

Ensuring information channels are open between agencies is critical to identify and resolve challenges through transparent data sharing and consolidating known information. Customs administrations must frame their communications around the objectives they are trying to achieve, and effectively plan and communicate to targeted audiences during this time of heightened public concern. A Communication Plan that includes preparing pre-approved messages for specific circumstances that may arise will help to ensure effective information management. The WCO Guidance on How to Communicate During a Crisis provides vital steps for Customs administrations to ensure that those in charge of communicating messages internally, to stakeholders and to the public rely on accurate information.

Mapping importation pathways

Customs administrations should engage with their key stakeholders to define an end-to-end border clearance process for vaccines. These pathways would identify known origin and destination ports, suppliers and carriers. Each vaccine variant may cross borders in a variety of ways, from partly completed compounds through to ready to administer products. Working through the complexities of facilitating legitimate vaccines over the border through this process will help to ensure border controls are appropriate to identify and intercept illegitimate or illicit medicines.

Early identification of importation pathways will enable border facilitation to focus on legitimate vaccines. It will also assist with analysis and identification of risk indicators to inform targeting of suspected illegitimate or illicit goods. Customs administrations should seek to create suitable operational solutions for all variants of vaccines and their associated ingredients across the border continuum. The coordination group should meet regularly and work through requirements and challenges, including specific vaccine handling requirements.

Training and documentation

Developing training and documentation on expected pathways and handling requirements for the use of frontline officers at points of entry assists to facilitate legitimate shipments, particularly when the medicines or vaccines have unusual handling requirements e.g. cold storage or containers eligible for temporary importation etc.

Customs administrations should develop process maps for identified importation pathways for the use of frontline officers in ports expected to receive vaccine shipments. Process maps can enhance frontline officer awareness and remove ambiguity in border clearances, reducing risk of unnecessary delays for critical supplies.

Pharmaceutical companies and other supply chain actors may make guidance material available to customs administrations, health agencies or through the WCO, on identification and handling
requirements for specific vaccines and medicines. Customs administrations should make this guidance material available to operational areas directly or with additional guidance relevant to their national legislation or other requirements if required.

Training frontline officers on the handling of vaccines requiring cold storage can protect officers from hazardous packing and packaging materials (e.g. dry ice) while facilitating legitimate shipments. In addition, Customs administrations should develop guidance material on the identification, intervention and seizure of therapeutic goods suspected to be illegitimate or illicit. Customs administrations may wish to make use of material provided by the legitimate manufacturers of these products for this purpose.

**Process testing**

Where circumstances allow, Customs authorities should lead collaboration of whole-of-government and industry stakeholders through practice exercises involving dummy shipments from a vaccine manufacturer before real critical shipments begin to arrive. This will enable stakeholders to test and refine existing facilitation processes and procedures. Post-exercise debriefs enable analysis of factors that expedite or obstruct the cross-border movement of essential goods without unnecessary interruption or delay.

**Pre-shipment**

Before critical shipments depart their country of origin, it is vital to remain in contact with key industry stakeholders, including vaccine manufacturers. This allows customs administrations to respond to rapidly evolving requirements during public health events or natural disasters.

Each coordination group agency should establish a contact point. As unexpected delays or changes to shipments can occur at any time, the contact point should be staffed 24-hours, 7-days a week if possible. These may become critical in enabling border and health agencies to resolve any last-minute issues with a shipment of vaccines.

**Ensuring expedited border clearance**

Close engagement between Customs organisations and industry will enable high-level coordination on delivery schedules, and situational awareness of vaccine movements by stakeholders. Customs administrations should clarify pre-shipping requirements across their relevant stakeholders and consolidate known information on Government agencies’ regulatory approvals required for importing a biological vaccine. Given the limited number of approved vaccines, Customs administrations may wish to work directly with importers. Often, a Member’s Health agency will be the domestic importer or sponsor of vaccine shipments.

Customs administrations should also prioritise engagement with Health agencies to receive advance notice of delivery schedules ahead of importation. In addition, Customs administrations should liaise with identified logistics providers to receive real-time shipping information and understand any deviations in supply chain pathways. Importers and logistics providers should also be able to advise of anti-tamper measures deployed for each kind of COVID-19 vaccine.

As shipments begin to arrive, Customs administrations should check their process maps (see Training and Documentation above) and make any changes needed to ensure the documentation aligns with actual practice. These should include specific requirements around each vaccine manufacturer’s intended importation pathway, including contracted logistics providers, freight forwarders, Customs brokers, taxation arrangements and relevant health agency contacts. This is important, as some vaccines require cold storage (involving dry ice or other dangerous chemicals) and Customs officers should handle them with care. Customs officers should also note that some vaccines may be damaged if they are scanned or the packaging is opened.
### Pre-shipment Checklist

- Establish a coordination group involving border and health agencies

Through the coordination group, Customs administrations should confirm:

- Pharmaceutical/biological approvals – Manufacturer and Health agency sponsor
- Biosecurity approvals – Agriculture agency
- Taxation and customs duty requirements – Customs administration, Tax agency
- Transport Security requirements – Customs administration and/or transport security agency
- Identity of Customs Broker handling shipment – Manufacturer or Health agency sponsor
- Shipment tracking, possibly including GPS and anti-tamper measures – Health agency, Manufacturer, Consignor, Customs Broker and/or Logistics Provider

### Illicit Vaccines

Illicit COVID-19 vaccines include products claiming to be vaccines that are imported, manufactured, exported or supplied in contravention to Customs administration’s policy and legislation. For intervention purposes, illicit vaccines are assumed to be compromised. Illicit vaccines fall into five categories:

- diverted – genuine products that are stolen or misdirected from a lawful supply chain;
- fake – goods claiming to be vaccines, which are not available from or through any lawful supply chain;
- counterfeited – goods imitating genuine products;
- unapproved – goods claiming to be vaccines that have not been approved;
- otherwise approved – genuine vaccines that are not permitted by a Member’s health authority to be imported, exported, manufactured or supplied but have been approved in other jurisdictions. For example, a WCO Member’s Government may only have approved two vaccines for use within its jurisdiction. Its Customs administration needs to ascertain with its Health agency how to treat shipments of these kinds of vaccine.

### Border Protection Measures

Customs administrations are required to identify and enable proactive pre-border identification and clearance of legitimate vaccines while implementing specific targeting parameters to identify and intercept illegitimate COVID-19 vaccines. Officers involved should focus on coordinated activities to inspect imported cargo across all modes of transport suspected of containing unapproved vaccines. Engagement with medicine and vaccine suppliers, supply chain operators and Customs brokers involved in the importation pathway will reduce the likelihood of legitimate shipments being selected for screening, reducing the risk of unintended delays or potential spoilage of legitimate shipments.

Security considerations are important for vaccines – there may be organised criminal groups seeking to gain access to vaccines before shipment, at the border, and post-border. The WCO recommends working with trusted, vetted logistics providers and customs brokers.
Intervention

Customs administrations should aim to identify and mitigate threats by supply chain actors engaged in the importation of illicit vaccines. Before and at the border, Customs officers should assess, triage and refer threats and supply chain actors of concern. Engagement with medicine and vaccine suppliers, supply chain operators and Customs brokers involved in the importation pathway will assist with the development of targeting profiles to identify suspected illicit shipments. Customs administrations should aim to leverage their domestic and international intelligence sources to combat shipments of illicit vaccines.

WCO Secretariat guidance under Operation STOP assisted members to utilise the WCO’s checklist of COVID-19-related goods and a useful indicator of illicit trafficking associated with the COVID-19 pandemic.

Customs administrations were able to prevent national markets being infiltrated by date-expired, illegal and counterfeit medicines (in addition to related medical and personal protective equipment such as ineffective sanitizers, COVID-19 test kits, masks, goggles, thermometers and medical gowns not compliant with the requisite healthcare standards or not authorized by the competent authorities). Analysis of the data obtained during the operation provides information on the main routes used and modi operandi involved, as well as highlighting the most commonly trafficked products linked to the COVID-19 pandemic. The results of the operation enabled WCO Members to enhance the management of operational risks faced by Customs and ensure more effective targeting of illegal goods at global, regional and national levels.

Operation STOP II is a follow-up to the findings of Operation STOP. Operation STOP II aims to protect the public against counterfeit/illicit medicines and other medical supplies and equipment linked to COVID-19. This Operation will also take into account vaccines being circulated in connection with the COVID-19 pandemic in order to protect Members’ populations against fake vaccines. Interpol Operation VIGILANT can also refer partner detections of illicit vaccines to Customs administrations for operational awareness.

Broad participation in Operation STOP II and any further follow up operations will bolster Customs administrations’ collective intelligence holdings while ensuring enhanced international operational cooperation between Customs administrations, law enforcement agencies, health authorities and the private sector.

At Border

WCO Members should ensure all border agencies have an up-to-date and consolidated view of known, approved and expected vaccine suppliers. Customs administrations should stay in contact with logistics providers to monitor the shipment as it arrives onshore, and stand ready to process it quickly through the vaccine manufacturer’s agreed logistics pathway. Doing so will provide visibility of incoming shipments and enable facilitation of goods in accordance with national procedures.

It is important for Member administrations to act quickly upon receipt of information regarding the imminent arrival of vaccines. The priority activities are ensuring frontline officers are aware of the circumstances of the vaccines’ arrival, and that the Customs administration can quickly confirm all permits, revenue and security requirements.

Collaborating with responsible agencies can ensure border barriers are identified prior to arrival and resolve any identified issues with responsible agencies. However, it may be necessary for the Customs administration to use the coordination group’s 24-hour hotline to contact other agencies if unexpected issues arise at the last minute.

Expedited Facilitation

Customs administrations must work co-operatively with common and accepted standards to maximize the security and facilitation of COVID-19 vaccines as cargo shipments and transport conveyances move along the nodes of the global trading system. The WCO SAFE Framework of Standards provides a consolidated platform to enhance vaccine facilitation. It will improve the ability of Customs to detect and deal with high-risk consignments and increase efficiencies in the administration of goods, thereby expediting the clearance and release of legitimate vaccines.

Some WCO Members are experimenting with providing facilitation for vaccines similar to what they provide for Authorized Economic Operators. Others are using ‘express’ lanes at their borders to ensure vaccine shipments get priority clearance.
Role of Customs in facilitating and securing the cross-border movement of situationally critical medicines and vaccines

Targeting illicit vaccines at the border

At the border, Customs administrations should implement profiles/targeting processes to identify and intercept unapproved or illicit vaccines imported through all transport streams. Profiles/targeting processes should be informed by the Mapping Importation Pathways process above. Identification of importation pathways will enable targeting of purported medicines or vaccines through illegitimate channels. For example, awareness that express carriers will exclusively handle COVID-19 vaccines allows Customs administrations to target illegitimate vaccine importations through International Mail gateways. Customs administration profiles/targeting processes should be crafted carefully and remain up-to-date to avoid delaying legitimate shipments on the approved vaccine lists. Customs administrations will be able to build targeting parameters as they receive information from intelligence partners and other sources.

Cooperation against illicit vaccines

Customs administrations will need to focus on enhanced cooperation with key stakeholders to ensure timely and efficient de-confliction, referral assessment and response to illegitimate vaccines.

Officers should undertake post-detection analysis in the event that cargo is identified as likely to be linked to illegitimate activity. Health agencies must work real-time with Customs administrations on detected suspicious goods to confirm whether or not the Health agency has issued any permit for the shipment. Customs administrations should be able to act quickly on a direction from the Health agency to conduct trade enforcement against a shipment.

Post-Border

Customs administrations should ensure the identified and cleared consignment transitions correctly to the identified domestic network, as intended by relevant health agencies.
Referring Illicit Vaccines

Enhanced targeting efforts by Customs administrations will assist in intervention through detections of illegitimate vaccines portrayed to be COVID-19 vaccines. Most Customs administrations have an established referral process with law enforcement agencies to assess jointly detections of illegitimate goods for any identified criminal aspects and, where appropriate, pursue investigative or prosecution options.

Seized shipments should be appropriately handled in accordance with national requirements (i.e. destroyed, provided to Health and/or other Law Enforcement agencies for sampling and analysis, etc.). Customs administrations should also aim to notify international counterparts of the nature of the detection through Operation STOP II/CENComm.

Continued cooperation with Health agencies will assist in identifying opportunities to improve community messaging and disrupt criminal activity.

Post-Border Checklist

Through the coordination group, Customs administrations should:

- □ Immediately alert the Health agency and/or its secure logistics provider that the Customs administration has completed border clearance processes
- □ Expedite cargo for transport from a Customs Controlled Area to the Health agency’s secure storage facility by a vetted logistics service provider
- □ Confirm cargo has left Customs Controlled Area
Annex II

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)

