Australian Border Force
25 January 2021
Australia's Approach to Facilitating COVID-19 Vaccines

1. Which of the measures outlined in the WCO Resolution on the role of Customs in facilitating the cross-border movement of situationally critical medicines and vaccines has your Customs administration implemented in practice? Please provide details of the implementation.

The Australian Border Force (ABF) has considered all 12 measures to support the expedient importation of COVID-19 essential goods including vaccines.

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

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

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

2. Was any relevant information concerning the Customs clearance of COVID-19 vaccines and the goods and devices used for their shipment and transportation, made publicly available, for example on the Customs administration's web-site? If yes, please provide a URL. If not made publicly available, was relevant information provided to the supply chain stakeholders – manufacturers, exporters, importers, logistics providers, etc.?

The TGA has publicised the vaccine approval process at https://www.tga.gov.au/covid-19-vaccine-approval-process.

Given the limited number of approved vaccines and importers, the ABF has worked directly with those importers rather than publishing information online.

3. Was any dedicated guidance made available to the field Customs officers with regard to the Customs clearance of COVID-19 vaccines for export, transit and import, as well as the goods and devices used for the vaccines' shipment and transportation? If yes, please provide details on how the guidance was disseminated.

The ABF has developed a number of procedures that maps the importation pathway for COVID-19 vaccines to enhance ABF officers' understanding of the processes and to remove ambiguity in the border clearance process. This includes information on the handling of vaccines requiring cold storage, noting the dangers of dry ice.

In addition to enhancing awareness of the importation pathways, the ABF has developed specific guidance material on the identification, intervention and seizure of therapeutic goods suspected to be illegitimate or illicit.

4. Has any training been provided to the staff of your Customs administration in anticipation of the COVID-19 vaccines distribution effort, for example training for handling of time- and temperature-sensitive items, training for handling of dangerous goods (e.g. dry ice), training for identifying the COVID-19 vaccines on import or export documentation?

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

5. What mode of transport was used for the exportation/importation of COVID-19 vaccines from/into your country?

The ABF has planned for importation through dedicated air cargo freighters. As the storage requirements and shelf life of the imported vaccine changes, sea cargo could be used for importation. International mail is not viable, and targeting efforts against illicit vaccines focuses on mail clearance.

6. What are the documents required for the exportation of COVID-19 vaccines from your country? *(applies to the Members exporting COVID-19 vaccines)*

N/A

7. Which national authorities are responsible for the checking and clearing the COVID-19 vaccines shipments for exportation? How is the cooperation between these authorities arranged? *(applies to the Members exporting COVID-19 vaccines)*

N/A

8. Is there any exchange of information/data between the Customs authorities of the exporting country and the Customs authorities of the importing country? What type of information is exchanged? How is the exchange of information arranged/regulated?

N/A

9. Was the Customs transit procedure used for the COVID-19 vaccines imported into your country? If yes, why/what was the rationale?

Goods imported to Australia from Europe via air or sea generally transit through ports/airports in other countries.

Conscious of the importance of Australia as a transit hub for our Pacific neighbours, the ABF is considering transhipment/transit procedures. The ABF will be in a position to implement these in the near future.

10. Does your administration implement risk management techniques related to the cross-border movement of COVID-19 vaccines?

The ABF undertakes a risk assessment process through the JPG, which also oversees ongoing risk mitigation.

11. What are the documents required for the importation of COVID-19 vaccines in your country?

- A sponsor (usually a pharmaceutical company) must first submit a provisional determination application.
- The TGA will assess the application against specific eligibility criteria, such as the nature of preliminary clinical data, evidence of a plan to submit comprehensive clinical data, and the clinical need.
- To register a COVID-19 vaccine in Australia, a sponsor is required to submit a comprehensive dossier that includes specific information on clinical studies, non-clinical/toxicology studies, chemistry, manufacturing, risk management and other information.
- The TGA may agree upfront to accept a limited number of rolling submissions of data during the evaluation phases, as well as reports from comparable overseas regulators.
- The TGA will make a preliminary assessment whether to accept the submission for evaluation and will notify the sponsor.
- If the TGA grants provisional determination, the sponsor is then eligible to apply for provisional registration of the vaccine in the Australian Register of Therapeutic Goods (ARTG).
- Customs documentation is then completed electronically through the ABF's Integrated Cargo System, our customs single window.

12. Which national authorities are responsible for the checking and clearing the COVID-19 vaccines shipments for importation? How is the cooperation between these authorities arranged?

Cooperation among the following agencies is handled through the JPG.

- ABF
- TGA
- Department of Agriculture, Water and the Environment
- Office of Gene Technology Regulator (OGTR)

13. If information is available, what was the time required for the release of the COVID-19 vaccines shipments imported into your country?

The ABF is aiming to clear the vaccines immediately without unnecessary interruption. For goods requiring a referral to specialists in TGA, the ABF is expecting to have cleared status within:

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

14. Has your government considered duty and tax waivers for the importation of COVID-19 vaccines?

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

15. Please include any other relevant information you wish to share.

For further context on COVID-19 vaccines, please refer to:

- the Department of Health web page https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/about-covid-19-vaccines/australias-vaccine-agreements
- the TGA web page https://www.tga.gov.au/covid-19-vaccine-approval-process