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Operational Guidelines for the Facilitation of Situationally Critical Medicines and Vaccines

COVID-19 Vaccine Facilitation

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

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Coordinated Border Management

Early stages

Establish a Coordination Group

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

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

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

Strategic communication

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

Mapping importation pathways

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

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

Training and documentation

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

Customs administrations should develop process maps for identified importation pathways for the use of frontline officers in ports expected to receive vaccine shipments. Process maps can enhance frontline

officer awareness and remove ambiguity in border clearances, reducing risk of unnecessary delays for critical supplies.

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

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

Process testing

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

Pre-shipment

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

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

Ensuring expedited border clearance

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

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

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

Pre-shipment Checklist

- Establish a coordination group involving border and health agencies

Through the coordination group, Customs administrations should confirm:

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

Illicit Vaccines

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

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

Border Protection Measures

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

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

Intervention

Customs administrations should aim to identify and mitigate threats by supply chain actors engaged in the importation of illicit vaccines. Before and at the border, Customs officers should assess, triage and refer threats and supply chain actors of concern. Engagement with medicine and vaccine suppliers, supply chain operators and Customs brokers involved in the importation pathway will assist with the development of

targeting profiles to identify suspected illicit shipments. Customs administrations should aim to leverage their domestic and international intelligence sources to combat shipments of illicit vaccines.

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

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

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

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

At Border

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

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

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

Expedited Facilitation

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

Some WCO Members are experimenting with providing facilitation for vaccines similar to what they provide for Authorized Economic Operators. Others are using 'express' lanes at their borders to ensure vaccine shipments get priority clearance.

At Border Checklist

Through the coordination group, Customs administrations should:

- Act quickly upon receipt of advice that a shipment is imminent.
- Alert frontline Customs officers at the relevant port of arrival/border crossing to ensure they are able to identify the shipment (including the vessel/vehicle, expected time/date of arrival, consignment number etc).
- Confirm Health and Agriculture agencies have approved any relevant permits.
- Confirm shipment meets revenue and security requirements.
- Ensure any inspections/scanning is done in accordance with the Manufacturer's requirements and in a manner that does not compromise safety.
- Once the Customs administration has completed all of the above, it should aim to provide fastest possible customs clearance, including tracking the shipment, facilitating it through an 'express' lane (if available), removing any 'holds' and escalating any issues to the coordinating group for rapid resolution.

Targeting illicit vaccines at the border

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

Cooperation against illicit vaccines

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

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

Post-Border

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

Post-Border Checklist

Through the coordination group, Customs administrations should:

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

Referring Illicit Vaccines

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

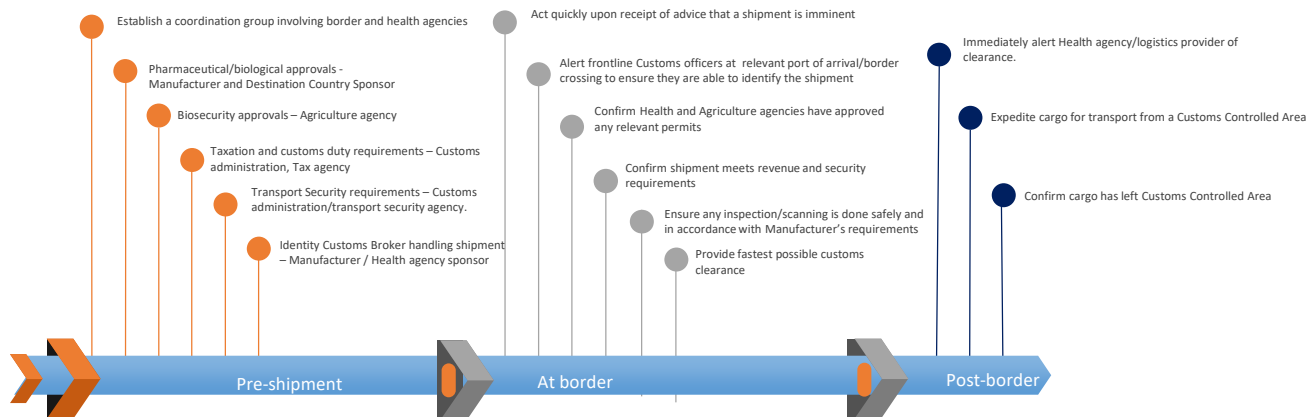
Seized shipments should be appropriately handled in accordance with national requirements (i.e. destroyed, provided to Health and/or other Law Enforcement agencies for sampling and analysis, etc.). Customs administrations should also aim to notify international counterparts of the nature of the detection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

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

Process Flow

Customs to check approvals from:

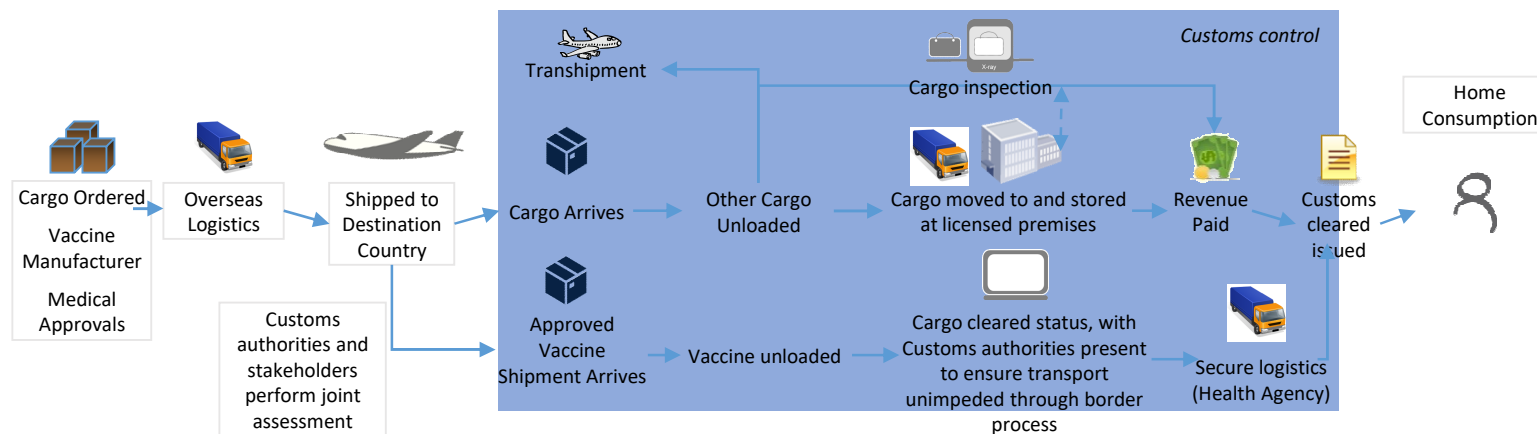
- Biosecurity
- Health
- Transport security



Stakeholders

- Customs administration
 - Organised through coordination group
- Police Administrations
- Health agency
 - Pre-negotiated supply
 - Secure logistics tracking
- Foreign Affairs – Transhipment to foreign partners
- Department of Industry
- Transport Security
- Aviation Authority
- Industry;
 - Depot/warehouse employees
 - Customs broker
 - Importer
 - Freight forwarders

Border clearance



Intelligence Sources

- Customs administration Intelligence Threat Assessments
- Vaccine Manufacturers Threat Assessments
- INTERPOL Op VIGILANT referrals – Offshore detections
- WCO Op STOP II referrals – Offshore detections

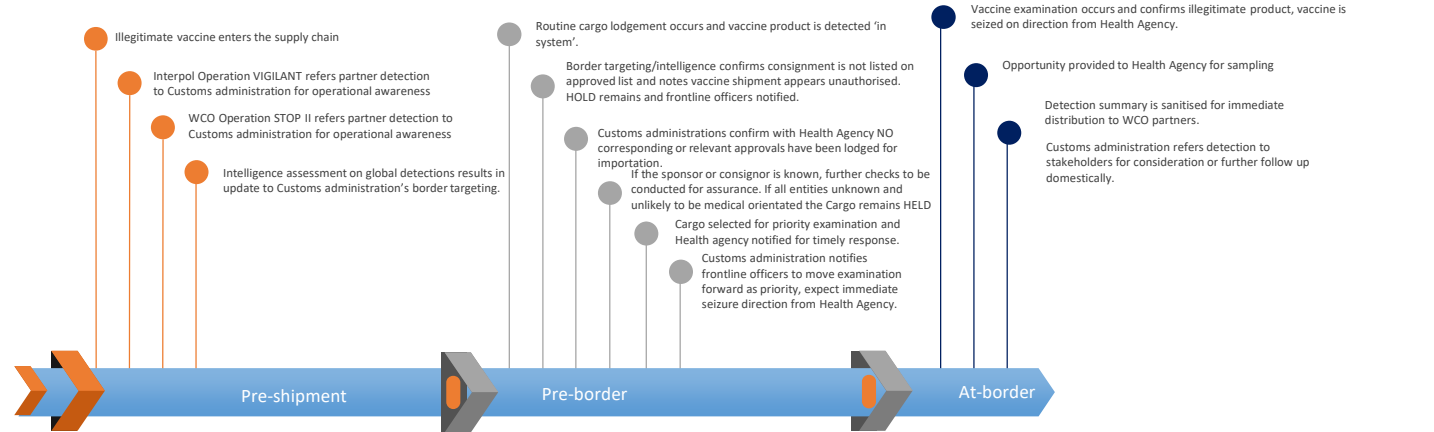
Enhanced measures to give assurance to efficient the COVID-19 vaccine importation

- Establishment of a coordination group that fosters and encourages an environment of transparent information sharing among all relevant agencies in the vaccine importation stream (from vaccine manufacturers to delivery to secure supply chain post border clearance).
- The importation of biological vaccines is complex and requires regulatory oversight from multiple stakeholders across Government.
- The process map enhances the routine importation process for medicines and vaccines by allowing importation approval functions from across Government to be aligned prior to the goods interacting with the border continuum.

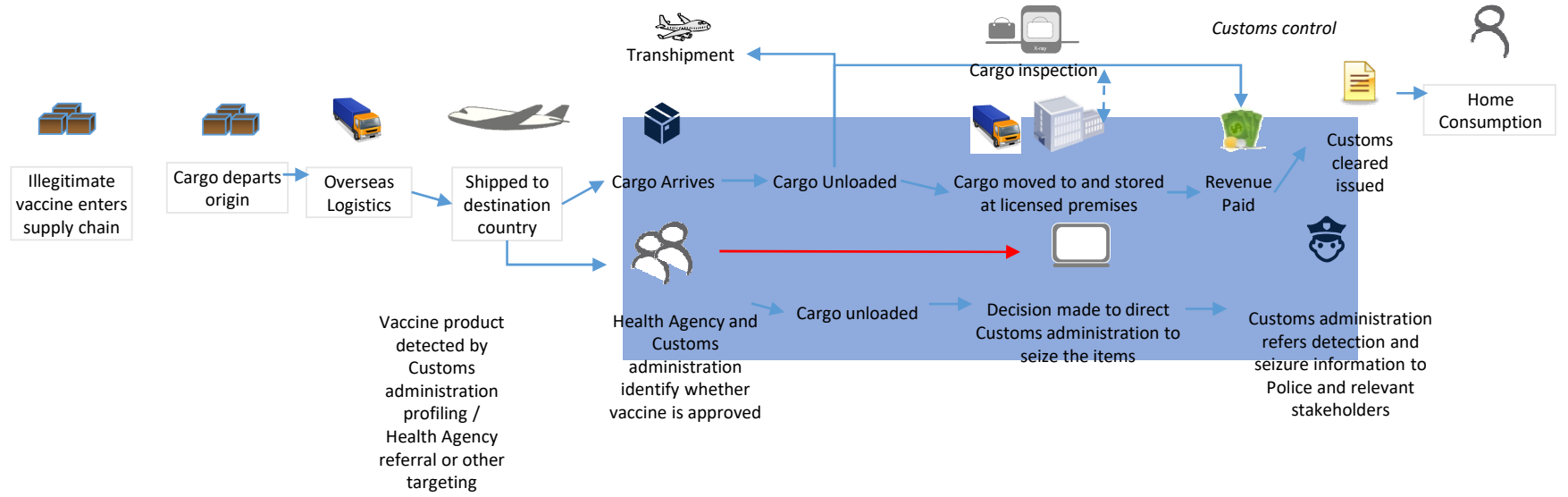
Approvals



Process Flow



Border clearance



Stakeholders

- Customs administration
 - Coordinated through Intelligence centre
- Police Administrations
- Health agency
 - Pre-negotiated supply
 - Secure logistics tracking
- Foreign Affairs – Transshipment to foreign partners
- Department of Industry
- Transport Security
- Aviation Authority
- Industry;
 - Depot/warehouse employees
 - Customs broker
 - Importer
 - Freight forwarders

Intelligence Sources

- Customs administration Intelligence Threat Assessments
- Vaccine Manufactures Threat Assessments
- INTERPOL Op VIGILANT referrals – Offshore detections
- WCO Op STOP II referrals – Offshore detections

Establishment of a coordination group comprising of representation from across Customs administrations and relevant stakeholders such as Health Agencies.

The coordination group will support Customs administrations' targeting efforts through consolidating the flow of intelligence related material and introducing a single view of the threat of illegitimate vaccines.

Targeting

'VACCINES'

Vaccines are categorised as medicines. Customs administrations work with Health Agencies to have understanding on how medicines must be entered for importation.

Customs administrations and Health Agencies

Customs administrations effect border controls on therapeutic goods in accordance with Health Agencies.

Routine Biological Profiling / Targeting

Health Agencies have robust profiling solutions to identify illegitimate biological products and identify products that may have certain permit conditions that need to be evaluated prior to border clearance.

Additional Customs administrations Profiling

Target 1: VACCINES

Goods described broadly as 'vaccines' – excluding approved sponsors for health vaccines, and veterinarian vaccines. Will detect broad vaccines from unapproved entities

Target 2: 'COVID-19' VACCINES

Goods described specifically as 'COVID-19 vaccines' – only excludes approved sponsors for COVID-19 vaccines and will detect unauthorised importations.

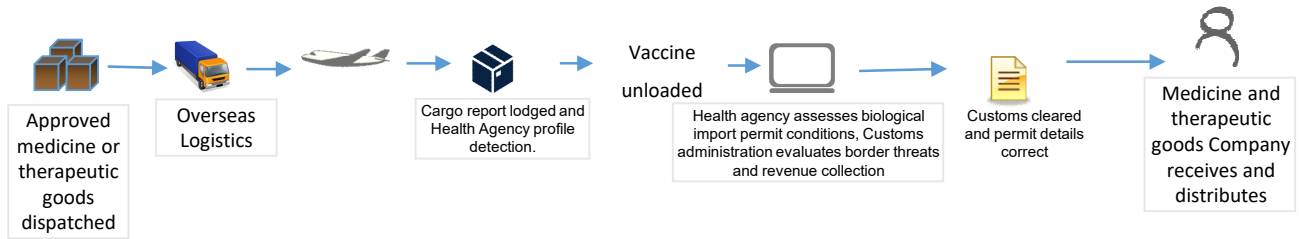
Alerts: Referrals received and validated

Information from partners will be assessed and where relevant border alerts placed at the entity level.

Real-time assessments

Information from partners on observed detections will be provided in visual form for the aid of frontline officer selection.

Routine medicines and therapeutic goods importation process



Required approvals before vaccine Importation



Health Agency approved providers

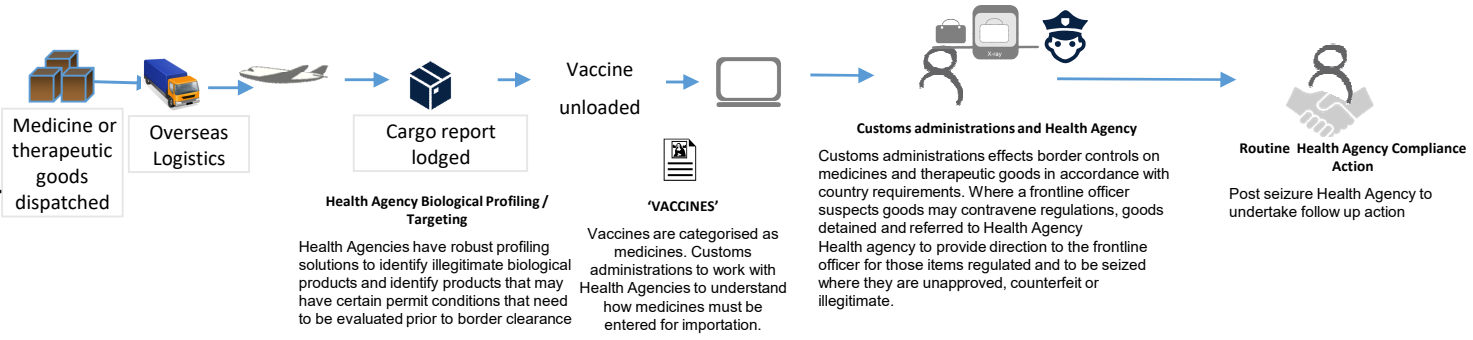
- Pre-negotiated contracts
- Approved manufacturers
- Medical product approvals and sponsors
- Permit approval required
- Medical product approvals where the product is modified organism



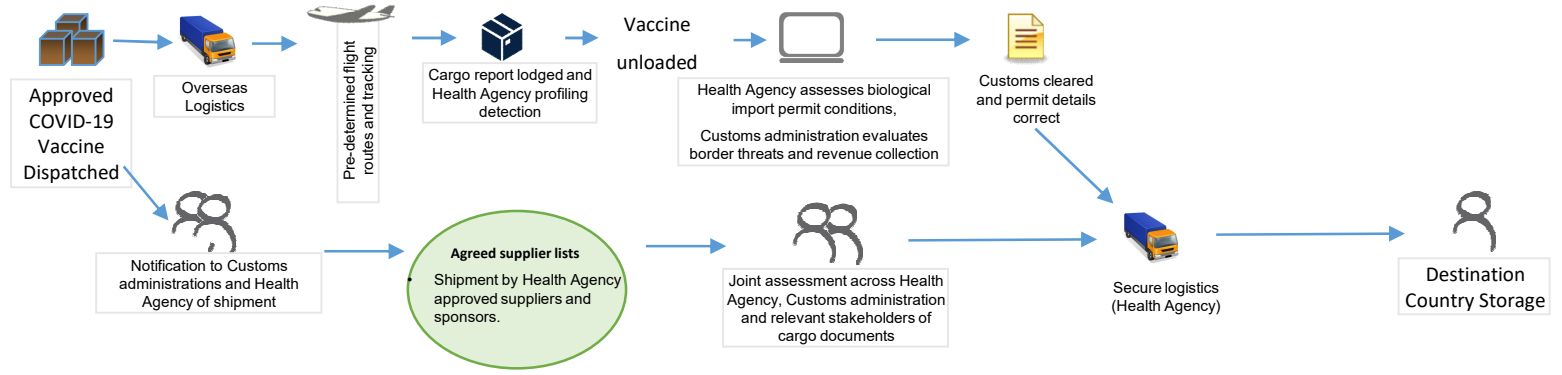
Transport Security

- Does the shipment fall into an existing prohibition category for bio-organisms?

Routine therapeutic goods intervention process



Additional COVID-19 Measures to support expedited clearance



Additional COVID-19 Border Measures

Enhanced Intelligence Integration
Establishment of a coordination group with representation from across Customs administrations and relevant stakeholders such as Health Agencies. The joint working group will support Customs administrations' targeting efforts through consolidating the flow of intelligence related material and introducing a single view of the threat of illegitimate vaccines.

Additional Customs administration Measures

Targeting Illicit Vaccines
Customs administrations should implement new profiles to target, identify and intercept counterfeit or illicit vaccines imported through all modes of transport. The profiles should be designed carefully to avoid delaying legitimate shipments that are on an approved vaccine list.

Additional Policing Referral
Customs administrations should establish a referral process with Police to jointly assess illegitimate detections for any identified criminal aspects and, where appropriate, pursue investigative options.