

Rawinkhan Srinon; Duangpun Kritchanhai; Thananya Wasusri

Working Paper

International transport and logistics of vaccines across borders: The case of the Asia-Pacific region

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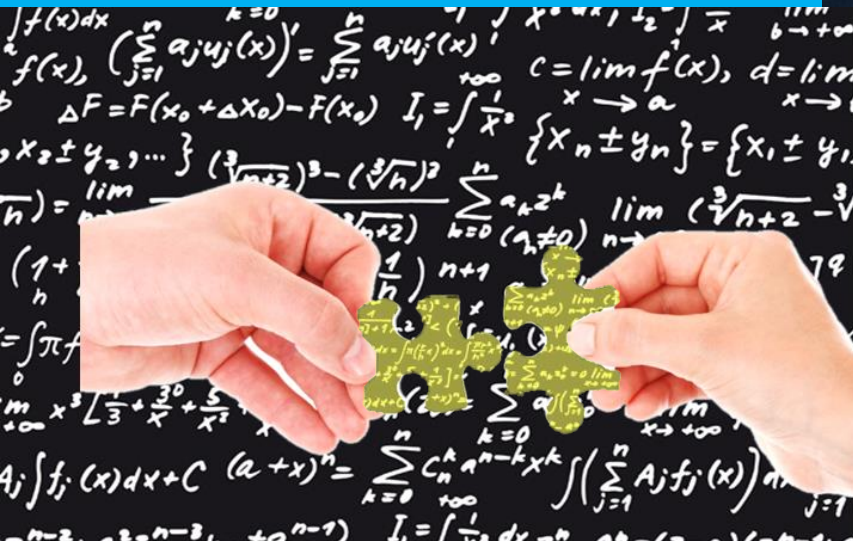
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Special Series on Trade and Health

International Transport and Logistics of Vaccines Across Borders: The Case of the Asia-Pacific Region



**Rawinkhan Srinon
Duangpun Kritchanhai
Thananya Wasusri**

ASIA-PACIFIC RESEARCH AND TRAINING NETWORK ON TRADE

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ASIA-PACIFIC RESEARCH AND TRAINING NETWORK ON TRADE

WORKING PAPER

International Transport and Logistics of Vaccines Across Borders: The Case of the Asia-Pacific Region

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Abstract

Vaccines against the coronavirus disease (COVID-19) have provided hope for containing the pandemic, but there are challenging obstacles to international transport and logistics of the new vaccines and vaccine inputs needed for manufacturing. This study identifies key barriers in the Asia-Pacific region to the timely and effective transport of vaccines from the countries where they are manufactured to the countries where they are needed.

The main hurdles for vaccines are import and export restrictions and limitations, and the lack of policy priority. Major bottlenecks include securing vaccine import approval by the national food and drug authority, having correct and efficient shipment routes (reliable direct flights and transport capacity), ensuring timeliness on customs clearance along with security control measures, assuring cold chain integrity along the supply chain and implementing transparency and visibility through tracking and tracing systems. It is recommended that Governments develop a national cold chain tracking and tracing system to ensure information sharing and monitoring. Furthermore, there is a lack of cold chain capacity for traditional, frozen and ultra-cold vaccines, in particular in low-income and lower-middle-income countries in the Pacific and Central Asia subregions.

To overcome obstacles and ease bottlenecks for import and export of vaccines and vaccine inputs, it is recommended that Governments in the region ensure good cooperation and coordination, including national, regional and international cooperation, among key industrial stakeholders in the public and private sectors. Such cooperation and coordination will help to smooth and ease the import and export process for both vaccines and vaccine inputs. Many countries in the region, such as Australia, India, Indonesia and Thailand, have reduced the cross-border processing time to less than three hours. Lastly, cold chain facilities and readiness are the key to the supply chain of vaccines. Where complying with different requirements and procedures for temperature management and control of different vaccines during transportation and cross-border processing is a challenge, it is recommended to conduct country-wide personnel training with an easy-to-understand procedure manual in local languages to build flexibility and capability.

Keywords: COVID-19, vaccines, logistics, supply chain, Asia-Pacific

JEL Codes: F10

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1. Introduction

The emergent situation of the coronavirus disease (COVID-19) pandemic caused many issues and challenges in international logistics and supply chain of pharmaceutical products and vaccines. As of 10 March 2022, more than 451.89 million people worldwide have been infected and more than 6.04 million people have died of COVID-19.⁴ At an early stage of the pandemic in 2020, many logistical challenges, including supply shortages, imbalanced demand and supply and obstacles to on-time delivery, affected the availability of medical supplies, such as personal protective equipment, surgical masks and alcohol sanitizer. The challenges were multiplied by abrupt demand surges and supply disruptions. The causes of disruptions ranged from manufacturers that halted production because of the outbreak or because of raw material shortages, to border closures. These concerns required both industry and the Government to act quickly to boost the supply and put measures in place to smoothen cross-border procedures. Additional challenges affect vaccines, for example, new vaccines must be approved by the national food and drug administration (FDA) and the integrity of the cold chain and quality of the vaccines must be assured while following lot release protocols, which entail continuous monitoring of product quality, through review and testing by FDA, for every vaccine batch imported into the country.

Since medication to ensure an immediate cure is not yet available, vaccines against COVID-19 have been developed in the hope of achieving herd immunity. In late 2020, many vaccines were produced and approved under emergency use authorization. Although there is demand for COVID-19 vaccines in every country, there are many obstacles and limitations that prevent vaccine development and production in some countries (OECD, 2021). The production of the COVID-19 vaccines or other vaccines of the Expanded Programme on Immunization (EPI) is complicated, requiring specialized equipment and inputs, storage facilities, highly skilled labour and other capacities. Thus, vaccines are generally produced in countries with those capacities and then exported to different parts of the globe. The latest available data from CEPII BACI database (2018) show that more countries imported vaccines and fewer countries exported them. Cross-border importing of vaccines and vaccine inputs into a country is often more complicated than exporting. The complex steps and requirements often cause bottlenecks which result in delays. Asia and the Pacific is an enormous region covering approximately 22 per cent of the global land area. The region is diverse and conditions vary depending on context. The United Nations Economic and Social Commission for Asia and the Pacific (ESCAP) and the four other United Nations regional commissions in collaboration with the United Nations Conference on Trade and Development (UNCTAD) is implementing a Development Account project on transport and trade connectivity in the age of pandemics. This project responds to a call to action to tackle the many social and economic dimensions of the COVID-19 crisis, as contained in the report of the Secretary-General of the United Nations on “Shared responsibility, global solidarity: Responding to

⁴ www.worldometers.info/coronavirus/.

the socio-economic impacts of COVID-19”. One of the outputs of the project is to develop regional cooperation on trade in times of crisis and pandemic through research, capacity-building and intergovernmental agreements, as appropriate.

In this context, ESCAP and the World Health Organization are implementing the research project “From Lab to Job: Improving Asia-Pacific’s Readiness to Produce and Deliver Vaccines”. The aim is to better understand the determinants of vaccine production and delivery in Asia with a focus on questions related to cross-border cooperation, trade and transportation. The findings of the project should help developing countries in the Asia-Pacific region to improve vaccine trade and transport connectivity, better prepare for the next pandemic and fight other communicable diseases.

1.1 COVID-19 vaccine cold chain supply chain

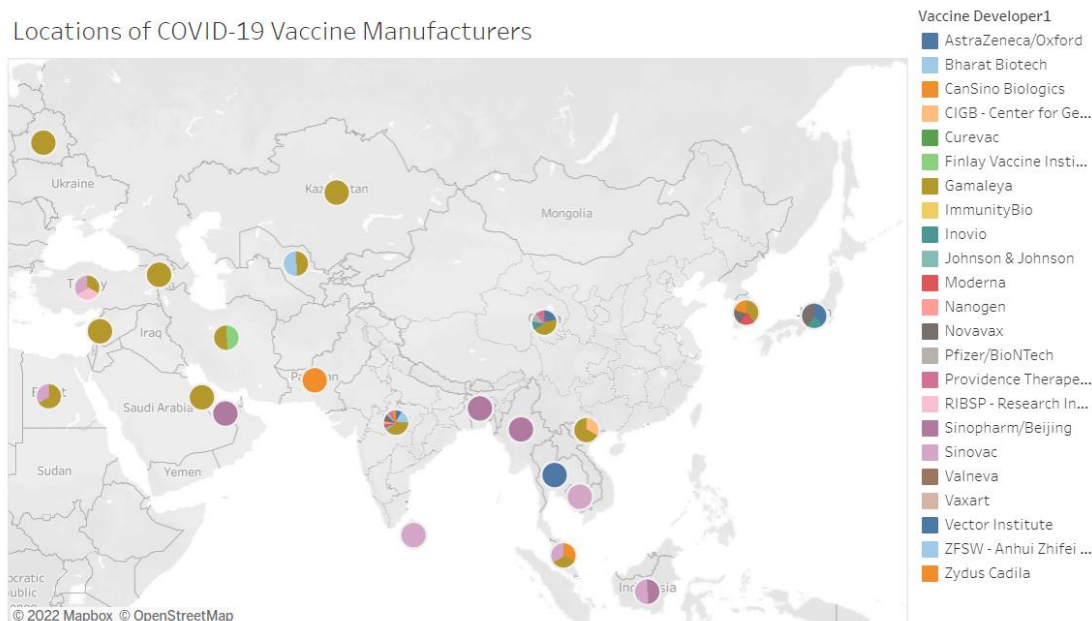
New vaccines typically take more than 10 years to develop and receive approval; however, COVID-19 vaccines were approved in a short period flowing a “pandemic paradigm” (WTO, 2020). Complete details of the development and delivery of COVID-19 vaccines worldwide can be seen in annex 1. In general, there are four key stages of the vaccine supply chain, starting from drug discovery process, mass production, distribution and administration, and reverse logistics. Yet, the timeline of developing COVID-19 vaccines was significantly shorter due to the pandemic and emergency use authorization. While vaccines manufacturers are located only in some countries, supplies of some vaccine inputs are also concentrated in only a few countries. In responding to the pandemic, developing a vaccine was not enough. As stated by Frank Apple, “Vaccines are in development, but their ability to end this pandemic depends on an effective supply chain that can connect diverse production locations to the public” (WTO, 2020). A large vaccination roll-out was challenging, particularly in the developing economies in Asia and the Pacific.

Critically, the vaccine supply chain includes different geographical locations at different stage. Vaccine development is concentrated mostly in the high-income countries, however vaccine production sites are spread in all over the world and in countries with different income levels. Table 1 shows manufacturing countries, income groups and region groups and figure 1 depicts locations of COVID-19 vaccine manufacturers in the Asia-Pacific region.

Table 1: List of countries manufacturing coronavirus disease vaccines, by Asia-Pacific subregion			
Region	Country	Income level	Number of manufacturing sites
Central Asia	Armenia	Upper middle income	1
	Kazakhstan	Upper middle income	1
	Russian Federation	Upper middle income	2
	Türkiye	Upper middle income	3
	Uzbekistan	Lower middle income	2
	China	Upper middle income	5

Table 1: List of countries manufacturing coronavirus disease vaccines, by Asia-Pacific subregion			
Region	Country	Income level	Number of manufacturing sites
East Asia	Japan	High income	3
	Republic of Korea	High income	4
Oceania	Australia	High income	1
South Asia	Bangladesh	Lower middle income	1
	India	Lower middle income	10
	Pakistan	Lower middle income	1
	Sri Lanka	Lower middle income	1
South-East Asia	Cambodia	Lower middle income	1
	Indonesia	Upper middle income	2
	Malaysia	Upper middle income	3
	Myanmar	Lower middle income	1
	Thailand	Upper middle income	1
	Viet Nam	Lower middle income	2

Figure 1: Locations of coronavirus disease vaccine manufacturers in the Asia-Pacific region



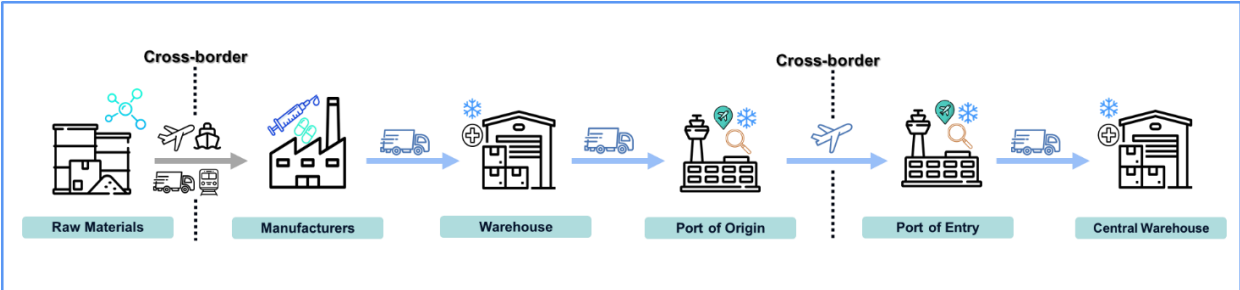
Vaccine developers have made manufacturing agreements with manufacturers around the world. The primary locations of these manufacturers, along with the vaccine developers can be seen in this map. Sources are publicly available pharmaceutical company and manufacturer press releases and media reports. Last updated February 14, 2022.

Source: www.knowledgeportal.org/covid19-vaccine-manufacturing.

Disclaimer: The boundaries and names shown, and the designations used on this map do not imply official endorsement or acceptance by the United Nations.

With a population of 9.3 million, Israel was one of the first countries to administer the COVID-19 vaccine along with China, the United States and the United Kingdom (Rosen, Waitzberg and Israeli, 2021). As of 10 March 2022, statistics and research on COVID-19 vaccination by *Our World in Data* indicated that at least one dose of a COVID-19 vaccine was received by approximately 63.4 per cent of the world population, while only approximately 13.7 per cent of the people in low-income countries received the first dose.⁵ Vaccine supply chain is critically significant, and there are strong trade interdependencies along the chain. Vaccines require safe and timely delivery, and these depend on supply chain efficiencies, governing its production and distribution. Figure 2 shows the international COVID-19 vaccine supply chain from importing vaccine inputs for manufacturing and then the cross-border transport of vaccines to destination countries for immunization campaigns.

Figure 2: International coronavirus disease vaccine supply chain



Since vaccines are volatile and valuable, international transport and logistics of vaccines and vaccine inputs pose several challenges, mainly those procedures related to regulation and customs clearance, while cold chain capacity and readiness for new vaccines raise even more concerns about ensuring vaccine quality and efficacy. Inputs needed for vaccine production are critical and some materials must be imported. Any delay of vaccine inputs leads to a delay in the final vaccine production and could cause supply shortages. For instance, Pfizer slashed its production targets in late 2020 due to unexpected lead time of the raw material supply chain.⁶ Similarly, Novavax Inc. dissolved its production target timelines due to shortages of vaccine inputs such as bags used to grow cells.⁷ The worst COVID-19 surge in India, which has the world’s biggest vaccine production capacity, led to domestic vaccines shortages and a large volume of exports were delayed as vaccine makers struggled to boost production.⁸ Inputs used in vaccine manufacturing was classified into 13 product groups using the six-digit Harmonized System (HS) codes under the Joint Indicative List of Critical COVID-19 Vaccine Inputs for Consultation.⁹ The List would potentially serve to reduce occurrences of one common

⁵ <https://ourworldindata.org/covid-vaccinations>
⁶ <https://pharmaphorum.com/news/pfizer-cut-vaccine-production-targets-because-of-raw-material-shortage-reports/>
⁷ www.reuters.com/business/healthcare-pharmaceuticals/novavax-says-supply-shortages-delaying-full-speed-production-its-covid-19-2021-04-13/
⁸ www.reuters.com/business/healthcare-pharmaceuticals/indias-new-covid-19-infections-hit-5-month-high-2021-03-26/
⁹ www.wto.org/english/tratop_e/covid19_e/vaccine_inputs_report_e.pdf.

mistake importers make in custom clearance process, and that is using incorrect HS codes.

Additionally, one of the key differences in the storage and transport of COVID-19 vaccines compared to other vaccines is temperature requirements. Most countries are familiar with traditional EPI cold chains that require a temperature range between 2°C and 8°C. However, several technologies were used to develop COVID-19 vaccines, and different temperature ranges are required for their storage and transportation (see annex 2). For example, viral vector vaccines produced by Janssen and AstraZeneca are to be kept in traditional cold chain range, while mRNA vaccines produced by Pfizer-BioNTech are to be kept at approximately -70°C and mRNA produced by Moderna are to be kept at approximately -20°C. Moreover, mRNA vaccines appear to be more effective, therefore, they are most sought after. However, most countries are not familiar with and do not have enough capacity for ultra-cold chain systems (-80°C to -70°C) and frozen cold chains (-20°C to -15°C). Increasing cold chain capacity for mass immunization poses more challenges for lower-income countries. Cold chain capacity deficits affect procurement, transportation and cross-border logistics efficiency. Suppliers may be reluctant to release vaccines for international shipment if a cold chain breach during cross-border transportation is likely.

1.2 Objectives, scope of work and expected results

The focus of this thematic paper is on the international transport and logistics of vaccines across borders in the Asia-Pacific region. Vaccines are often produced in a limited number of countries and must be shipped abroad. Most importantly, vaccines are sensitive to temperature and therefore require consistent cold chains and swift handling at the border is needed. The focus of this study is on the challenges for international shipment and handling of vaccines and vaccine inputs across borders in the Asia-Pacific region, including international transports and logistics, border clearance, cold chain storage and related matters. It covers the process and activities starting from the manufacturer warehouse or the original warehouse immediately after the vaccines have been produced and kept, mapping vaccine inputs and vaccine flows, transporting the vaccines to the port of origin and crossing the border, arriving at the port of destination, and delivering to the central/national warehouse (the first warehouse) of the destination country. This thematic paper includes proposals for solutions to smooth the activities and improve the processes that ensure timely and efficient international transport and logistics of vaccines and vaccine inputs across borders. It also includes a self-assessment guide for policymakers to identify the position and bottlenecks of their country in each area concerned.

1.3 Study methodology

This study used qualitative assessments. To assess situation of international transport and logistics of vaccines across borders in the Asia-Pacific region, the authors analysed the ecosystem of COVID-19 vaccine supply chains and then conducted a deep-dive analysis of the bottlenecks of transport and logistics of vaccines across borders. Four key axes of research were anticipated to answer the following assessments questions:

- (1) What are the key activities in transportation and cross-border logistics for vaccines?
- (2) What is the national capacity for handling the COVID-19 vaccine cold chain across borders?
- (3) What are the bottlenecks in terms of cold chain competencies in the Asia-Pacific region and are the recommendations to improve the integrity of the cold chain?
- (4) What do policymakers need to know to carry out a self-assessment of the position and bottlenecks of their country in each area concerned?

Data collection methods

Desk review

More than 41 relevant documents were reviewed to assess the current situation of the COVID-19 vaccine supply chain system and the international transport and logistics of vaccines across borders as well as the vaccine cold chain capacity in the region. The data and information from the desk review were analysed and synthesized. Results from this stage were used as a basis for the in-depth interviews, and key findings were gathered in a report.

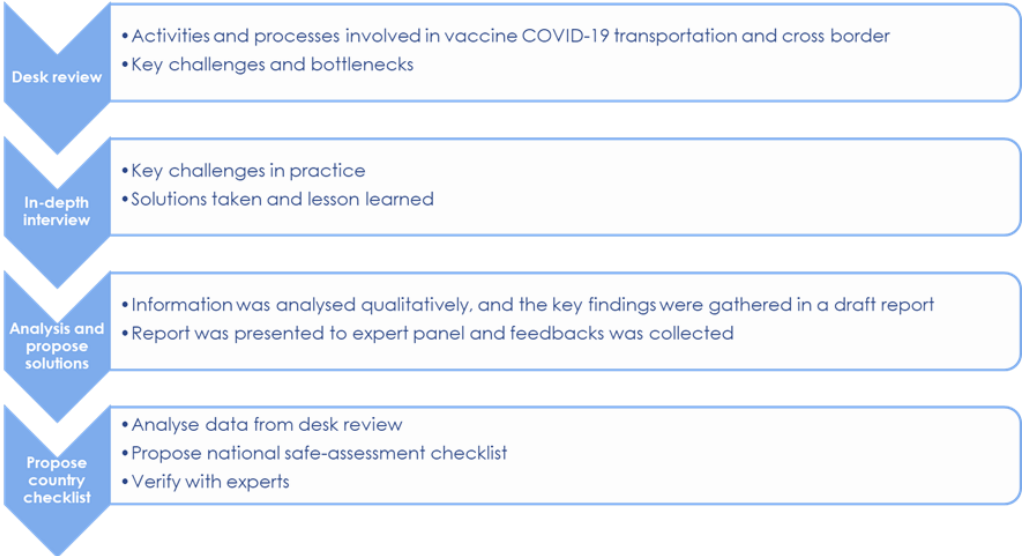
In-depth interviews

The authors interviewed key informants in the vaccine ecosystem, for example, importers (government organization), distributors, logistics service providers and FDA and customs officials. The questions in the interviews focused on the main procedures and documents to import vaccines, stakeholders in process, lead time, communication, key cross-border activities for vaccines and vaccine inputs, cold chain capacity integrity, security, bottlenecks and hurdles, and measures to solve and prevent future problems.

Data management and analysis

Variables from interviews were cross-checked with desk review results. Root-cause analysis was carried out to identify underlying causes of identified challenges and produce recommendations. As shown in figure 3, the analysis was an input to the national assessment checklist, which was vetted by experts.

Figure 3: Overall approach to the research

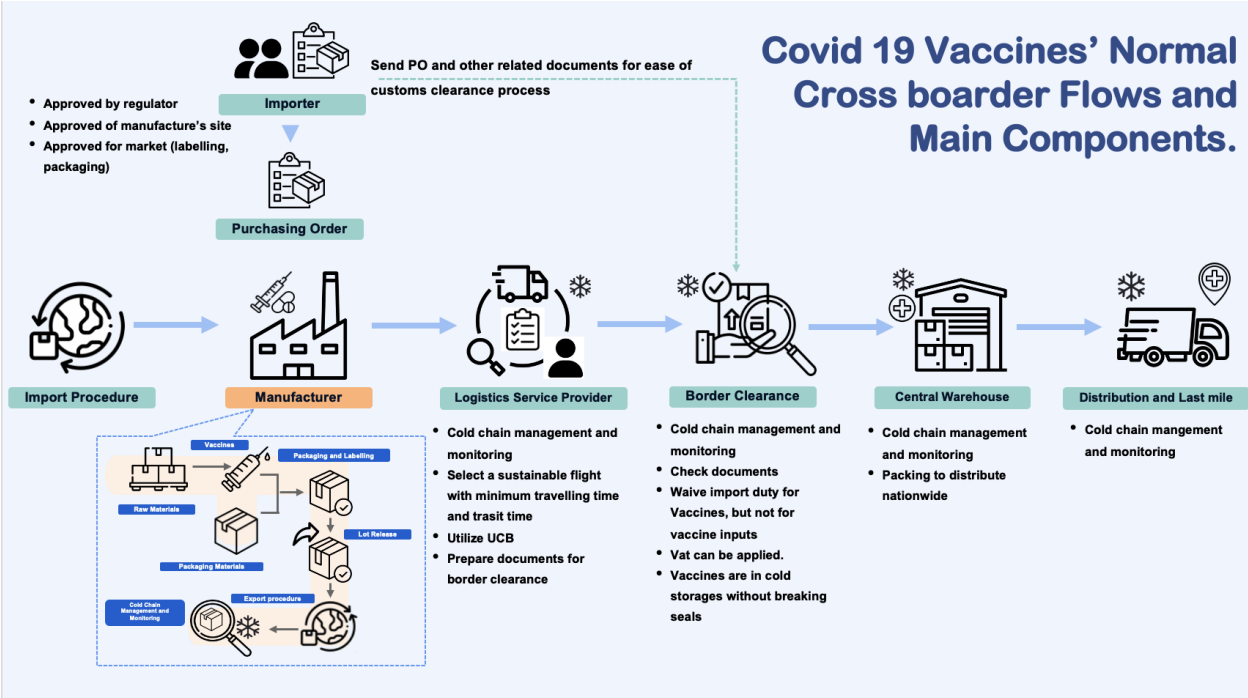


2. Comparison of existing vaccine transport and cross-border processes in the Asia-Pacific region

2.1 Procedures and issues in international transport and logistics of pharmaceutical products

The literature (DHL, 2020; ADB, 2021; WCO, 2021) and in-depth interviews revealed the normal flows of COVID-19 vaccines and vaccine inputs (figure 4).

Figure 4: Normal cross-border flows and main components of coronavirus disease vaccines



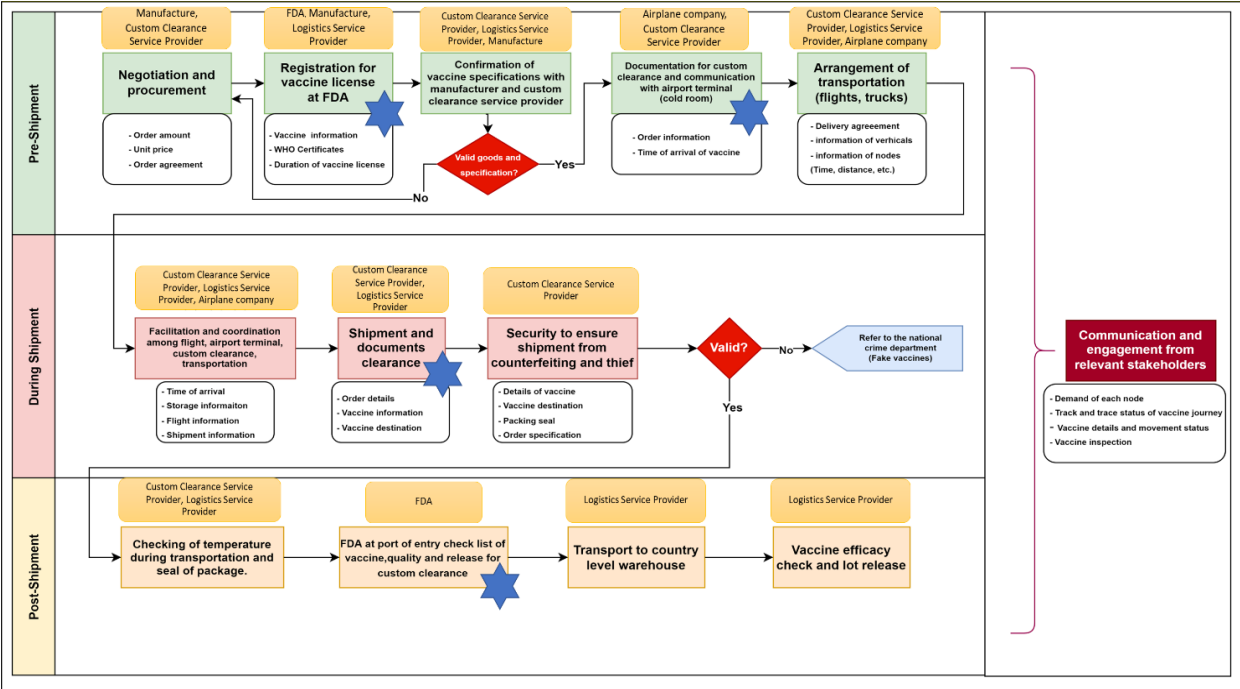
The cross-border flows of COVID-19 vaccines starts with demand in importing countries for vaccines that have been approved by regulators such as FDA. Vaccine names, manufacturing sites, lab tests, labelling and packaging must be approved. Once vaccines have been approved to import, purchasing orders will be sent to vaccine developers and vaccine manufacturers.

Vaccine manufacturers may import raw materials to produce vaccines along with packaging materials to pack and label vaccines according to the demands of importers. Importers test and review imports and lot releases occur when samples pass all standard tests. Exporting vaccines will normally be arranged by a capable third-party logistics service provider that can ensure compliance with temperature control requirements for vaccines, such as -70°C for Pfizer-BioNTech and -20°C for Moderna. The use of track and trace systems needs to be applied since vaccines were loaded into ultra-cold boxes throughout the journey of vaccines. Air transport capacity is limited as a result of airports closing and the lack of flights during the pandemic. About 8,000 cargo jumbo jets would be needed to deliver vaccines for 7.8 billion people worldwide, but only 400 flights were available in 2020 (ADB and ESCAP, 2021). This information has been confirmed by a key informant who noted that flight limitations were troublesome. The priorities are the frequency of flights along with flying time and transit time. The logistics service providers must complete all documents for customs clearance process. The customs clearance process for COVID-19 vaccines has been conducted without physical inspections to speed up the process and protect the vaccine temperature. For vaccine inputs, including ultra-cold storage facilities, the normal customs clearance process is applied with or without physical inspection. All imported vaccines will then be moved to a central warehouse by a logistics service provider with cold chain integrity, while vaccine inputs will be shipped to a vaccine manufacturer. Table 2 and figure 5 provide summaries of key activities involving international transport and logistics during pre-shipment, shipment and post-shipment.

Pre-shipment	Shipment	Post-shipment
<ul style="list-style-type: none"> • Negotiation and procurement • Apply to FDA for vaccine license • Confirmation of goods and product specifications • Documentation for custom clearance and communication with airport terminal (cold room) • Arrangement of transportation (flights, cold chain compliant trucks) • Communication and engagement all related stakeholders 	<ul style="list-style-type: none"> • Coordination and facilitation among flight, airport terminal, custom clearance, transportation • Shipment and documents for clearance • Security measure to ensure shipment from counterfeiting and theft 	<ul style="list-style-type: none"> • Checking of temperature during transportation and seal of the package. • FDA at port of entry check list of vaccine, quality and release for custom clearance • Vaccine efficacy check and testing for compliance with lot release* requirements • Transport to country level warehouse
Communication and engagement from all relevant stakeholders including government agencies and private sectors		

*Lot release is a mechanism that enables FDA to continuously monitor the quality of several biological products in real time through review and testing.

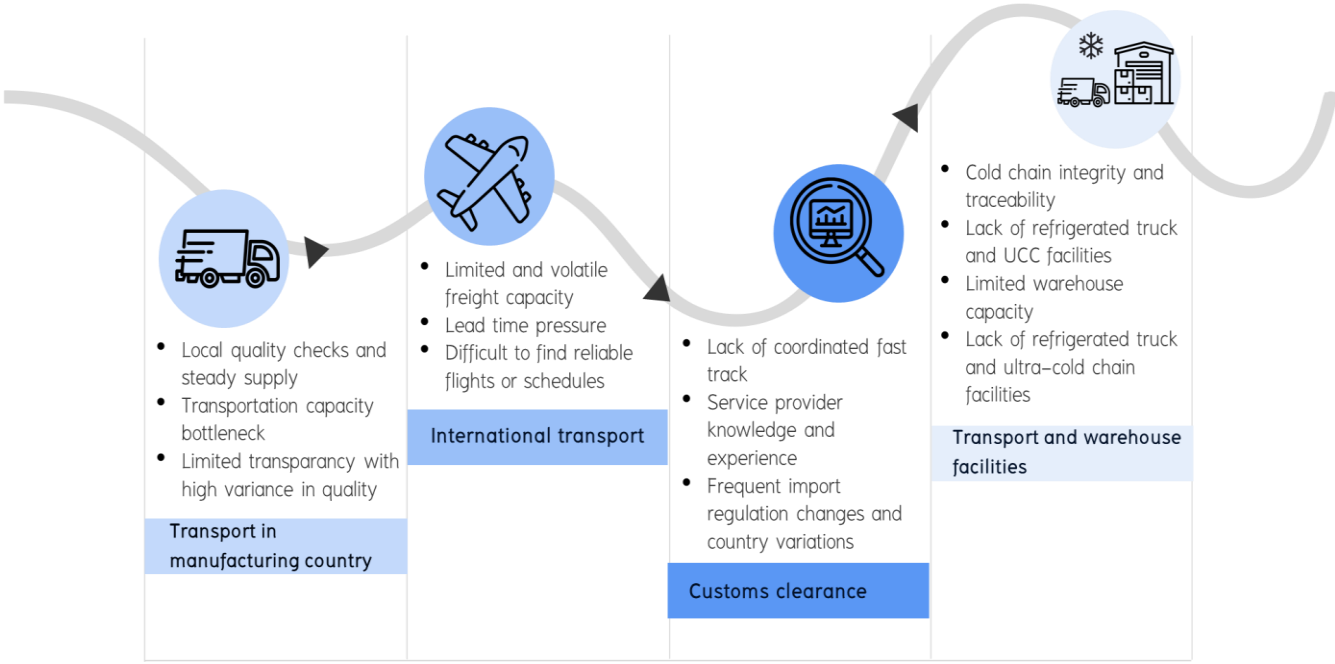
Figure 5: Activity flow regarding and stakeholder engagement



Approximately one year into the pandemic (late 2020), vaccines were developed and gradually rolled out. Vaccines have similar logistics-related pain points to medical supplies (figure 6), but international transport and logistics of vaccines pose even more sophisticated and critical challenges, particularly related to cold chain integrity and the readiness of equipment/facilities along the supply chain to maintain temperature control through the last mile distribution to the patients. Vaccine cold chains must be assured and maintained throughout the process. Cold chain facilities play a critical role in ensuring vaccine quality and patient safety. Maintaining the cold chain requires refrigerators, vaccine containers, data loggers, as well as skilled personnel. Some training may be required for staff using new ultra-cold chain technology. Normally, only a small workforce would be involved in the traditional EPI cold chain, but scale of mass vaccination to immunize people against COVID-19 mean that health-care supply chain staff nation-wide must have appropriate training for cold chain integrity management.

Most of the traditional (EPI) vaccines are stored at the temperature of 2°C to 8°C, which is the common standard for the vaccine cold chain (James, 2021). With new vaccine production technology, some of the COVID-19 vaccines must be kept in a frozen chain (-20°C) or an ultra-cold chain (-80°C to -70°C). For example, the Pfizer-BioNTech vaccine, COMIRNATY, must be stored at -70°C (ADB, 2021) to be usable.

Figure 6: Similar pain points of logistics and distribution of coronavirus disease vaccines



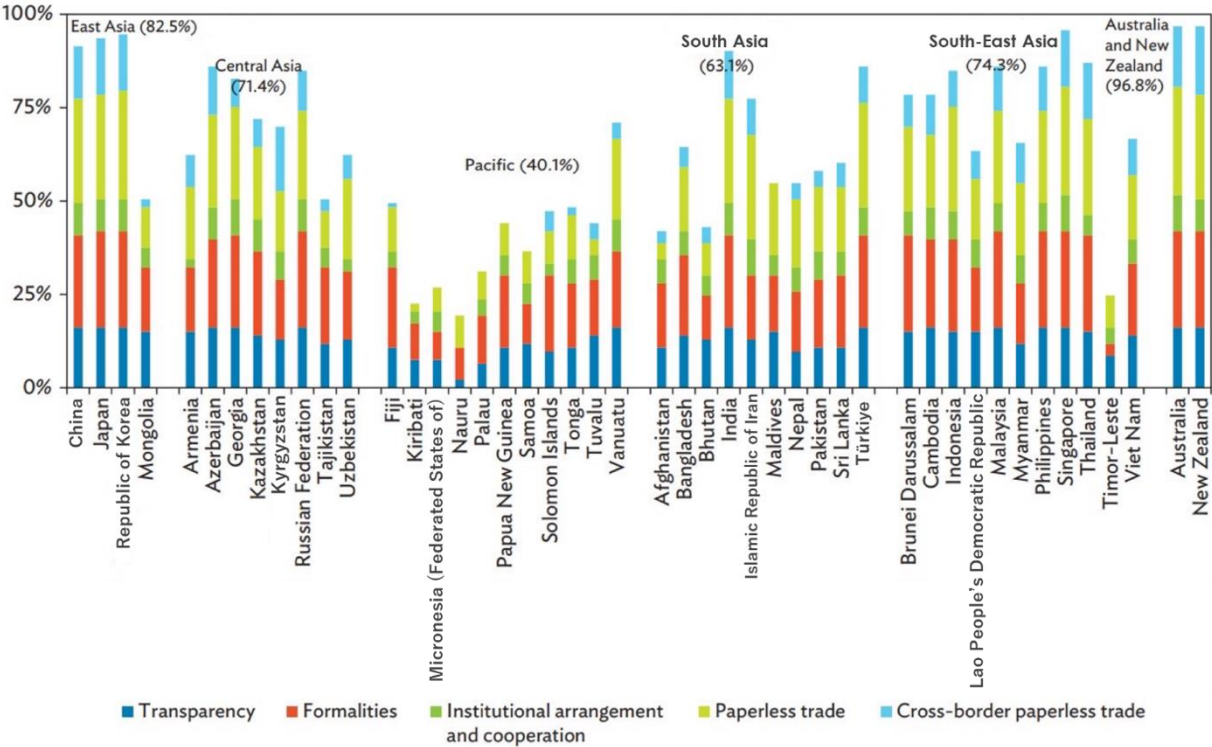
Source: Adapted from DHL, 2020.

2.1.1 Facilitation of cross-border trade of vaccines and vaccine inputs

In 2016, members of the Economic and Social Commission for Asia and the Pacific (ESCAP) adopted the Framework Agreement on Facilitation of Cross-Border Paperless Trade in Asia and the Pacific, a United Nations treaty, and commenced on 20 February 2021 to enable the electronic mutual recognition of trade-related documents and data and facilitate transactions among national single windows and/or other paperless trade systems (ADB and ESCAP, 2021).

In 2021, findings of the United Nations Global Survey on Digital and Sustainable Trade Facilitation indicated that Asia and the Pacific continues to streamline trade procedures. Despite the COVID-19 pandemic, across the region 31 general and digital trade facilitation measures were implemented in 2020, which represented an increase of approximately 6 per cent compared to 2019 (ADB and ESCAP, 2021). Australia and New Zealand implemented approximately 96.8 per cent of trade facilitation measures, followed by East Asia (82.5 per cent), South-East Asia (74.3 per cent), Central Asia (71.4 per cent), and South Asia (63.1 per cent) (figure 7). The Pacific is behind other subregions with 40.1 per cent implementation of trade facilitation measures. Different regions have different capabilities to handle cross-border trade that can affect cost, time, response to counterfeit goods as well as quality of cross-border products. The findings or issues of cross-border operations for the trade of vaccines and vaccine inputs are discussed below.

Figure 7: Implementation of trade facilitation measures in Asia-Pacific countries



Source: UN Global Survey on Digital and Sustainable Trade Facilitation. Available at www.untfsurver.org.

Note: Among the 58 measures surveyed across the United Nations regional commissions, three measures, including “electronic submission of sea cargo manifests”, “alignment of working days and hours with neighbouring countries at border crossings”, and “alignment of formalities and procedures with neighbouring countries at border crossings” are excluded when calculating the overall score as they are not relevant to all countries surveyed. Four transit facilitation measures are also excluded for the same reason. Additionally, for comparison, “sustainable trade facilitation” and “other trade facilitation” are excluded as these newly added groups of measures were not included in the earlier surveys.

2.1.2 Vaccine inputs

Vaccine inputs do not benefit from “green channels” or other simplified customs clearance procedures, and so importing vaccine inputs requires several documents and the frequent renewal of licenses and certificates (WTO, 2021). Customs clearance may take five working days in some countries. Importing new machines, facilities or supplies to scale up manufacturing capacities is slow and sometimes requires sophisticated procedures. It was occasionally difficult for importers to complete consular transactions or to submit documents needed for cross-border trade of vaccine inputs as some embassies and consulates remained closed during nation-wide lockdowns. In addition, import and export restrictions in some countries may be unpredictable, which makes it complicated for manufacturers to plan and manage the sourcing of critical inputs.

As vaccine inputs do not have any priority, they are subject to the normal customs clearance process. Table 3 provides supply chain lead time and clearance time of general cargo from the World Bank Logistics Performance Index in 2018 for Asia-Pacific subregions. In general, export and import processes require lead time of at least one day

in Australia and Brunei Darussalam, but it takes more time in some countries. Custom clearance would also require at least one day for some countries, but many require more days than that. For example, total import lead time, including clearance time for vaccine inputs, was 2 days for Australia, 5 days for Viet Nam, 7 days for Thailand, 8 days for Cambodia, 10 days for Myanmar and 11 days Indonesia. Additionally, import and clearance into countries in South and Central Asia is likely to require more lead time (figures 8 and 9) while much less time is required for import and clearance into countries in Oceania (figure 10).

Table 3: Airport supply chain lead time and clearance time in selected Asia-Pacific countries

Subregion	Country	Export - Lead time (days)	Import - Lead time (days)	Clearance time without physical inspection (days)	Clearance time with physical inspection (days)
Oceania	New Zealand	2	3	N/A	2
	Australia*	1	1	1	2
East Asia	Republic of Korea*	2	3	1	2
	China*	2	6	1	2
	Japan*	2	3	1	1
	Hong Kong, China	N/A	2	1	2
	Taiwan, China	1	2	1	1
	Mongolia	N/A	N/A	1	1
South-East Asia	Viet Nam*	2	3	1	3
	Thailand*	4	5	1	1
	Singapore	2	2	N/A	1
	Indonesia*	2	4	1	7
	Malaysia*	2	2	N/A	1
	Cambodia*	3	4	2	2
	Philippines	1	2	2	2
	Brunei Darussalam	1	1	N/A	1
	Myanmar*	3	4	2	3
	India*	3	3	1	2
	Bangladesh*	4	5	2	3
	Sri Lanka*	6	4	2	4
	Nepal	1	2	1	1
	Pakistan	4	8	2	5
Central Asia	Uzbekistan*	16	3	1	1
	Kyrgyzstan	1	2	1	1
	Armenia*	7	N/A	N/A	N/A
	Kazakhstan*	10	N/A	10	5
	Afghanistan	5	N/A	2	2
	Georgia	2	2	1	1
	Azerbaijan	3	2	2	2
Tajikistan	14	14	1	1	
Pacific	Papua New Guinea	2	2	1	3

Source: World Bank, available at <https://lpi.worldbank.org/domestic>.

* Vaccine manufacturing site.

N/A indicates that the item is not applicable.

Figure 8: Import-export lead time and clearance time, countries in Central Asia

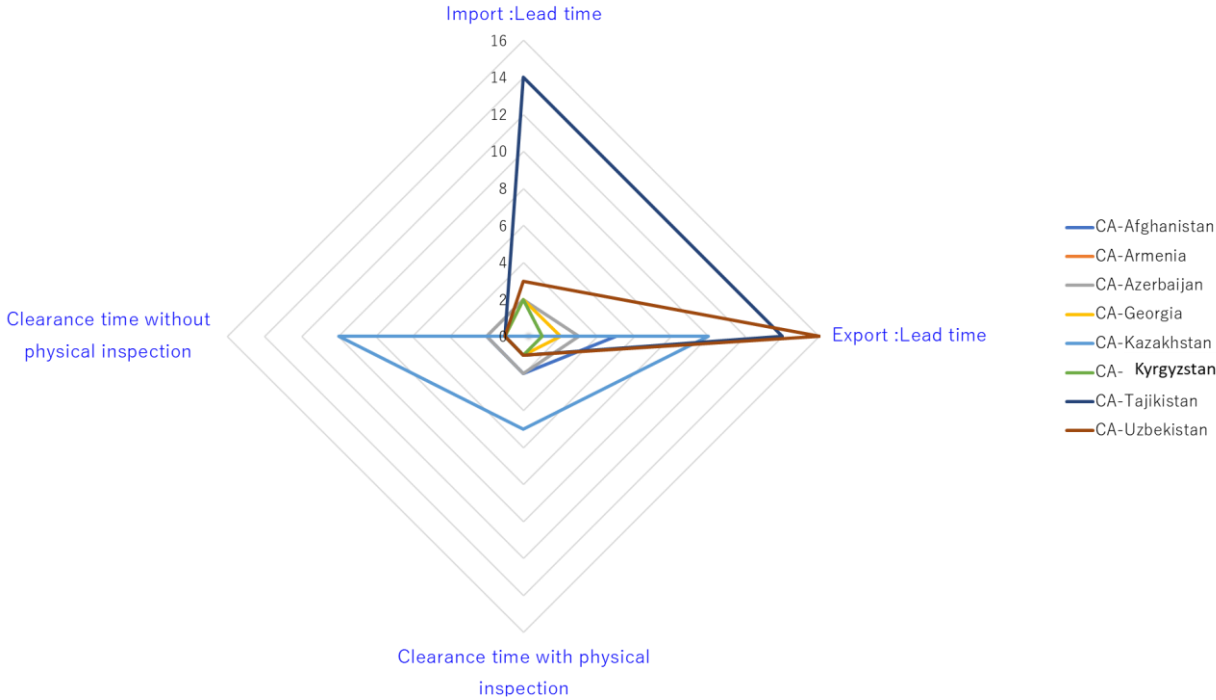


Figure 9: Import-export lead time and clearance time, countries in South Asia

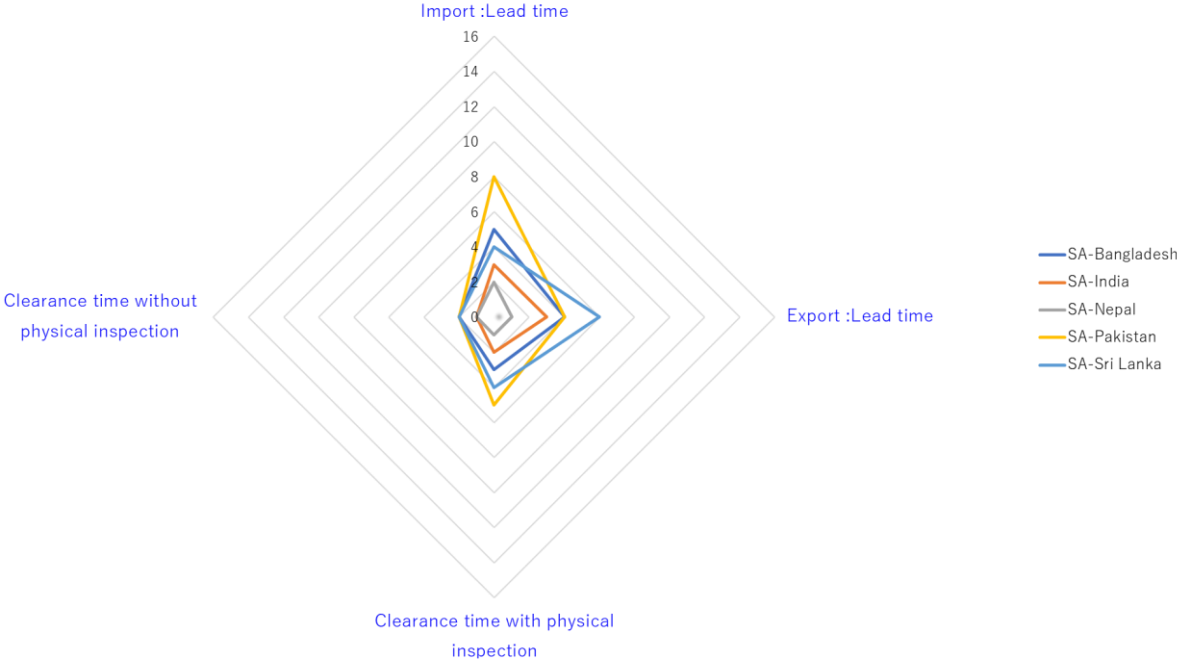
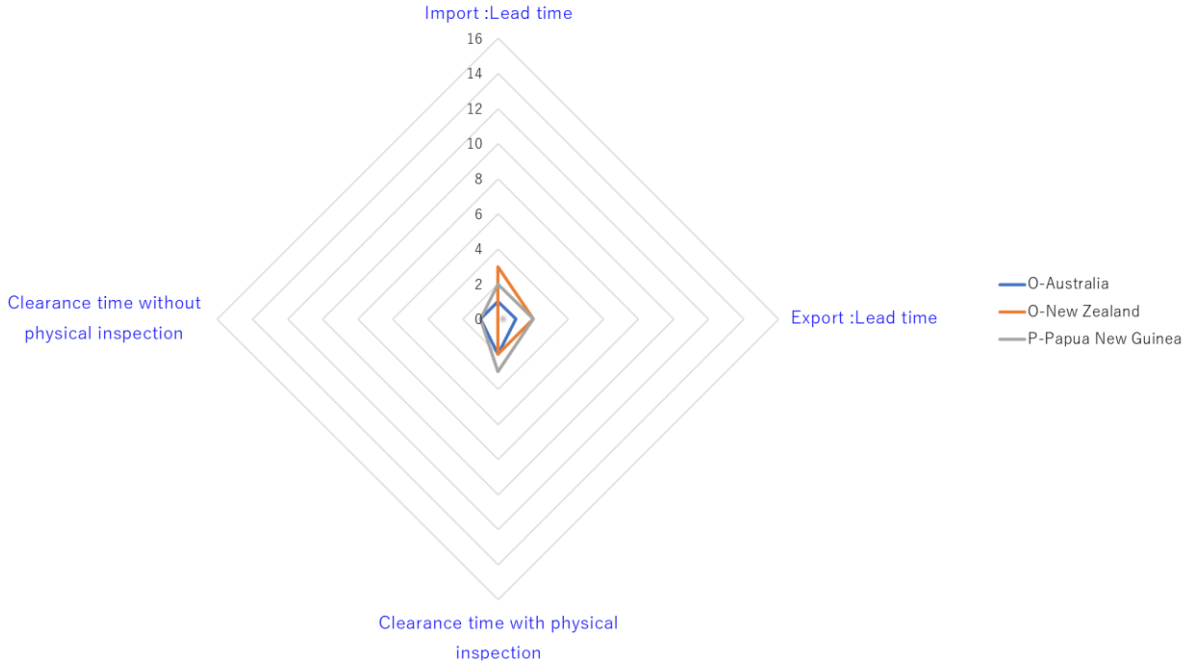


Figure 10: Import-export lead time and clearance time, selected countries in Oceania and the Pacific



2.1.3 Vaccines

Frameworks and procedures have been newly adjusted or approved for ease of importing and exporting COVID-19 vaccines. In other words, intervention strategies have been implemented to support the flows of vaccines in several countries, as shown in the following examples from the Asia-Pacific region.

Australia customs

The Australian Border Force (ABF) formed a Joint Planning Group (JPG) in November 2020 to unify the planning for border agencies accountable for vital COVID-19 commodities to safeguard the population while ensuring border protection procedures are adequate to detect illegal versions of the COVID-19 vaccine. The JPG looked at whether variables help or impede the seamless flow of critical products across borders. The JPG allowed the ABF and other government agencies to merge customs, biosecurity and health-related permissions – and eliminate obstacles – to ensure optimum convenience for the COVID-19 vaccine. Government agencies and businesses worked on test runs using dummy shipments to fine-tune the procedure. Furthermore, the Therapeutic Goods Administration and the Department of Health led the interaction between pharmaceutical producers and importers, while ABF and the Department of Agriculture, Water and the Environment provided information on import regulations at the border. Strong collaboration between the Government and businesses created a high degree of coordination on delivery schedules and broad knowledge of vaccination movements among all parties. The World Customs Organization (WCO) and the Department of Health, in collaboration with COVID-19 vaccine producers, are now hosting a series of training sessions for operational locations.

The AFB aims to clear vaccines immediately without unnecessary delay. The expected time to clear COVID-19 vaccines that require cold storage is 2 hours while 24 hours clearance time is expected for vaccine related goods that do not require cold storage (WCO, 2021).

Customs Administration of India

The Central Board of Indirect Taxes and Customs, and the Central Drugs Standard Control Organization are the national agencies in charge of inspecting and clearing COVID-19 vaccine parcels for export and import and ensuring the safe and secure management.

The Customs Administration of India has built a single window for electronic communication between customs and other partner government agencies such as the Central Drugs Standard Control Organization. The Joint Secretary (customs) has been designated as the focal entity for expedited national level clearance of imports related to COVID-19. Locally, focal persons at ports are designated to coordinate customs clearance. Their contact information is available on the website of the Customs Administration of India, which offers a toll-free hotline and an email address. The implementation of the single window together with the expediting of COVID-19 vaccines and related products can reduce the border clearance process time to half an hour (WCO, 2021).

Indonesia customs

Standard operating procedures for importing COVID-19 vaccines have been established and implemented with the collaboration of the customs agency in Indonesia, the Indonesia National Single Window Agency, National Agency on Drug and Food Control, and the Ministry of Health. The collaboration enhances the simplification of import authorization and the risk management implementation for the clearance process for COVID-19 vaccines. The single submission provided by the Indonesia National Single Window Agency is an integrated import permit application, but document inspection, physical inspection, including the clearance process, are conducted by the customs agency in Indonesia (WCO, 2021).

Indonesia has implemented an immediate-release facility. The immediate-release facility supports the vaccines and relevant items by submitting document together with import permissions and guarantee of taxation and import duties exemptions. The import declaration can be submitted within three working days after goods are released. However, pre-arrival, the customs agency in Indonesia, relevant government agencies and importers work together to ensure compliance with import formalities. The lead time for the release of imported COVID-19 vaccine shipments under the immediate-release facility is approximately 2 hours if all required documents are provided, excluding pre- and post-clearance lead time (WCO, 2021).

Singapore customs

Singapore customs has also established a joint task force including border agencies, relevant regulatory bodies, the health authority and private stakeholders to support the import and distribution of COVID-19 vaccines. The shipments are processed pre-arrival through the Singapore National Single Window that connects all relevant partners (WCO, 2021).

Thailand – COVID-19 vaccine lead time and clearance time

Lead time through the airport (table 3) would take four days for export and five days for import of general goods or commodities. Key informant interviews with export/import stakeholders and customs clearance officers in Thailand revealed that the lead time and clearance for importing general vaccines is approximately one day. However, customs clearance for imported COVID-19 vaccines have been conducted in under three hours, through the collaboration of importers, logistics service providers, FDA and Thailand customs. Data and trade related documents can be electronically submitted via the national single window prior to the arrival of vaccine shipments. The vaccines are imported without duty, and only value-added tax is charged.

Vaccines are highly valuable products. It is necessary to ensure that shipments are secure from theft and counterfeiting at all points in the supply chain. Security measures, including physical and cybersecurity measures, and border management must be in place (ADB, 2021).

Country	Lead time
Australia	2 hours
India	30 minutes
Indonesia	2 hours*
Thailand	Less than 3 hours

Source: WCO, 2021, and in-depth interviews.

* If all required documents are provided, excluding pre- and post-clearance lead time.

2.1.4 International transport capacity

The literature review and our in-depth interviews confirm that commercial flights in the global route network were dramatically reduced during the COVID-19 pandemic (ADB and ESCAP, 2021; IATA, 2021; WTO, 2021). Each individual route will be carefully considered before it is restarted to ensure that it would cover cost and revenue targets (IATA, 2021). Temporary storage areas in cargo terminals, such as cold storage and freezers, must be used to hold vaccines, and dry ice can be used as a refrigerant (IATA, 2021). A logistics service provider should have an established worldwide logistics network with a broad range of modes of transportation as well as intercontinental infrastructure to ensure reliable international transportation schedules (DHL, 2020). Security and screening procedures must be in place to keep valuable cargo shipments secured. Decisions about the volume of vaccine shipments, the origin point, the destination point and consignors and regulated agents are required for early planning, starting from transport to the aircraft, loading onto the aircraft, departure of the aircraft and arrival at the destination, including unloading and moving to terminal storage to ensure that shipments are protected against all sources of interference, including aviation security and criminal threats (IATA, 2021). Tracking and tracing of shipments should be conducted to ensure that the vaccine shipments remain secured throughout the supply chain. Tracking and tracing can be done in real time or at the destination. Transportation

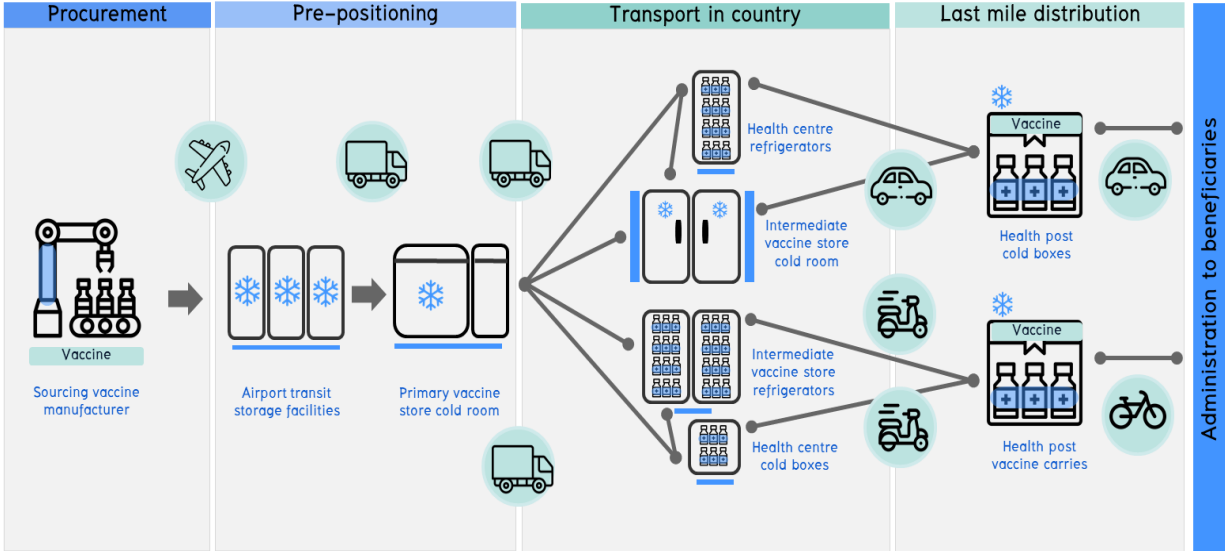
and logistics transparency and visibility are necessary to maximize usage of transport and logistics capacity. Stakeholders should make data available on the shipments planned, executed parameters, disruptions and alternative plans (IATA, 2021).

2.1.5 Cold chain facilities

COVID-19 vaccines require different temperatures ranging from 2°C to -80°C for storage and distribution. Each level of the vaccine cold chain systems needs different equipment, such as freezers, refrigerators, cold boxes and refrigerated trucks, to ensure the integrity of the cold chain from end to end. Moreover, different temperature monitoring devices, such as vaccine vial monitors, electronic temperature loggers and electronic freeze indicators, are necessary to monitor temperature and to support tracking and tracing systems. An illustration of the cold chain is contained in figure 11.

Vaccines are shipped out in a variety of quantities, requiring the readiness of storage and handling equipment during shipment, in particular cold chain facilities in-country, both traditional cold chains (2°C to 8°C) and ultra-cold chains (as low as -80°C), must be ready. These requirements impact the international transport and logistics of COVID-19 vaccines, and they are also relevant to releasing vaccines from the manufacturer warehouse and the possible availability of the vaccines and vaccine wastage. The ultra-cold chain freezers are also in demand, and low- and middle-income countries may not have them in their existing health/immunization system. To speed up the distribution of vaccines, equipment must be ready, meaning that freezers and other storage and handling equipment must be procured. Yet, the problem does not end at having the equipment: getting it to work can be challenging.

Figure 11: Flows and main components of vaccine cold chains



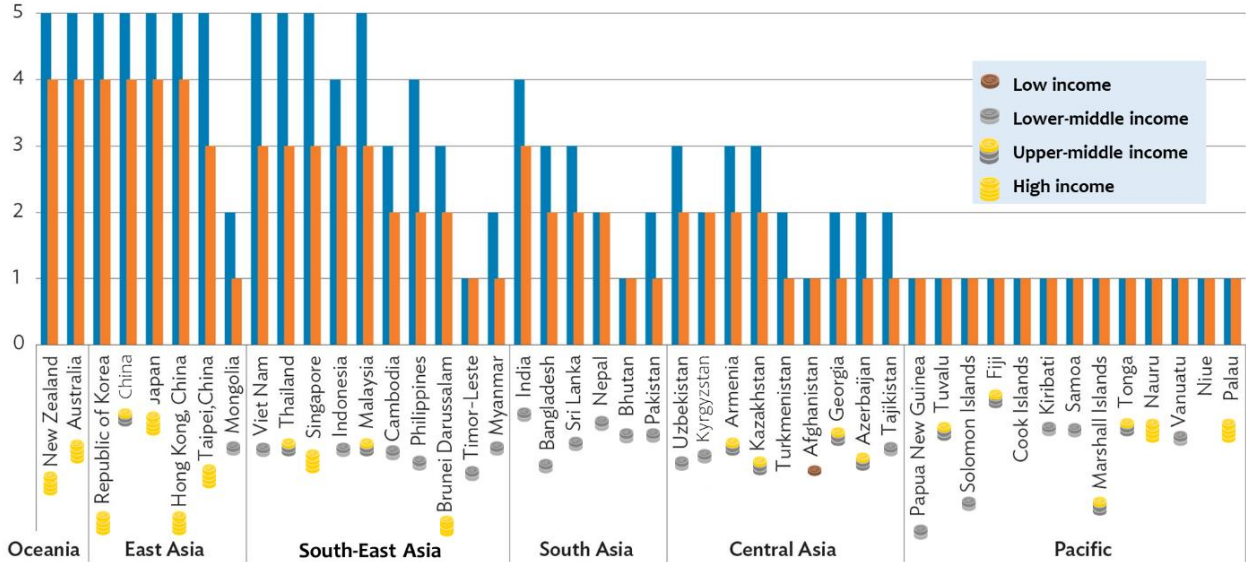
Source: ADB, 2021.

Preparedness for cold chain capacity is shown in figure 12, and most of countries in the Pacific and Central Asia subregions do not have enough capacity to handle both

conventional cold chains and ultra-cold chains as the level of preparedness for cold chain logistics is in level 1. Meanwhile, higher income economies such as New Zealand, Australia, Japan, China and the Republic of Korea have level 5 preparedness in conventional cold chains and level 4 preparedness for ultra-cold chains. Lower-middle-income and low-income economies must invest more on cold chain capacity to handle higher volume shipments, in particular for ultra-cold storage (WTO, 2021).

Furthermore, lack of a proper storage system in remote locations might also lead to a delay in vaccine delivery (Rosen et al., 2021). In addition, some COVID-19 vaccines are extremely temperature sensitive, and if the vaccine temperature is not maintained in transit from manufacturers to consumers, especially in tropical regions, the vaccine efficacy will be lower (Lin, Zhao and Lev, 2020).

Figure 12: Preparedness for cold chain logistics in Asia-Pacific countries



Source: ADB, 2021.

Note: Preparedness is ranked from 1 (lowest) to 5 (highest). Blue lines represent traditional cold chains (2°C to 8°C); and orange lines represent ultra-cold chains (as low as -80°C).

2.1.6 Human resource and management

Insufficient skills, knowledge and management capacity can lead to vaccine wastage (ADB, 2021). Logistics staff, officers of customs, and handling and transport personnel should be appropriately trained and qualified to handle time- and temperature-sensitive products (IATA, 2021). Some types of refrigerants, such as dry ice, are defined as dangerous goods. The packing or loading operators must ensure that shipments maintain vaccines at the required temperature without exceeding dry ice limits for a particular aircraft type. Standard operating procedures between business partners must be established to fulfil regulatory requirements and meet customer’s expectations (IATA, 2021).

Operational risks should be considered to prevent or mitigate the effect of logistics and transport constraints, such as delayed or cancelled flights, unavailability of temperature-controlled environment, closure or limited operation of airports, duration of the transport journey, limitations of available manpower and lack of appropriate training and relevant knowledge (IATA, 2021).

2.2 International transport and logistics hurdles and bottlenecks of vaccines and vaccine inputs

There are many hurdles and bottlenecks in the Asia-Pacific vaccine supply chain. This part of the report contains a summary of these hurdles and bottlenecks and other relevant case studies.

2.2.1 Low international transportation capacity

Due to national lockdowns in response to the COVID-19 pandemic, some airports closed, and flights were cancelled. Air transport capacity is much lower than transportation demand (ADB, 2021). In-depth interviews with a logistics service provider for Pfizer vaccines confirmed that it is challenging to obtain a direct and reliable flight schedule, including a transit flight with a minimum total travel time less than 72 hours. A key criterion to select a flight is the quality of the airport terminal, including facilities for temporary cold storage.

2.2.2 Security and cross-border management

Vaccine inputs are not considered a high priority in cross-border operations (IATA, 2021), and lack of expedited processing time can delay the total supply chain time of the COVID-19 vaccines. Moreover, manufacturing sites may need to import new equipment or machines, and the delay of the import permission can affect the production of COVID-19 vaccines.

As vaccines are priority products, the total lead time for import has then been reduced in several countries, such as Australia, India and Thailand. It remains essential to secure vaccine shipments from theft, counterfeiting and wastage. Both physical and cybersecurity measures must be in place to protect vaccines. Synchronization and collaboration between customs, health authorities, importers and logistics service providers with timely regulatory approvals, inspection and clearance is crucial (IATA, 2021).

2.2.3 Inadequate cold chain capacity

The level of preparedness of cold chain logistics is low in particular in the Pacific island countries and low- and lower-middle-income countries (ADB, 2021). The following cases of vaccine cold chain management in several Asia-Pacific countries are provided, along with good practice examples from Malaysia, Singapore and Thailand.

Philippines

In the Philippines, demand for vaccines is high, but cold chain capacity is limited. The Government of the Philippines was preparing to allocate refrigeration storage for meat and fish to handle COVID-19 vaccines (Calonzo, 2021). Moreover, it is difficult to access rural and remote areas due to unpredictable weather, security concerns and poor infrastructure. Health-care workers needed to hire private motorcycles and pump boats to deliver and administer vaccines because of inadequate transporters. Power supply for health centre refrigerators in rural areas is unstable with no back-up power source. A lack of skilled personnel leads to vaccine wastage (ADB, 2021).

In January 2022, the Government of Australia supported the Government of the Philippines to scale up COVID-19 vaccines through the United Nations Children’s Fund (UNICEF), by officially providing cold chain equipment to help address gaps in storage capacity at all levels of the country’s health system.

The UNICEF country office in the Philippines procured 30 solar-powered vaccine refrigerators and eight walk-in cold rooms.

Source: UNICEF, 2022, “Australia, UNICEF partner to strengthen PH vaccine supply chain”. Press release, 28 January. Available at www.unicef.org/philippines/press-releases/australia-unicef-partner-strengthen-ph-vaccine-supply-chain.

Lao People’s Democratic Republic

Rural areas of the Lao People’s Democratic Republic have higher dropout rates in vaccine campaigns than urban areas. Supply-side difficulties include vaccine shortages, limited funds and poor data and cold chain capacity. In addition, reports of health workers noted that they must use their own vehicle, usually a motorbike, to transport cold boxes, and have difficulties balancing the box. This is one reason why vaccine campaigns cannot reach rural areas (ADB, 2021).

Pakistan

In Pakistan, 7 in 10 people live in rural areas and approximately 40 per cent of children below 5 years of age, especially in poor and rural areas, are not immunized or are under-immunized. Demand for vaccines in rural areas is lower due to cultural resistance and the limitations of health infrastructure. Moreover, the immunization centres were not equally available throughout the country and the immunization schedule was insufficient, lacking proper cold chain monitoring and equipment maintenance. The back-up power source was insufficient to keep or maintain cold chain integrity (ADB, 2021).

India

The Universal Immunization Programme of India provides free immunization across the country, but it can be limited by vaccine refusal of misinformed people and the difficulty of reaching isolated villages. Moreover, the percentage of immunized children is lower in rural areas. Around

8 per cent of the programme's vaccines are wasted due to expiry and problems maintaining cold chain integrity. In rural areas, cold storage facilities can store about a month's supply of vaccine and only a third of storage facilities work properly (ADB, 2021).

Getting ultra-cold chain freezers ready in Indonesia

As one of the countries receiving COVID-19 vaccine donations from the Covax initiative, Indonesia received 17 ultra-cold chain freezers, funded by Gavi in August 2021 to hold a combined 3.5 million COVID-19 vaccines that require storage at up to -70°C.

Having freezers delivered and putting the freezers to work was very challenging, including tasks such as re-gassing the freezers. The refrigerant gas was removed before air shipment, following airline safety protocols.

Source: UNICEF, 2021, "Ultra-cold chain freezers: boosting Indonesia's COVID-19 vaccine rollout", 24 November. Available at www.unicef.org/supply/stories/ultra-cold-chain-freezers-boosting-indonesias-covid-19-vaccine-rollout.

Getting 26 ultra-low temperature freezers to Bangladesh

DHAKA, 28 September 2021 – In August 2021, 26 ultra-low temperature freezers were delivered by UNICEF through the Covax initiative. The freezers are enabling the delivery, storage and distribution of large quantities of COVID-19 vaccines to people in Bangladesh.

Each of the 26 freezers can hold over 300,000 doses of COVID-19 vaccines, supporting the delivery of these vaccines into districts beyond Dhaka. The shipment boosts their ultra-cold chain capacity to store almost 9 million vaccines.*

It was very challenging to receive the freezers and put them to work, including re-gassing the freezers.

Source: UNICEF, 2021, "The historic push to provide ultra-cold chain freezers around the world", 20 September. Available at www.unicef.org/supply/stories/historic-push-provide-ultra-cold-chain-freezers-around-world.

Malaysia

The Government of Malaysia purchased special freezers to secure ultra-cold chains for Pfizer vaccines (Malay Mail, 2021).

Singapore

Singapore is leading the South-East Asia subregion in cold chain system management particularly for ultra-cold chains. The Singapore airport has become a centralized warehouse of COVID-19 vaccines with 18 cold storage rooms, temperature-controlled truck docks as well as

active temperature-controlled containers. Cool dollies were designed to secure the movement of pharmaceutical products under a temperature-controlled system. The new infrastructure protects temperature-sensitive vaccines such as Pfizer and Moderna from spoilage, and if further enhances the role of the Singapore airport as a reliable and quality air hub for supply chains of pharmaceutical and perishable goods (Khanzada, 2021).

Thailand

The Government of Thailand has prepared to implement vaccine cold chain system since the beginning of the COVID-19 pandemic in early 2020, and close collaboration has been established between the Government of Thailand and the Federation of Industry. Freezers, cold boxes, devices that monitor temperature using the Internet of things, Internet Wi-Fi services as well as power back-up resources were installed throughout the country. The collaboration extended beyond cold chain facilities, and collaboration between the Ministry of Public Health, the Federation of Industry, hospitals, logistics service providers, Thailand research funding agency, and universities has been established to implement a real time track and trace system to monitor the end-to-end vaccine cold chain. The status of vaccines can be monitored in real time, including useful information on temperature, location, vaccine name, manufacturing site, production lot/batch, expiry date, injection date and other related records.

2.2.4 Improper handling of vaccines

Vaccine wastage can be caused by improper handling of vaccines during storage and transport in various stages of the cold chain. Cold chain breakdowns in refrigeration tend to take place in rural areas during distribution and storage of vaccines, leading to high losses of vaccine. The major causes are found to be poor temperature management, use of low-level technology, and insufficient skills, knowledge and management capacity (ADB, 2021).

2.2.5 Lack of information sharing

Vaccines are high-value products, and the vaccine journey must be transparent to protect against several issues, such as theft, counterfeiting and failure of cold chain integrity, and to ensure traceability of vaccines. The tracking and tracing of shipments should be done in real time or near real time to share information about location and temperature (IATA, 2021). Table 5 contains a summary of major hurdles and bottlenecks of some selected Asia-Pacific countries.

Table 5: National hurdles and bottlenecks	
Country	Hurdles and bottlenecks
Lao People’s Democratic Republic	- Vaccine shortages - Lack of funds - Poor data - Poor cold chain management and cold chain facilities
India	- Expiry and problems in the cold chain - Limited cold storage facilities
Indonesia	-Insufficient ultra-cold chain facilities
Pakistan	- Cultural resistance

	<ul style="list-style-type: none"> - Health infrastructure was limited - Lack of cold chain monitoring - Inadequate a back-up power source to support cold chain integrity
Philippines	<ul style="list-style-type: none"> - Insufficient cold chain facilities - Power supply for refrigerators of health centres is intermittent in rural areas with no back-up power source

3. Key findings and recommendations

3.1 Major challenges

Reviews and analyses of documents, guidelines and available resources, and in-depth interviews with key stakeholders in the COVID-19 vaccine cold chains identified major challenges in international transport and cross-border trade. These are addressed below.

- Cold chain infrastructure is inadequate. Capacity is lacking for traditional, frozen and ultra-cold chains in particular in low- and lower-middle-income countries in the Pacific and Central Asia subregions. In some countries such as the Lao People’s Democratic Republic, Pakistan and the Philippines, backup power sources, proper cold chain monitoring and equipment maintenance may be insufficient.
- Requirements and procedures differ in terms of temperature management and control for vaccines during transportation and cross-border (annex 2). Moreover, different procedures are needed for handling passive and active cold boxes.
- It is difficult to implement vaccine and temperature tracking and tracing systems, as well as data sharing among parties in vaccine cold chains to create supply chain visibility and temperature monitoring. Obstacles include insufficient budgets and technology, and the data management silos of parties in the supply chain.
- Seamless collaboration between importer and customs clearance, and among logistics service provider, health authority and FDA is difficult to achieve.
- International transportation capacity differs between countries and volatile freight capacity is limited. Moreover, there are no direct flights from manufacturing countries to most of the importing countries in the region, therefore, vaccine cargos need to go through at least one connecting flight. This could cause delays and pose more risk to the cold chain, especially in low-income countries in the region where cold chain airport facilities are limited.
- There is a lack of priority “green channels” and coordinated fast track for vaccine inputs during cross-border trade. Additionally, the Pacific is behind other subregions with 40.1 per cent implementation rate of general and digital trade facilitation measures. Low capability to handle cross-border trade can affect cost, time, response to counterfeit goods as well as quality of products traded across borders. This poses challenges in Central Asia and South Asia where manufacturing sites are in are low-income countries, for example, Bangladesh, India, Sri Lanka and Uzbekistan.
- Personnel training country-wide can help to build flexibility in correctly handling different cold chains. Some types of refrigerants, such as dry ice, are defined as

dangerous goods. The packing or loading operators must ensure that shipments maintain vaccines at the required temperature without exceeding the limit for a particular aircraft type.

- Cultural resistance to vaccination.

3.2 Recommendations

- **Cooperation and coordination:** There should be a national working group and the Government should announce and implement a policy for cooperation and coordination among private and government organizations regarding transportation and cross-border logistics. Key stakeholders must be identified to ensure a smooth, timely and effective cross-border trade processes. Furthermore, government officials should be designated as key contact points for cross-border procedures. Additionally, someone should be on duty 24 hours per day and seven days per week to ensure cross-border logistics are processed swiftly.
- **Cross-border policy and regulations:** Harmonized policies and regulations among country partners are needed, including sharing information and effective collaboration. Relevant measures can be implemented to facilitate and secure cross-border movement, coordinate with other government agencies and stakeholders, prioritize and facilitate clearance and control risks (see annex 3).
- **Work with professionals and experts in pharmaceutical logistics:** It might cost more to work with experts and professionals, however, it is more reliable and vaccine efficacy would be affected if cold chain integrity is lost. In Thailand, there are two main well-known logistics service providers handling COVID-19 vaccines. One works with traditional cold chain vaccines, and another works with frozen and ultra-cold vaccines. They both increased their cold chain capacities and won logistics contracts from the government.
- **Cold chain logistics, infrastructure and readiness:** Governments need to ensure the readiness of cold chain equipment and facilities, and conduct a capacity assessment. Advanced vaccine distribution planning can provide estimates of space requirements in each temperature range. If possible, pharmaceutical grade refrigerator/cold room procurement is recommended. More importantly, countries in the region should work together to improve cold chain logistics planning and request that donor countries and organizations contribute cold chain equipment and facilities.
- **Develop a national cold chain track and trace system** to ensure information sharing and the monitoring of cold chain integrity.
- **Offer human resources training** and easy-to-understand procedure manual in local languages to ensure compliance. Knowledge sharing among member countries and e-learning are helpful as well. Customs officers should have a better understanding of cold chain requirements and integrity so that they authorize paperwork in timely manner.

Furthermore, key findings and recommendations are shown in figure 13.

Figure 13: Key findings, recommendations and stakeholder mapping

	Procedure and human resources	Regulations and cold chain infrastructure
Major challenges	<ul style="list-style-type: none"> • Difficulty in seamlessly collaboration among relevant parties • Key contact point should be assigned to ensure 24/7 availability. • Different cold chain with different handling requirement and procedures • Vaccine quality and efficacy assurance • Country-wide personnel training to build flexibility in correctly handling different cold chains 	<ul style="list-style-type: none"> • Limited and volatile freight capacity • Readiness of cold chain transport truck with temperature monitoring. • Lack of priority "green channels" and coordinated fast track for vaccine inputs during cross borders. • Inadequate cold chain infrastructures. • Vaccines and temperature track and tracing system • Temperature reports and seals of the package
Key success factors	<ul style="list-style-type: none"> ➢ Cooperation and coordination: key stakeholders must be identified to ensure a smooth, timeliness, and effective process of cross border transports. ➢ Cross-border policy and regulations: harmonized policies and regulations among country partners are needed, including share of information and effective collaboration. Implementation of relevant measures used to facilitate and secure cross-border movement ➢ Cold-chain logistics, infrastructure and readiness: availabilities of a complete cold-chain readiness must be in place, along with training and compliance. Member countries in the region work together to 	
Stakeholder mapping	<ul style="list-style-type: none"> • Working group among the key stakeholders from government agency and private sectors • Vaccine manufacturers and inputs suppliers • Logistics service providers • Government agencies for example, FDA, department of disease control (DDC), and custom. 	<ul style="list-style-type: none"> • Working group among the key stakeholders from government agency and private sectors • FDA at port of entry, customs administrator and security measures controllers • Ministry of Health • Logistics service provider & warehouse • Airport terminal staff

3.3 Additional recommendations to improve national cold chain systems

Many actions could be taken to overcome national cold chain challenges (Khanzada, 2021). Shipment size can be optimized and vaccine distribution approaches can be designed to reduce the refrigeration requirements of frozen and ultra-cold chains. Additionally, the private-sector can support cold chain capacity, especially freezer and ultra-cold capacities. Finally, Governments can invest in cold chain capacity and data management systems with future use in mind.

Each COVID-19 vaccine can be stored at 2°C to 8°C for a certain amount of time before it is administered. If countries plan and implement reliable vaccine distribution with lead time within that time frame, the vaccines could be kept in traditional cold storage at subnational distribution points. This reduces the demand for space in national warehouses and the need for ultra-cold chain or -20°C freezer capacity, especially at subnational levels. Additionally, Governments can explore packaging optimization, for example, packing vaccines in smaller ultra-cold chain packaging units. It might be less cost efficient for international transportation, however, they could be distributed to subnational levels without having to break bulk cargo at national warehouses. This would reduce the requirements for ultra-cold capacity, equipment and personal training, and it would reduce the risk of waste or breakage. Nevertheless, more cold chain capacity may be needed in some countries regardless of planning due to the volume associated with COVID-19 mass immunization that exceed the requirements of traditional EPI cold chain. Furthermore, buffer capacity is needed to deal with unexpected delays or supply disruptions. At national and subnational levels, it could include adding permanent ultra-cold chain, freezer or cold room capacity. A more economical choice, however, is to temporarily rent warehouse capacity from the private sector, such as pharmaceutical cold storage at the required temperature range.

Additionally, much of the required capacity could be met by cost effectively repairing existing broken cold chain equipment, and Governments may wish to assess this possibility. A best practice is to back up cold chain equipment capacity with emergency generators (if reliant on electrical power), supported with proper maintenance to maximize its useful life (Khazada, 2021). Moreover, any investment made in expanding cold chain capacity at national and subnational levels for COVID-19 vaccines should be made with long term benefit to the health-care system. For instance, any additional cold chain storage should have adjustable temperature range capability to serve future needs of the routine immunization cold chain such as modifiable between traditional to frozen chains. Furthermore, investments in data systems to support immunization campaigns and end-to-end cold chain traceability.

3.4 Checklist for policymakers

Based on in-depth interview, desk review and analysis, a checklist for policymakers deliberating potential challenges and recommended actions regarding international transport and logistics of vaccines across borders is proposed. There are six key policy areas in the checklist. The first area is facilitation and security of cross-border process for vaccines, vaccine inputs, supplies and equipment. Issues to consider are the development of operating procedures, the prevention of sub-standard and counterfeit vaccines and the digitalization of customs procedures. The second policy area is international transport capacity concerning availability of capacity. The third policy area is cold chain facility and equipment readiness. The issues to consider are the adequacy and quality of existing cold chain capacity for each temperature range. The fourth policy area concerns the readiness of human resources to handle the vaccine cold chain. The issues in the fourth policy area include workforce capability, training methods and technology. The fifth policy area concerns cold chain cooperation and coordination. Issues to consider concern cooperation between government agencies and the private sector, and utilizing professional health-care logistics service providers (LSP). Lastly, the sixth policy area is information technology (IT) readiness, including facilities, infrastructure and cold chain trace and traceability systems. The details of each policy checklist area are provided below.

Policy area 1: Facilitate and secure the cross-border process for situationally vaccines, vaccine inputs and related supplies and equipment

Issue 1.1: Develop operating procedures for import and export of COVID-19 vaccines and vaccine inputs, supplies and equipment.

Topic	Details	Remark
Guiding questions	<ol style="list-style-type: none"> 1. Who is responsible for administering the cross-border process of vaccines and vaccine inputs, supplies and equipment? 2. Which actors are likely to be involved in the initiation of the standard operating procedures for import and export of COVID-19 vaccines and vaccine inputs, supplies and equipment, and what are their roles? 3. What are the standard operating procedures for import and export of COVID-19 vaccines and vaccine inputs, supplies and equipment? 4. What are HS codes for vaccines and vaccine inputs, supplies and equipment to expedite the release and clearance process? 5. How are “green lanes” / priority lanes applied to the clearance of COVID-19 vaccines and vaccine inputs, supplies and equipment? 6. What documents are needed for import and export of COVID-19 vaccines and vaccine inputs, supplies and equipment? 7. What are time and place limitations to conduct the release and clearance process? 	<p>2.1.1 Facilitation of cross-border trade of vaccines and vaccine inputs</p> <p>2.1.2. Vaccine inputs</p> <p>2.2.2. Security and cross-border management</p>
Potential challenges	<ol style="list-style-type: none"> 1. Lack of clear identification of the roles and responsibilities of relevant actors may delay the initiation of standard operating procedures for import and export of COVID-19 vaccines and vaccine inputs, supplies and equipment. 2. Lack of proper understanding of import and export procedures COVID-19 	<p>2.1.1. Facilitation of cross-border trade of vaccines and vaccine inputs</p> <p>2.1.2. Vaccine inputs</p>

Topic	Details	Remark
	<p>vaccines and vaccine inputs, supplies and equipment may increase cross-border lead time.</p> <ol style="list-style-type: none"> 3. Lack of effective cross-functional/cross-organizations in cross-border procedures. 4. Different countries require different information in the import and export of COVID-19 vaccines and vaccine inputs, supplies and equipment. 5. Lack of the approval procedure for new vaccine inputs, supplies and equipment may delay imports of those items. 6. Customs clearance procedures are not publicly shared or clearly communicated. 7. The release and clearance process can be only conducted during official working hours and in a particular customs clearance area. 	<p>2.2.2. Security and cross-border management; 3.1 Major challenges</p>
Recommended actions	<p>National</p> <ol style="list-style-type: none"> 1. Form a high-powered national committee/task force with responsibility for the COVID-19 pandemic to coordinate the import and export of vaccines and vaccine inputs, supplies and equipment. The committee must include customs, health authorities, LSPs and importers. 2. Identify all potential actors involved in the import process of vaccines and vaccine inputs, supplies and equipment. 3. Set up standard operating procedures to expedite the import and export of vaccines and vaccine inputs, supplies and equipment. 4. Establish release and clearance procedures with the minimum information to indicate the goods and authorize the goods declaration. 5. Create green lanes to accelerate the release and clearance process at borders for vaccines and vaccine inputs, supplies and equipment. 	<p>3.2 Recommendations: Cooperation and coordination, cross-border policy and regulations, human resources training</p>

Topic	Details	Remark
	<ol style="list-style-type: none"> 6. Make all relevant information publicly available and easy to access. 7. Communicate and train relevant staff to understand and perform the release and clearance process according to the standard operating procedures. 8. Facilitate pre-arrival processing of imported vaccines. 9. Facilitate the release and clearance process outside official working hours or away from customs offices and waive any charges. 10. Provide a contact point 24 hours a day, seven days a week, for unexpected delays or shipment changes. 11. All customs locations should have a COVID-19 response team for instant clearance. 	
	<p>Regional</p> <ol style="list-style-type: none"> 1. Form a high-powered national committee/task force including WCO and WHO to establish Harmonized System (HS) classification of vaccines and vaccine inputs, supplies and equipment to expedite the release and clearance process in line with established international guidance on disaster relief. 2. Procedures or measures to support compliance and cooperation between border agencies. 	<p>3.2 Recommendations: Cooperation and coordination, cross-border policy and regulations</p>

Issue 1.2: Control COVID-19 medicines and prevent substandard or counterfeit vaccines

Topic	Details	Remark
Guiding questions	<ol style="list-style-type: none"> 1. Who is responsible for administering the national effort to control substandard or counterfeit vaccines? 2. Which actors are likely to be involved in the control of substandard or counterfeit vaccines? 	<p>2.2.2. Security and cross-border management 2.2.5.</p>

Topic	Details	Remark
	<ol style="list-style-type: none"> 3. Who are trusted logistics providers and customs brokers? 4. What are risks related to substandard or counterfeit vaccines? 5. What measures prevent and control substandard or counterfeit vaccines? 6. What vaccine inspection activities facilitate the cross-border movement of genuine vaccines, and report and halt the movement of substandard or counterfeit vaccines? 7. What procedures deal with illegitimate vaccines? 	Lack of information sharing
Potential challenges	<ol style="list-style-type: none"> 1. Lack of clear roles and responsibilities of relevant actors may delay the initiation of import procedures. 2. Lack of risk identification in the import of illicit vaccines. 3. Lack of measures to prevent and control substandard or counterfeit vaccines. 4. Lack of proper inspection procedures to facilitate the cross-border movement of genuine vaccines, and report and halt the movement of sub-standard or counterfeit vaccines. 5. Lack of real-time shipping information. 6. Lack of procedures to deal with illegitimate vaccines. 	2.2.2. Security and cross-border management 2.2.5. Lack of information sharing 3.1 Major challenges
Recommended actions	National <ol style="list-style-type: none"> 1. All customs locations should have a COVID-19 response team to facilitate instance clearance. 2. Standardized process for handling the vaccine on arrival including the places for storage and handling 3. Collaborate with vaccine suppliers, supply chain operators, importers, and Customs brokers to develop targeting profiles to identify suspected unlawful shipment. Doing so will reduce the 	3.2 Recommendations: Cross-border policy and regulations, human resources training

Topic	Details	Remark
	<p>likelihood of inspection in legally shipments.</p> <p>4. Focus on coordinated activities to inspect imported vaccines across all modes of transport suspected of containing unapproved vaccines.</p> <p>5. Working with trusted, vetted logistics providers and customs brokers</p> <p>6. Collaborate with identified logistics providers to receive real-time shipping or shipment tracking such as GPS as well as anti-lamper measures.</p> <p>7. Establish a referral process with law enforcement agencies to assess jointly detections of unlawful vaccines for any identified criminal aspects, as well as pursue investigation or prosecution options.</p>	
	<p>Regional</p> <p>Customs administrations should notify international counterparts of the nature of the detection of illegitimate vaccines</p>	<p>3.2</p> <p>Recommendations: Cross-border policy and regulations</p>

Issue 1.3: Digitalized export and import customs procedures

Topic	Details	Remark
Guiding questions	<p>1. Who is responsible for administering the national effort to develop and utilize digitalized export and import customs procedures?</p> <p>2. Which actors are likely to be involved in the initiation of the digitalized export and import customs procedures and what are their roles?</p> <p>3. What are tools connected devices attached to container used to monitor or tracking the status of the vaccines?</p> <p>4. What are digitalized import and export Customs procedures?</p>	<p>2.1.1.</p> <p>Facilitation of cross-border trade of vaccines and vaccine inputs</p> <p>2.2.5.</p> <p>Lack of information sharing</p>

Topic	Details	Remark
Potential challenges	<ol style="list-style-type: none"> 1. Lacking clear identification of the roles and responsibilities of relevant actors may delay the initiation of import procedures. 2. Lack of tools used to monitor or tracking the status of the vaccines 3. Lack of digitalized import and export Customs procedures or electronic single window system 4. Lack of electronic submission of customs declarations 5. Lack of electronic application and issuance of import and export permits 6. Lack of electronic submission of sea/air cargo manifests 7. Lack of electronic application and issuance of preferential certificate of origin 8. Lack of electronic payment of customs duties and fees 9. Lack of electronic application for customs refunds 	<p>2.1.1. Facilitation of cross-border trade of vaccines and vaccine inputs</p> <p>3.1 Major challenges</p>
Recommended actions	<p>National</p> <ol style="list-style-type: none"> 1. Form a high-powered national committee/task force to develop or utilize electronic customs clearance procedures 2. Establish a National Single Window (NSW) to facilitate the digitalized import and export Customs procedures and accept electronic customs data and digital copies of documents 3. Provide non-intrusive inspection rather than physical inspection to reduce the clearance process time and prevent vaccines damaged from temperature variations. 	<p>3.2 Recommendations: Cross-border policy and regulations, cooperation and coordination, human resources training</p>
	<p>Regional</p> <ol style="list-style-type: none"> 1. Form a high-powered national committee/task force or delegate the responsibility to develop and implement regional single windows. 	<p>3.2 Recommendations: Cross-border policy and</p>

Topic	Details	Remark
	<p>2. Develop/implement regional single windows for document submissions and clearance compliance with WTO TFA and the Framework Agreement on Facilitation of Cross-Border Paperless Trade.</p> <p>3. It requires complex coordination of legal and technical standards for international interoperability and efficiency.</p>	regulations, cooperation and coordination

Policy area 2: International transport capacity

Issue 2.1: Availability of international transport capacity

Topic	Details	Remark
Guiding questions	<p>1. Who is responsible for administering the national effort for international transport capacity?</p> <p>2. Which actors are likely to be involved in the initiation of increasing international transport capacity, and what are their roles?</p> <p>3. What are modes of transport available to transport vaccines?</p> <p>4. What is equipment used to properly handle vaccines during transportation?</p> <p>5. What is the maximum transportation time to transport vaccines according to the vaccines' standard?</p> <p>6. What are capacities of the handling and storage at origin, transit, and destination?</p>	<p>2.1.4. International transport capacity</p> <p>2.2.1. Low international transportation capacity</p> <p>3.1 Major challenges</p>
Potential challenges	<p>1. Lack of enough airport capacity</p> <p>2. Lack of a direct flight</p> <p>3. Need to handle a transit flight</p> <p>4. Capacities of the handling and storage at origin, transit and destination are not enough or proper</p> <p>5. Lack of prioritization of critical shipments</p>	<p>2.1.4. International transport capacity</p> <p>2.2.1. Low international transportation capacity</p> <p>3.1 Major challenges</p>

Topic	Details	Remark
Recommended actions	<p>National</p> <ol style="list-style-type: none"> 1. Form a high-powered national committee/task force or delegate the responsibility to increase international transport capacity. 2. Government should support a regional or global level the grant of additional direct traffic rights on a temporary basis for transporting the COVID-19 vaccines and other critical products. 3. Airlines should prioritize the movement of critical shipments, including but not limited to vaccines. 4. Facilitate freighter charter and/or logistics service provider what have strong regional and global networks to consider feasible airport pairs, routes, and time. 5. Coordinate the supply chain stakeholders to ensure integrated solutions and processes to maximizing the shipment capabilities to the extent possible. 	<p>3.2 Recommendations: Cooperation and coordination</p>
	<p>Regional</p> <p>Interline operations and multilateral interline agreements should be established to enable interline operations.</p>	

Policy area 3: Cold chain facility and equipment readiness

Issue 3.1: Insufficient cold chain quality and capacity

Topic	Details	Remark
Guiding questions	<ol style="list-style-type: none"> 1. What is the status of the pandemic, and what are the quantity and types of desired vaccines? 2. Who is responsible for administering the national effort to ensure enough capacity of vaccine cold chain facility and equipment? 3. Which actors are likely to be involved in the survey and evaluation of the existing 	<p>This affects space capacity required for each temperature range.</p>

Topic	Details	Remark
	<p>facility and equipment capacity and readiness, and what are their roles?</p> <p>4. How to acquire more cold chain facility and equipment for each temperature range?</p>	
Potential challenges	<ol style="list-style-type: none"> 1. Lacking clear identification of required vaccine quantity and brand which affect traditional and ultra-cold chain space capacity requirement may delay the vaccine import. 2. Lacking clear identification of the roles and responsibilities of relevant actors may delay the import procedures. 3. Lacking of evaluation readiness of equipment and facility may result in cold chain break and vaccine wastage. 	<p>2.1.5. Cold-chain facilities</p> <p>2.2.3 Inadequate cold-chain capacity</p>
Recommended actions	<p>National</p> <ol style="list-style-type: none"> 1. Form a high-powered national committee/task force or delegate the responsibility to the existing national pandemic response entity to coordinate the cold chain planning and readiness evaluation. 2. The same committee/taskforce monitors the situation of the pandemic and assess national vaccine requirements and procurement plan. 3. Identify all potential actors involved in the vaccine import, storage, and transport process. 4. Create traceability system to monitor vaccine cold chains. <p>Regional</p>	<p>3.2 Recommendations, Cooperation and coordination</p> <p>3.2 Recommendations, Develop national cold chain track and trace system</p>

Topic	Details	Remark
	<ol style="list-style-type: none"> 1. Form a high-powered international committee/task force from existing national pandemic response entity to coordinate and share cold chain evaluation, preparation, and management experience. 2. Work together to attract facilitation for low-income country members in the region so that they have adequate and appropriate cold chain facility and equipment for incoming vaccines. 	<p>3.2 Recommendations, Cold-chain logistics, infrastructure and readiness</p>

Policy area 4: Human resource development and management

Issue 4.1: Training to build capability and flexibility

Topic	Details	Remark
Guiding questions	<ol style="list-style-type: none"> 1. Is there a national standard operation procedure (SOP) document for vaccine cold chain management? 2. If so, does the document include operations for frozen and ultra-cold chains? Are they in local language and easy to understand? 3. Who is responsible for creating the national SOP for vaccine cold chains? 4. Which actors are likely to be involved in the initiation of producing the SOP and training, and what are their roles? 	
Potential challenges	<ol style="list-style-type: none"> 1. Lacking clear identification of the roles and responsibilities of relevant actors may result in non-existing proper handling procedures. 2. Lacking proper understanding of the procedures required to handling cold chains may result in vaccine wastage. 	<p>2.1.6. Human resource and management 3.1 Major challenges, country-wide personnel training to build flexibility</p>
Recommended actions	<p>National</p> <ol style="list-style-type: none"> 1. Form a national committee/task force or delegate the responsibility to the existing national pandemic response entity 	

Topic	Details	Remark
	<p>including training or education institutes to create appropriate SOP documents and training course.</p> <p>2. Identify all potential actors involved in the vaccine import, storage, and transport processes to train their workforce.</p>	3.2 Recommendations, Human resources training
	<p>Regional</p> <p>1. Form an international committee/task force or the existing national pandemic response entity to share SOP documents, and experience in solving cold chain handling problem caused from human errors.</p> <p>2. Share effective training techniques among member countries.</p>	

Issue 4.2: Training method and technology

Topic	Details	Remark
Guiding questions	<p>1. Who is responsible for national cold chain manager and workforce training?</p> <p>2. What is their training procedure or method?</p> <p>3. Is there any training media or technology in place?</p> <p>4. Which actors are likely to be involved in the initiation of training cold chain manager and workforce, and what are their roles?</p>	
Potential challenges	<p>1. Lacking clear identification of the roles and responsibilities of relevant actors may result in insufficient cold chain handling knowledge.</p> <p>2. Lacking proper training method and technology may result in cold chain break.</p>	
Recommended actions	<p>National</p> <p>1. Form a national committee/task force together with training or education institutes to turn SOP document into effective training material and modules.</p>	

Topic	Details	Remark
	2. Survey and evaluate existing training platform or technology and integrate SOP training material into existing training or education platform.	
	Regional Form an international committee/task force to share training techniques and if possible, training platform.	

Policy area 5: Cold chain Cooperate and Coordination

Issue 5.1: Cooperate and coordinate (between government and the private sectors)

Topic	Details	Remark
Guiding questions	1. Who are in the supply chain responsible for the cold track and trace system? 2. How does the cooperation and coordination build?	
Potential challenges	1. Lack of supply chain cooperation and coordination 2. Form supply chain stakeholders to responsible for cooperation and coordination	
Recommended actions	National Supply chain coordination and cooperation must be formed within the country.	3.2 Recommendations, Cooperate and Coordinate
	Regional Cross border must be smoothly flown by the stakeholders' cooperation and coordination.	

Issue 5.2: Government work with professional logistics service providers (LSPs)

Topic	Details	Remark
Guiding questions	1. What are the standard operating procedures (SOP) for business partners to comply with regulations? 2. Are LSPs trained for handling and transport?	

Topic	Details	Remark
	3. What is the meaning of seamless LSPs across the border?	
Potential challenges	<ol style="list-style-type: none"> 1. Training for LSPs on vaccine SOPs must be provided. 2. LSPs must be aware of effective seamless vaccine handling operations across borders. 	3.2 Recommendations
Recommended actions	National Professional LSPs should be trained and the number of professional LSPs should be increased.	
	Regional Cross-border LSPs must practice the same standard across the region.	

Policy area 6: Information technology readiness and cold chain visibility

Issue 6.1: Information technology facility and infrastructure

Topic	Details	Remark
Guiding questions	<ol style="list-style-type: none"> 1. Who provides the information technology facilities for both infrastructure and applications? 2. What is the method to deliver temperature monitoring via existing information technology facilities? 	
Potential challenges	<ol style="list-style-type: none"> 1. Lack of a clear host for infrastructure and the applications development. 2. Lack of standard operating procedures for temperature monitoring via existing information technology facilities. 	
Recommended actions	National <ol style="list-style-type: none"> 1. Identify the information technology needs for the provided infrastructure and its application. 2. Identify the owner of the tasks above and control their actions. 	

Topic	Details	Remark
	Regional Form a consortium for sharing information technology facilities and standard operating procedures for monitoring temperature.	3.2 Recommendations

Issue 6.2: Tracking and tracing

Topic	Details	Remark
Guiding questions	<ol style="list-style-type: none"> 1. Who owns the temperature track and trace tasks? 2. Who has the authority or is accountable for temperature track and trace in the cold chain? 3. Is there any regulation for the vaccine track and trace system? 	
Potential challenges	<ol style="list-style-type: none"> 1. Lack of an owner of the vaccine track and trace tasks. 2. Lack of an owner for authorized regulations for vaccine track and trace system. 3. Lack of international synchronization. 	3.1 Major challenges
Recommended actions	National <ol style="list-style-type: none"> 1. Identify the authorized functions which can provide vaccine track and trace monitoring. 2. Control temperature of the vaccine within a particular range. 	
	Regional <ol style="list-style-type: none"> 1. Set regulations and practices together for temperature control and track and trace system. 2. Form a consortium to synchronize the country-level track and trace system. 	

Issue 6.3: Develop national cold chain track and trace system

Topic	Details	Remark
Guiding questions	<ol style="list-style-type: none"> 1. Who ensures the temperatures remains within the acceptable range? 2. Who can be responsible for the out-of-range cold chain? 	

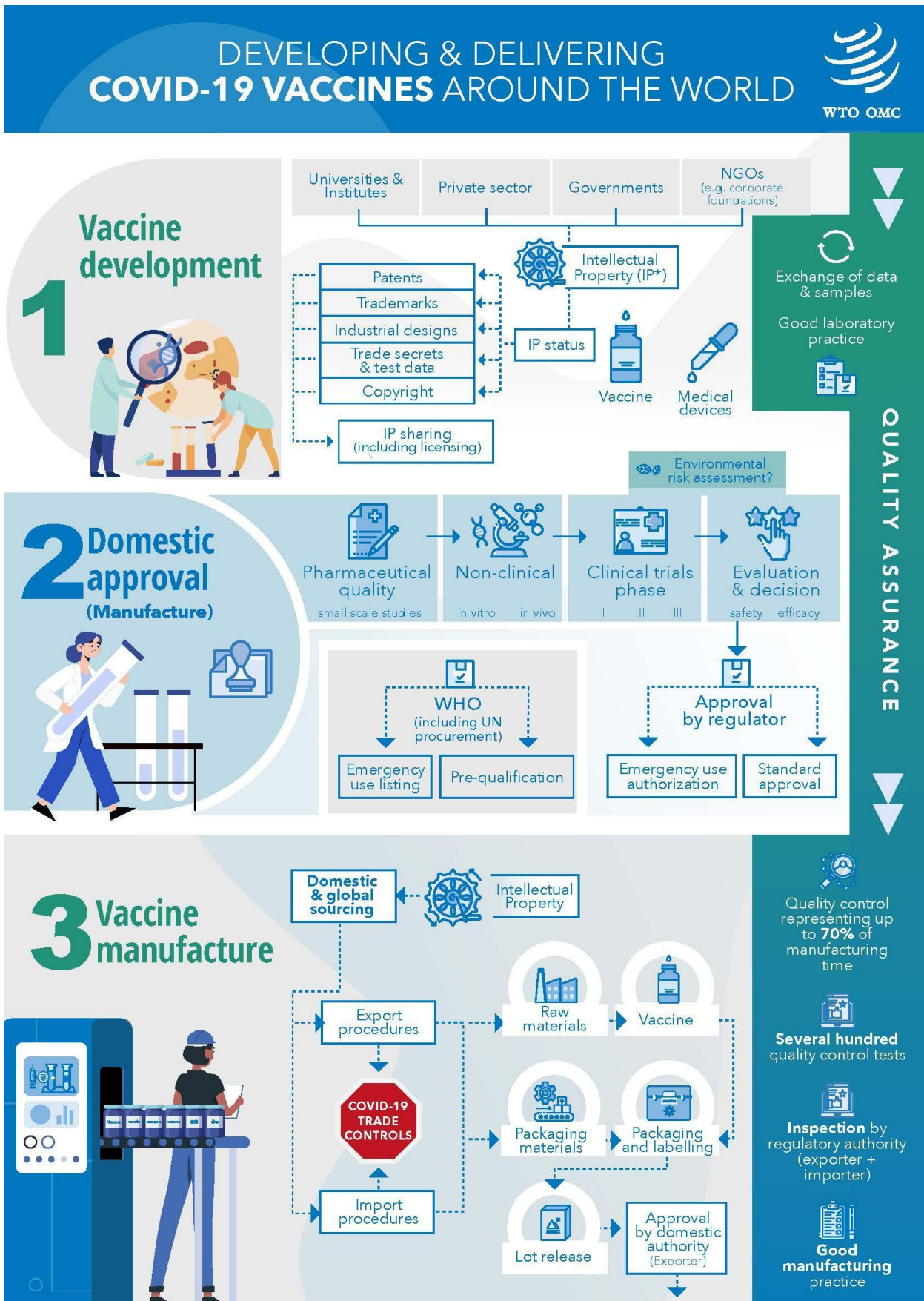
Topic	Details	Remark
Potential challenges	<ol style="list-style-type: none"> 1. Lack of knowledge about cold chains. 2. Lack of designated government function to control temperature throughout the supply chain. 	
Recommended actions	<p>National</p> <ol style="list-style-type: none"> 1. Raise awareness about cold chain needs and facilities. 2. Establish a national cold supply chain. 	3.2 Recommendations
	<p>Regional</p> <p>Apply a cold supply chain throughout the region.</p>	

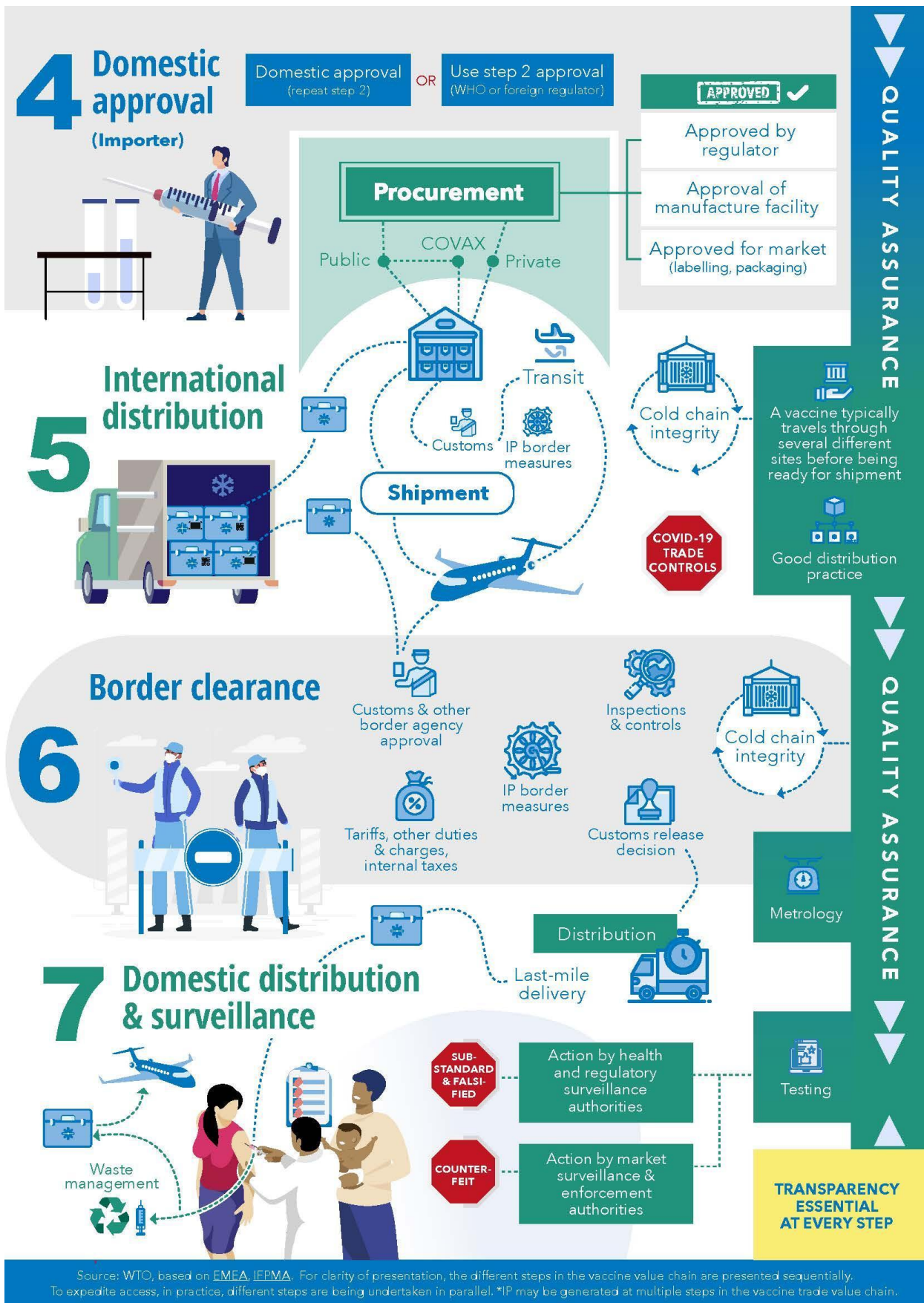
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Annex 1: Developing and delivering coronavirus disease vaccines around the world





(WTO, 2020)

Annex 2: COVID-19 vaccine storage and handling guides

1. Pfizer-BioNTech <https://www.cvdvaccine-us.com/16-up-yearsold/storage-and-handling>

1.1 Shipping and Handling guidelines: Medium Thermal Shipping Container <https://webfiles.pfizer.com/medium-shipping-container-brochure>

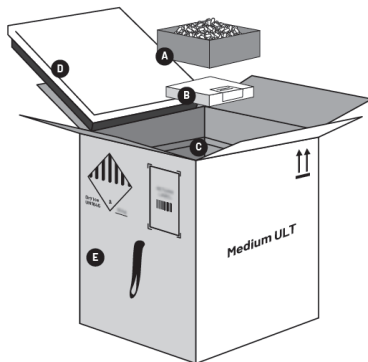
The following information is part of the guidelines.

CONTENTS AND PACKAGING

There are multiple types of thermal shipping containers and vial carton sizes, all with similar components.

The example shown below is for illustrative purposes only and may not exactly replicate the thermal shipping container you receive.

Be sure to read all instructions that are included with the thermal shipping container and its components.



The thermal shipping container you received may vary in weight and should be opened on the floor, as it may be heavy.

Item	Description
A DRY ICE POD	Holds the top layer of dry ice
B VIAL CARTONS	Each vial carton contains multiple dose vials and may appear different, depending on the size of your order
C VIAL CARTON COMPARTMENT	Fixed compartment within the thermal shipping container that holds the vial cartons
D FOAM LID	Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box
E THERMAL SHIPPING CONTAINER	Outer box of the thermal shipping container

GENERAL INFORMATION

This guide details user processes and procedures that must be followed upon receiving the vaccine.

The nature of this vaccine requires it to be kept at extremely low temperatures during shipment. To achieve this, multiple dose vials of the frozen vaccine are shipped in insulated thermal shipping containers containing dry ice. This allows the vaccine to remain frozen at this low temperature.

For information about specific temperature requirements and ranges to monitor, as well as dry ice safety, storage, and handling, please go to www.cvdvaccine.com.

FACTS ABOUT DRY ICE

Dry ice is the frozen form of carbon dioxide. When heated, most frozen solids melt to a liquid form, but dry ice transforms directly into a gas (sublimation). Dry ice sublimates at temperatures at or above -109°F (-78°C).

The main hazards of dry ice include **asphyxiation** and **burns**. Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen, causing asphyxiation. Exposed skin should be protected from contact with dry ice. To ensure appropriate controls are in place, review the enclosed Dry Ice Safety Data Sheet BEFORE accessing the contents from the thermal shipping container and consult with your Occupational Health Department.

HANDLING

Use caution when lifting the thermal shipping container, as it may be heavy. Depending on the amount of vaccine ordered, the thermal shipping container will vary in weight. Do not place anything on top of the thermal shipping container. Contact Pfizer Customer Service at 1-877-VAX-C019 (1-877-829-2619) immediately to communicate any issues.

Do not open the vial cartons or remove vials until you are ready for thawing or use. Visit www.cvdvaccine.com for further information.

You will need to take precautions when preparing to handle dry ice. Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, causing asphyxiation. Make sure you are wearing safety goggles or safety glasses with side shields and waterproof insulated gloves when handling dry ice.

To ensure all appropriate safeguards are in place, review the enclosed Dry Ice Safety Data Sheet, and consult with your Occupational Health Department.



Masks were worn due to pandemic; refer to SDS for dry ice protection.

In the event of vial breakage, damage, or leakage, to prevent cuts and exposure to the product, do not handle the vial with bare hands. Wear protective gloves and dispose of the vial pieces in a medical sharps container using forceps, tongs, or other appropriate tools.

RETURNING TEMPERATURE-MONITORING DEVICE AND THERMAL SHIPPING CONTAINER

The thermal shipping container may be used as temporary storage for up to 30 days from delivery.

After use, the thermal shipping container, including the Temperature-Monitoring Device, must be returned to the supplier to help Pfizer fulfill its commitment to reusable resources. Do not return vaccine or vaccine vials. Please see instructions below for proper disposal.

When the thermal shipping container is ready to be returned, and all the components are inside, seal it with tape. A preprinted return shipping label will be included inside the thermal shipping container or already adhered to the flap of the thermal shipping container. When coordinating the return of the thermal shipping container, apply the preprinted return shipping label over the existing shipping label. Some thermal shipping containers have a peel-away tape backing under the flaps to seal the container closed. When coordinating the return of that type of thermal shipping container, follow the instructions on the flap of the thermal shipping container to ensure the return label is facing outside. **Contact the carrier identified on the return label to arrange the return.**

Ensure Authenticity—Help Prevent Counterfeiting: Ensure the safety of the vaccine vials by limiting access to only authorized personnel. The location they are stored in must be secure and locked when not in use. To prevent counterfeits, discard vaccine vials in sharps containers and empty vial cartons as medical waste or deface or safely crush all materials so they cannot be reused. Remember, the vaccine is only available through government-authorized vaccination centers—such as doctors' offices, authorized pharmacies, outpatient clinics, community vaccination locations, and hospitals. The vaccine can only be administered by licensed healthcare professionals, or other individuals that are approved vaccinators, at government-authorized vaccination sites. Individual doses are not for sale.

Elements Required for Return

- Thermal shipping container and inner components
- Temperature-Monitoring Device
- Dry ice pod

1.2 Shipping and Handling guidelines: Single-Use Thermal Shipping Container

<https://webfiles.pfizer.com/single-use-thermal-shipping-container>

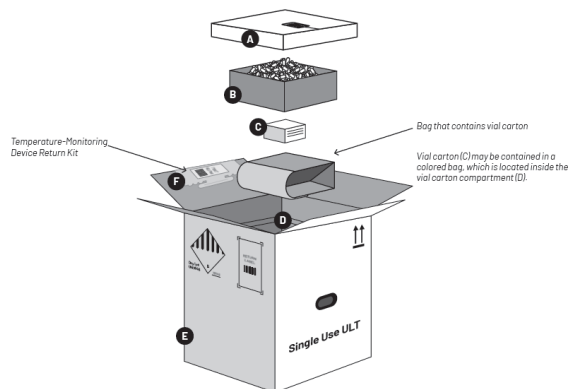
The following information is part of the guidelines.

CONTENTS AND PACKAGING

There are multiple types of thermal shipping containers and vial carton sizes, all with similar components.

The example shown below is for illustrative purposes only and may not exactly replicate the thermal shipping container you receive.

Be sure to read all instructions that are included with the thermal shipping container and its components.



The thermal shipping container you received may vary in weight and should be opened on the floor, as it may be heavy.

Item	Description
A FOAM LID	Removable top foam lid that includes an embedded Temperature-Monitoring Device
B DRY ICE POD	Holds the top layer of dry ice
C VIAL CARTONS	Each vial carton contains multiple dose vials and may appear different, depending on the size of your order
D VIAL CARTON COMPARTMENT	Area that holds the vial cartons within the Single-Use Thermal Shipping Container
E THERMAL SHIPPING CONTAINER	Outer box of the Single-Use Thermal Shipping Container
F TEMPERATURE-MONITORING DEVICE RETURN KIT	Kit used to return the Temperature-Monitoring Device that is embedded in the foam lid

RETURNING THE TEMPERATURE-MONITORING DEVICE

Important Return Instructions:

The **Temperature-Monitoring Device must be returned to the supplier** to help Pfizer fulfill its commitment to reusable resources. Remove the Temperature-Monitoring Device and the Temperature-Monitoring Return Kit from the Single-Use Thermal Shipping Container.

For complete instructions on how to return the Temperature-Monitoring Device using the included Temperature-Monitoring Return Kit, please refer to the **Return Instructions** downloadable resource available at www.cvdvaccine-us.com. Do not return the vaccine or vaccine vials.

For assistance on returns, you can contact:
US number: 1-701-540-4039
pfizer.logistics@controlant.com

After removal of the Temperature-Monitoring Device and Temperature-Monitoring Return Kit, the Single-Use Thermal Shipping Container should be disposed of at your facility.

1.3 Dry Ice Replenishment Sheet <https://webfiles.pfizer.com/dry-ice-replenishment>

The following information is part of the information sheet.

Thermal shipping container temporary storage dry ice replenishment instructions

IMPORTANT INFORMATION

- **24 Hours:** The thermal shipping container is qualified with a minimum of 18.5 kg or 20 kg of dry ice pellets (10 mm - 16 mm pellets), depending on the type of container received. The type of container is identified by the printed name on the outside of the box. Look for this name to determine whether the minimum kg of dry ice required is 18.5 kg or 20 kg, as follows:

If the outside of the container says:	The minimum kg of dry ice pellets is:
Cold Chain Technologies	18.5 kg
Softbox	18.5 kg
AEROSAFE	20 kg

If you are using the thermal shipping container as temporary storage, **the container must be opened, inspected, and replenished with dry ice within 24 hours of receipt**

- For the thermal shipping container to maintain the ultra-low temperatures required, it is recommended that the thermal shipping container itself be stored at 15°C to 25°C (59°F to 77°F)
- **To help maintain the level of dry ice and the temperature of the vaccine product:**
 - **2x/Day:** It is recommended that the thermal shipping container not be opened more than **2 times a day**
 - **3 Minutes:** The thermal shipping container should not be opened more than **3 minutes at a time**
 - **5 Days:** Replenish dry ice in the thermal shipping container **every 5 days**
- If more frequent openings are necessary, more frequent dry ice replenishment will be required. Be sure to replenish dry ice in the thermal shipping container at the end of business on days when the vaccination site will be closed the following day, such as weekends or holidays
- For information on handling the vial cartons and vials, please visit www.cvdvaccine-us.com
- **After use, the thermal shipping container and the temperature-monitoring device must be returned to the supplier to help Pfizer fulfill its commitment to reusable resources**

If using the thermal shipping container for storage (195-pack cartons only)

To help maintain the level of dry ice and the temperature of the vaccine product:

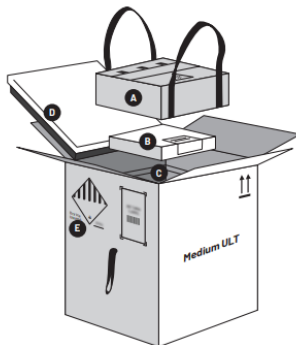
- 24 hours: The thermal shipping container must be replenished with dry ice within 24 hours of receipt
- 2x/Day: It is recommended that the thermal shipping container not be opened more than 2 times a day
- Minutes: The thermal shipping container should not be opened more than 3 minutes at a time
- 5 Days: The thermal shipping container should be replenished with dry ice every 5 days

DRY ICE REPLENISHMENT INSTRUCTIONS FOR MEDIUM THERMAL SHIPPING CONTAINERS

CAUTION: Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen, causing asphyxiation. Exposed skin should be protected from contact with dry ice. Wear safety goggles or safety glasses with side shields. To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents of the thermal shipping container and consult with your Occupational Health Department.

UNPACKING THE THERMAL SHIPPING CONTAINER

- 1 Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, causing asphyxiation.
- 2 Below is an overview of the components within the thermal shipping container for dry ice replenishment.



There are multiple types of thermal shipping containers and vial carton sizes, all with similar components.

The example shown here is for illustrative purposes only and may not exactly replicate the thermal shipping container you receive.

Be sure to read all instructions that are included with the thermal shipping container and its components.

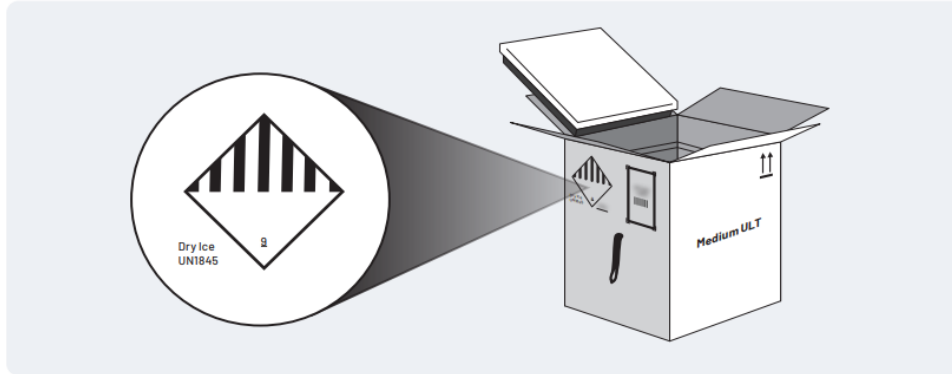
1.4 Return instructions for medium and single-use thermal shipping containers

<https://webfiles.pfizer.com/return-instructions>

The following information is part of the return instructions.

Returning the Thermal Shipping Container and Temperature-Monitoring Device

Note: Ensure the Dry Ice UN1845 markings and diamond-shaped Class 9 hazard label on the thermal shipping container are covered by placing a blank label over them in preparation for the return, as the container no longer contains dry ice.



Possible locations for blank stickers:

Blank sticker labels may be found on the back page of the Shipping and Handling Guidelines.

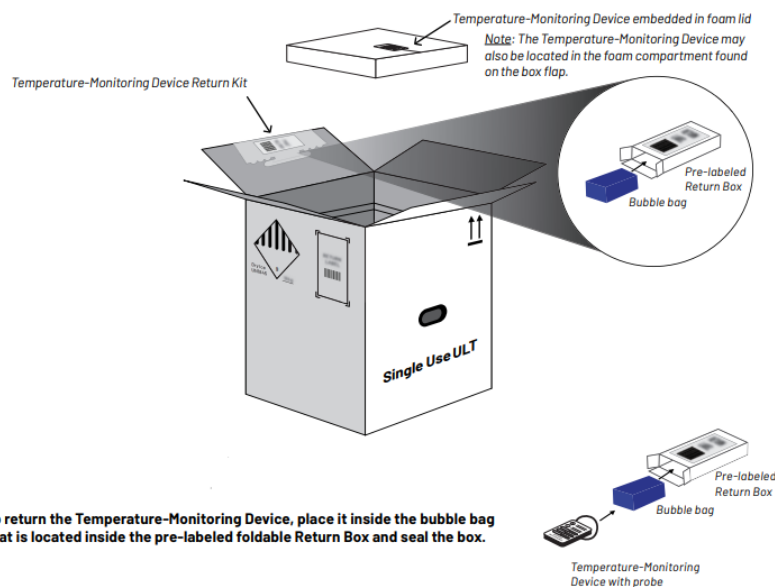
A label may also be found on the inside flap of the thermal shipping container. This label is to cover both the UN1845 markings and the original shipping label.

For assistance on returns, contact:
US number: +1701-540-4039
EU/UK number: +44 161-519-6199
pfizer.logistics@controlant.com




Returning the Temperature-Monitoring Device

The Temperature-Monitoring Device must be returned to the supplier to help Pfizer fulfill its commitment to reusable resources.

Remove the Temperature-Monitoring Device Return Kit from the flap of the Single-Use Thermal Shipping Container. Then, gently remove the Temperature-Monitoring Device with the probe from the foam lid (or foam compartment on box flap) and payload area. **After removal of the Temperature-Monitoring Device Return Kit and the Temperature-Monitoring Device with probe, and the dry ice is properly discarded, the Single-Use Thermal Shipping Container should be disposed of at your facility.** See instructions for Discarding Dry Ice and Disposal of Single-Use Thermal Shipping Container on page 5.



1.5 Vaccine Formulation/Presentation Guide [https://www.cvdvaccine-us.com/images/pdf/Vaccine Formulation Presentation Guide January%202022.pdf](https://www.cvdvaccine-us.com/images/pdf/Vaccine%20Formulation%20Presentation%20Guide%20January%202022.pdf)

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older ^{1,2}	12 years and older ³	5 through 11 years ⁴ ("Age 5y to <12y" on vial label)
Vial Cap Color			
Dose	30 mcg	30 mcg	10 mcg
Dose Volume	0.3 mL	0.3 mL	0.2 mL
Amount of Diluent Needed per Vial ⁵	1.8 mL	NO DILUTION	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)

Storage Conditions

Ultra-Low-Temperature (ULT) Freezer [-90°C to -60°C (-130°F to -76°F)]	9 months [†]	9 months [†]	9 months [†]
Freezer [-25°C to -15°C (-13°F to 5°F)]	2 weeks	DO NOT STORE	DO NOT STORE
Refrigerator [2°C to 8°C (35°F to 46°F)]	1 month	10 weeks	10 weeks
Room Temperature [8°C to 25°C (46°F to 77°F)]	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)
After First Puncture [2°C to 25°C (35°F to 77°F)]	Discard after 6 hours	Discard after 12 hours	Discard after 12 hours

^{*}Diluent: sterile 0.9% Sodium Chloride Injection, USP. Bacteriostatic saline or other diluents must NOT be used.

[†]Regardless of storage condition, vaccine should not be used past the 9-month expiry. For vials with expiry dates through February 2022: 6 months printed on the vial plus an additional 3 months. For vials with expiry dates after February 2022: vials will already reflect the 9-month shelf life.

[‡]Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.

Emergency uses of the vaccine have not been approved or licensed by FDA but have been authorized to prevent COVID-19 in ages 5+.

2. Moderna www.modernatx.com/covid19vaccine-eua/providers/storage-handling.pdf

Moderna COVID-19 vaccine storage and handling

The following information is part of the guidelines.

EMERGENCY USE AUTHORIZATION

The Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.

The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations: 5.5 mL and 7.5 mL. Primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation, preferentially using low dead-volume syringes and/or needles.

Frozen Storage

Can be stored frozen until expiration date*

-50° to -15°C (-58° to 5°F)

Do not store on dry ice or below -50°C (-58°F).
Store in the original carton to protect from light.

*Confirm vaccine expiration date by looking up the lot number at modernatx.com/covid19vaccine-eua



How supplied/storage and handling

Do not store on dry ice or below -50°C (-58°F). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2° to 8°C (36° to 46°F)

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (36° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (36° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C (36° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (36° to 46°F) until use.

Revised: Oct/20/2021

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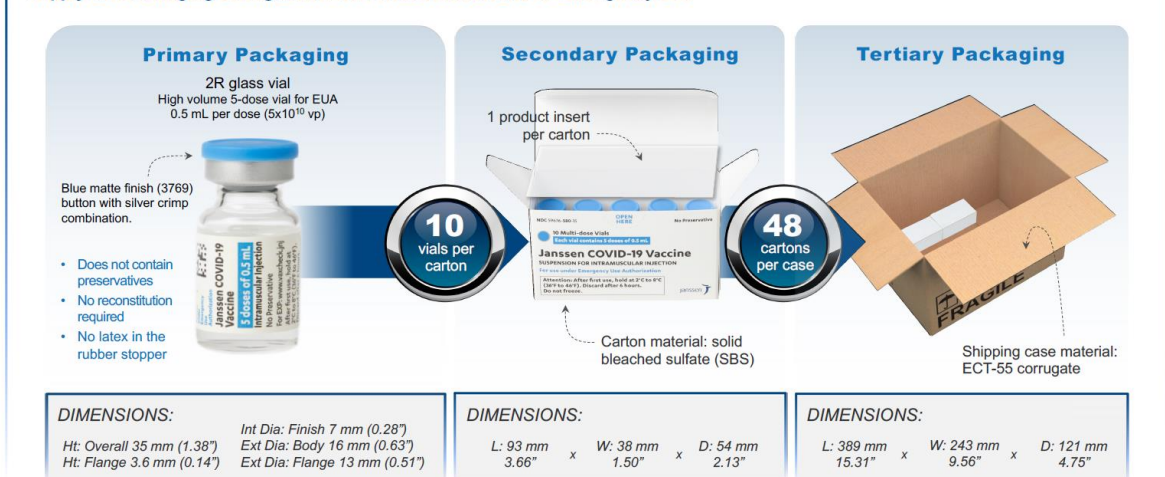
3. Janssen COVID-19 vaccine

3.1 Logistics Flashcard - Overview of pandemic supply logistics

www.janssencovid19vaccine.com/files/downloadables/cp-191118v11%20-%20Janssen%20COVID-19%20Vial%20and%20Logistics%20Flashcard.pdf

Janssen COVID-19 Vaccine

Supply and Packaging Configuration for Product Authorized for Emergency Use¹



2R = 2mL injection vial; EUA = emergency use authorization; Ext Dia = exterior diameter; Ht = height; Int Dia = interior diameter; vp = virus particles.

¹ Data on file, Janssen Vaccines & Prevention B.V.

Please read Important Safety Information on slides 6-10. Please read Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Including full EUA Prescribing Information available at www.JanssenCOVID19vaccine.com/EUA-Factsheet.

Janssen COVID-19 Vaccine

Storage and Handling for Product Authorized for Emergency Use¹

How Supplied

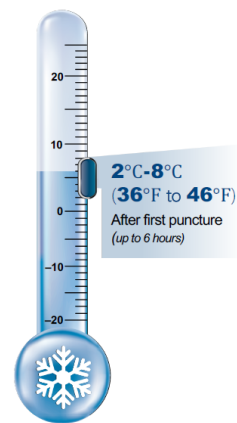
- Janssen COVID-19 Vaccine is supplied in a carton of 10 multi-dose vials. Each vial contains 5 doses. Do not pool vaccine from multiple vials
- The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F)
- If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). Do not refreeze once thawed

Storage Prior to First Puncture of the Vaccine Vial

- Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen
- Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours

Storage After First Puncture of the Vaccine Vial

- After the first dose has been withdrawn, hold the vial between 2°C to 8°C (36°F to 46°F) for up to 6 hours or at room temperature (maximally 25°C or 77°F) for up to 2 hours. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label
- Discard the vial if vaccine is not used within this time



EUA = emergency use authorization.

¹ Janssen COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full Prescribing Information. Janssen Biotech, Inc. <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>.

Please read Important Safety Information on slides 6-10. Please read Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Including full EUA Prescribing Information available at www.JanssenCOVID19vaccine.com/EUA-Factsheet.

3.2 The Janssen COVID-19 Vaccine. Storage, Dosage and Administration Guide

www.janssencovid19vaccine.com/files/downloadables/cp-202336v9%20-%20Janssen%20COVID-19%20Vaccine%20Storage,%20Dosage%20and%20Administration%20Guide.pdf



The Janssen COVID-19 Vaccine



Storage, Dosage and Administration Guide



How It's Supplied

The Janssen COVID-19 Vaccine is supplied in a carton of 10 multi-dose vials. A maximum of 5 doses of 0.5 mL can be withdrawn from the multi-dose vial. The vial stoppers are not made with natural rubber latex.



Storage and Handling

Storage Prior to First Puncture of the Vaccine Vial

- Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 36°F to 46°F (2°C to 8°C) and protect from light
- Unpunctured vials of the vaccine may be stored between 47°F to 77°F (9°C to 25°C) for up to 12 hours
- Do not store frozen

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 36°F to 46°F (2°C to 8°C). If vaccine is still frozen upon receipt, thaw at 36°F to 46°F (2°C to 8°C). If needed immediately, thaw at room temperature (maximally 77°F/25°C). Do not re-freeze once thawed.

- At room temperature, a carton of 10 vials will take ~4 hours to thaw
- At room temperature, an individual vial will take ~1 hour to thaw

Storage After First Puncture of the Vaccine Vial

- After the first dose has been withdrawn, hold the vial between 36°F and 46°F (2°C to 8°C) for up to 6 hours or at room temperature (maximally 77°F/25°C) for up to 2 hours
- Discard the vial if vaccine is not used within these times

Annex 3: Relevant measures used to facilitate and secure cross-border movement

Major measure	Sub-measure	Measure number
Coordination with other government agencies and stakeholders	Cooperate and coordinate with relevant government agencies: health authorities and supply chain stakeholders to get ready for complex task ahead	10
	Coordinate inspections by other government agencies and customs, if possible, to make it at the same time	6
Prioritization and facilitation the clearance	Prioritize process of export, transit and import to reduce any delay	1
	Provide mechanisms (import/export documentations) to easily identify the shipments	2
	Provide special procedures for authorized/recognized supply chain actors	3
Control of risks and others	Apply risk-based control and perform examinations on shipments only at the appropriate time and place	4
	When an examination is deemed necessary, perform non-intrusive inspections to the extent possible	5
	Take appropriate measures to prevent crime and to address the threat of sub-standard or counterfeit products.	12

Source: WCO, 2021.

Several good practices from the Asia-Pacific region and outside the region are given below (WCO, 2021).

Coordination with government agencies and stakeholders

Measures 10 and 6:

Australian Border Force

The ABF formed a Joint Planning Group (JPG) in November 2020 to unify the planning for border agencies accountable for vital COVID-19 commodities to safeguard the Australian people while ensuring border protection procedures remain adequate to detect illegal versions of the vaccine.

The JPG looked at whether variables help or impede the seamless flow of critical products across borders. The JPG allowed ABF and other government agencies to merge customs, biosecurity, and health-related permissions – as well as eliminate obstacles – to ensure optimum convenience for COVID-19 vaccines. Government agencies and business worked on test runs utilizing dummy shipments provided by a vaccine producer even before vaccinations arrived in Australia, allowing stakeholders to fine-tune the procedure.

Furthermore, the Australia's Therapeutic Goods Administration and the Department of Health had led an interaction between pharmaceutical producers and importers, while the Australian Border Force and the Department of Agriculture, Water and the Environment provide information on import regulations at the border. This strong collaboration between government and business created a high degree of coordination on delivery schedules and broad knowledge of vaccination movements among all parties.

The World Customs Organization (WCO) and the Department of Health, in collaboration with COVID-19 vaccine producers, are now hosting a series of training sessions for operational locations.

Customs Administration of India

The Central Board of Indirect Taxes and Customs, and the Central Drugs Standard Control Organization are the national agencies in charge of inspecting and clearing COVID-19 vaccine parcels for export and import and ensuring safe and secure management.

The Customs Administration of India has built a single window for electronic communication between customs and other partner government agencies such as the Central Drugs Standard Control Organization. The Joint Secretary (customs) has been designated as the focal entity for expedited clearance of COVID-19-related imports at the national level. Locally, focal persons at ports are designated to coordinate customs clearance. Their contact information is available on the website of the Customs Administration of India, which offers a toll-free hotline and an email address.

Prioritization and facilitation the clearance

Measures 1, 2 and 3:

Australian Border Force

The ABF works towards immediate vaccine clearance without unnecessary discontinuity. The ABF anticipates obtaining authorized status for goods that need a reference to experts in the Therapeutic Goods Administration within the following time frames:

2 hours from time of referral for cold storage;

24 hours from time of referral for non-cold storage.

Customs Administration of India

On arrival of imported COVID-19 vaccinations, the customs clearance procedure is completed in less than 30 minutes.

Customs Administration of the Dominican Republic (outside the Asia-Pacific region)

The officers of the customs offices were directed by a circular dated 11 February 2021 to expedite and treat the vaccines against COVID-19 with priority, without imposing tariffs, taxes or customs service fees.

Customs Administration of Peru (outside the Asia-Pacific region)

By engaging with various actors, necessary recommendations are able to be made for the import of vaccines. This procedure allows us to have an advantage in terms of follow-up. Similarly, vaccine clearance has been reviewed to guarantee not just speed, but also regulatory support for the right destination, which simplifies and speeds up the procedures.

The approximate time for the release of imported COVID-19 vaccines upon arrival in Peru is 15 minutes.

Control of risks and others

Measure 4, 5 and 12:

Customs Administration of Argentina (outside the Asia-Pacific region)

Due to the complexity of the items, Ezeiza Customs has specialized in dealing with employees who have the requisite knowledge and competence to carry out the appropriate processes in these circumstances, as well as cold chain, the handling of dry ice, and the aptitude for the use of X-ray systems (scanners) depending on their characteristics. The verification procedures are coordinated to be carried out at the importer's or exporter's facilities, allowing for the discharge of goods if necessary, due to storage conditions at extremely low temperatures (below -70°C) and their packaging in particular containers.

Australian Border Force

The Joint Planning Group, which also manages ongoing risk mitigation, conducts a risk assessment procedure for the Australian Border Force.

Customs Administration of India

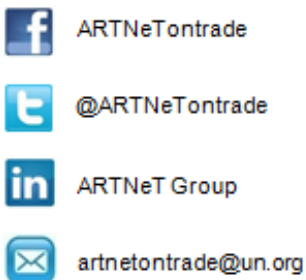
The Customs Administration of India has adopted an automated risk management system that employs risk-based selectivity principles to perform inspection and testing by government agencies such as the Central Drugs Standard Control Organization, whose risk criteria are also linked to the system.



The Asia-Pacific Research and Training Network on Trade - ARTNeT - is an open network of research and academic institutions and think-tanks in the Asia-Pacific region. Since its inception, ARTNeT aims to increase the amount of high quality, topical and applied research in the region by harnessing existent research capacity and developing new capacities. ARTNeT also focuses on communicating these research outputs for policymaking in the region including through the ARTNeT Working Paper Series which provide new and policy-relevant research on topics related to trade, investment and development. The views expressed in this publication are those of the authors and do not necessarily reflect the views of the United Nations and ARTNeT secretariat or ARTNeT members.

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