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LAWYERS  
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COVID-19  
AND THE  
JOURNEY TO  
RECOVERY



Exploring the Legal and Practical Issues  
in the Transport of Vaccines

RAJAH & TANN ASIA

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# INTRODUCTION



It has often been said that the world is getting smaller, with advancements in technology reducing the boundaries and distances of global transport, trade and communication. However, all journeys have their obstacles, and the events of the past few years have been a clear demonstration of this.

In recent times, the COVID-19 pandemic has been the unifying and defining experience of the international community. Cross-border transport of goods and people has been greatly curtailed, with tighter border restrictions and reduced frequency of passage. Countries have had to change the way they work and move.

The global journey appears now to be entering smoother waters, with countries headed more confidently towards stabilisation and recovery. One of the key components of the recovery plans being adopted by most countries is a concerted drive to provide vaccinations for their citizens and residents. The use of the vaccines reduces risk of transmission and chances of hospitalisation and serious symptoms resulting from COVID-19 infection. As such, it should be expected that vaccines will continue to be in high demand across the globe.

The distribution of vaccines remains a profound challenge in the continued fight against COVID-19. How are they being transported? What are the transport requirements of specific vaccines? What are the relevant regulatory and contractual issues that may arise in the transport of vaccines? These are the questions that are of particular relevance to members of the shipping and transport industry, against the backdrop of still fraught supply chains, globally.

Currently, vaccines are mainly being transported by air. However, the volume of vaccines being distributed, which continues to increase, is expected to exceed existing air freight capacity. This means sea and land transportation will become increasingly relevant in the medium and long term as the COVID-19 situation as well as vaccine production stabilises.

The transport of vaccines is further complicated by the fact that most vaccines must be stored at very low temperatures, require deft handling, and have limited shelf-life. This not only requires transporters and handlers to be well-versed in

cold-chain logistics, it also calls for close cooperation and coordination between those involved at the different stages of the distribution journey.

In this article, we take a look at these issues, particularly from the perspective of the Southeast Asian region from which we have invited invaluable input from the Rajah & Tann Asia network member law practices. The article explores the following:

- (a) Transportation requirements for selected vaccines;
- (b) Practical issues in the various stages of the transport of vaccines;
- (c) International guidelines or standards governing the transport of vaccines; and
- (d) Contractual issues which may arise in the transportation process.

*This publication is up to date as of April 2022.*

# TRANSPORT REQUIREMENTS OF VACCINES

Since the start of the pandemic, pharmaceutical companies have sought to develop vaccines that are effective against the threat of COVID-19. To date, there are a growing array of COVID-19 vaccines available, each with differing countries of origin and exacting storage/transportation requirements. Further, each country has approved the use of a different range of vaccines.

The table below analyses the transport features of some of the main vaccines currently in use in the Southeast Asian region.

Vaccine	Place of Manufacture	Storage/Transportation Requirements	Shelf Life
<b>Pfizer-BioNTech</b>	United States Europe	<ul style="list-style-type: none"> <li>Vaccine should be transported in ultra-cold freezer between -80°C and -60°C.</li> <li>The vaccine may be stored in the freezer between -25°C and -15°C for up to 2 weeks.</li> <li>If local redistribution is needed, the vaccine may be transported at -90°C to -60°C.</li> <li>Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C for up to 30 days.</li> <li>Once thawed, the vaccine should not be refrozen.</li> </ul>	<ul style="list-style-type: none"> <li>Ultra-low temperature freezers: 6 months</li> <li>Refrigeration units: 30 days</li> </ul>
<b>Moderna</b>	United States Europe	<ul style="list-style-type: none"> <li>Vaccine should be transported frozen between -50°C and -15°C.</li> <li>The vaccine may be stored in the refrigerator between 2°C and 8°C for up to 30 days.</li> <li>Once thawed, the vaccine should not be refrozen.</li> </ul>	<ul style="list-style-type: none"> <li>Standard freezers: 6 months</li> <li>Refrigeration units: 30 days</li> </ul>
<b>Janssen (Johnson &amp; Johnson)</b>	United States Europe India South Africa	<ul style="list-style-type: none"> <li>Vaccine should be transported at refrigerated temperatures between 2°C and 8°C.</li> </ul>	<ul style="list-style-type: none"> <li>Refrigeration units: 6 months</li> </ul>
<b>Oxford-Astrazeneca (Covishield)</b>	United States Europe India Australia	<ul style="list-style-type: none"> <li>Vaccine should be transported at refrigerated temperatures between 2°C and 8°C.</li> </ul>	<ul style="list-style-type: none"> <li>Refrigeration units: 6 months</li> </ul>

<b>Sinopharm</b>	China UAE	<ul style="list-style-type: none"><li>• Vaccine should be transported at refrigerated temperatures between 2°C and 8°C.</li></ul>	<ul style="list-style-type: none"><li>• Refrigeration units: 24 months</li></ul>
<b>Sinovac</b>	China Brazil Egypt	<ul style="list-style-type: none"><li>• Vaccine should be transported at refrigerated temperatures between 2°C and 8°C.</li></ul>	<ul style="list-style-type: none"><li>• Refrigeration units: 24 months</li></ul>

# PRACTICAL ISSUES IN TRANSPORT OF VACCINES

The transport of vaccines from manufacturer to end user in the quantities urgently needed is no mean feat. It potentially involves multiple forms of transport, various points of handover, and interim storage, and is further complicated by the involvement of numerous separate participants in the transportation process. Combined with the particular transport conditions required, it is imperative for the supply chain partners to have visibility of the practical issues at the various stages of transport.

The journey of a vaccine may involve the partners and follow the path set out below:



## Freight forwarders

- As the main organiser of the transportation process, the freight forwarder must plan the route of the vaccine, coordinate with the various agents and address the necessary logistics



## Airlines

- The main form of transport for vaccines is still via aircraft
- Airlines are in charge of the transport conditions of the vaccines on board the flight



## Ground handlers

- Once the vaccines reach the destination country, the ground handlers manage the movement of the vaccines from the plane/vessel to storage or further transport



## Airports

- Airports must facilitate the the movement of air travel, whether at the point of departure or arrival
- Airports may also have to address the appropriate storage conditions where necessary



## Customs

- The entry and exit of vaccines from a country's borders requires the cooperation of customs and border control



## Logistics providers

- Logistics providers are required to facilitate the last mile delivery of the vaccines to the relevant medical centres

Each supply chain partner has a critical role in the safe and effective transport of vaccines. At each stage, the participants must consider and address the transport conditions and timelines necessary to maintain the integrity of the vaccines. The issues to be considered may include the following:



# OVERVIEW OF GUIDELINES AND STANDARDS

## OVERVIEW

While the above sections have explored the practical issues in the transport of COVID-19 vaccines, supply chain partners should consider the regulatory issues that may arise as well, along with the corresponding legal consequences.

Whether the transportation process is governed by any legislation, regulation, or guidelines depends on the relevant jurisdictions where the vaccine is being transported from/to. While it is still not common for countries to have adopted bespoke legislation or regulation relating to the transport and storage of COVID-19 vaccines, certain jurisdictions have issued guidelines and standards that may be relevant.

In addition, international bodies have also published guidelines and recommended practices for the transport of COVID-19 vaccines. Supply chain partners should certainly take heed of these publications and assess the degree to which they are able to comply with the standards and processes contained therein.

## NOTABLE INSTANCES OF COUNTRY-SPECIFIC GUIDELINES IN THE ASEAN REGION

### Malaysia

- **Guidance on the Requirement to Import, Handle, Store and Distribute COVID-19 Vaccines in Malaysia** - Published by the Ministry of Health to provide guidance for those involved in the supply chain for COVID-19 vaccines. All such parties are required to adopt proper distribution and store management procedures.
- **Guideline on Good Distribution Practice** - Published by the National Pharmaceutical Regulatory Division to lay down the appropriate principles for those in the supply chain for pharmaceutical products.

### Singapore

- **Guidance Notes on Good Distribution Practice** - Published by the Health Sciences Authority to provide guidance for those involved in the storage, transportation and distribution of pharmaceutical products to ensure quality and integrity of the products.

### Thailand

- **Guideline on Storage and Transport of COVID-19 Vaccines** - Published by the Ministry of Public Health to provide guidance on ensuring that the procedures are in accordance with international standards.
- **Guidance Material for Transportation of COVID-19 Vaccines** - Published by the Civil Aviation Authority to assist and provide guidelines to entities that will participate in the movement of COVID-19 vaccines.

## Myanmar

- **National Deployment for Vaccination Program (NVDP)** - Developed by the Ministry of Health under the WHO Guidelines for developing a NVDP, for the transport and distribution of COVID-19 vaccines within the country.

## Cambodia

- **Good Distribution Practice and Good Storage Practice** - Issued by the Department of Drugs and Food on the distribution and storage of pharmaceutical products.

## Philippines

- **Good Distribution Practice and Good Storage Practice** - Issued by the Department of Health on the distribution and storage of pharmaceutical products.

## EXAMPLES OF INTERNATIONAL GUIDELINES AND STANDARDS THAT SHOULD BE CONSULTED ARE:

## ICAO Guidelines

- The International Civil Aviation Organisation has released its guidelines on the safe transport of COVID-19 vaccines on commercial aircraft.
- Identifies the specific areas related to the air transport of vaccines that may require action by the operator and regulator to facilitate safe transport.
- All ASEAN countries are member states.

## ITAA Guidelines

- The International Air Transport Association has released the Guidance for Vaccine and Pharmaceutical Logistics and Distribution.
- Summarises all the considerations to be taken into account for large-scale handling, air transport and distribution of vaccines.

## ASEAN Framework Agreement on Multimodal Transport

- Facilitates the movement of goods within ASEAN as well as between a Member Country and third countries by the five major means of transport.
- In force in Singapore, Cambodia, Indonesia, Lao PDR, Myanmar, Philippines, Thailand and Vietnam.

While the above guidelines address different segments of the transportation process and are pitched at varying standards, they do contain common themes in terms of the areas of concern and how these should be addressed. Supply chain partners should be guided by the relevant and applicable principles in the planning and conduct of their transport operations.

In the following section, we highlight some of the common principles detailed in these guidelines.



### Planning and procedure

- Policies and procedures setting out the responsibilities, processes and risk management principles should be clearly defined and maintained
- A risk based approach should be adopted in planning import, export, procurement, storage, transportation and distribution



### Packaging

- Proper and safe packaging of the vaccine must be ensured
- The identity of the vaccine should be clearly indicated on the packaging
- The packaging should display the handling and storage instructions of the vaccine



### Temperature control

- The temperature of the vaccine must be monitored at all stages of transit and storage via real time temperature monitoring device
- Proper storage must be provided to ensure the necessary temperature conditions for each type of vaccine



### Licences and approvals

- The necessary licences and approvals for the movement and distribution of the vaccine should be obtained, such as import/export licences and pharmaceutical licences
- Approval from supply chain partners should be obtained for the transport of dangerous goods and equipment (dry ice, data loggers)



### Facilities and equipment

- Storage facilities and transport equipment must be duly qualified (e.g. capacity, refrigeration, security)
- Storage and transport equipment should have temperature alarms and backup power systems



### Receiving and handling

- Packaging and handling instructions should be communicated at all stages of transport
- Identity and integrity of vaccines, as well as compliance with transportation conditions, should be verified upon receipt
- All personnel must be duly trained and briefed on the handling of vaccines

# CONTRACTUAL ISSUES IN THE TRANSPORTATION OF VACCINES

Despite the existence of various guidelines and standards, and even with the most meticulous of planning (with the best of intentions), it is inevitable that there will be instances where consignments of vaccines are damaged along the distribution line. This may lead to civil claims between the supply chain partners. When this happens, the parties have to determine how the loss is to be allocated, and what damages need to be paid.

The result of any claim will depend largely on the circumstances of the damage and on the provisions of the contracts governing the relationships between the supply chain partners. It is thus important for parties to comprehensively formulate their agreements to accurately reflect the intended allocation of foreseeable risks and obligations.

The transport and distribution of COVID-19 vaccines features some unique requirements as described in the earlier sections. As such, the relevant contracts may also require bespoke provisions, as opposed to template terms and conditions. In this section, we set out some of the provisions that supply chain partners should consider addressing their contracts. We also take a look at the legal issues that may arise in the event of a claim relating to damage occurring along the distribution chain.

## CONTRACTUAL PROVISIONS

### Conditions and warranties

- To ensure that counterparties are in compliance with transport and distribution standards, parties may wish to include them as conditions or warranties.
- Warranties may include: obtaining the necessary licences and approvals, providing the appropriate transport/storage conditions, observing the prescribed procedures, and compliance with applicable laws, regulations and guidelines.
- Conditions may include: timely delivery of the vaccines, delivery in suitable condition.
- Setting out the conditions and warranties provides a straightforward path for termination of contract or damages upon breach.

### Insurance

- Parties should address their minds to their respective insurance obligations, including the coverage and quantum of such insurance.
- The high value of each shipment means that insurance is particularly important in ensuring coverage of damages; insurers are often the parties footing the bill in such claims.

### Allocation and limits of liability

- Parties may allocate liability for any damage between themselves according to any prescribed causes of such damage.
- Parties may wish to include limitation clauses to limit the quantum of damages to an agreed sum.
- Parties may also wish to limit liability to exclude certain losses, such as consequential losses, loss of profits, business interruption, etc. (due to the potential wide scale of such losses).
- Given the conditions in which vaccines must be kept, delay, or damage due to delay, would be an area that should be provided for, e.g. a carrier would understandably wish to exclude liability for it, but the shipper or consignee would not.
- Parties may negotiate whether liability for negligence should be excluded.
- Parties should bear in mind the impact of the ASEAN Framework Agreement on Multimodal Transport (where applicable), which provides for an exclusion and limitation of liability regime.

### Acceptance and defective products

- The contract should set out the right of the recipient to reject defective products, have regard to product liability terms, and what constitutes a defective product.
- This is particularly important as a defective vaccine or a vaccine improperly transported/stored would be rendered entirely unusable.

### Governing law and jurisdiction

- Such supply chain contracts are likely to involve parties from different jurisdictions and the movement of goods across different countries.
- It is thus important to determine the applicable governing law and the forum having jurisdiction over any claim or dispute.
- If parties do not wish to submit the dispute to a local court, they should agree on an alternative dispute resolution mechanism that is acceptable to them, such as arbitration or a multi-tiered system.

### Force majeure

- The COVID-19 pandemic has in its own nature underscored that external events may greatly affect or even upend whether supply chain contracts can be performed. This includes disruptive forces such as border restrictions, flight restrictions and manpower disruption.
- Parties should agree on the force majeure events that will suspend or terminate their respective obligations under the contract.

## OTHER ISSUES

While contractual provisions will go some distance in defining the obligations and liabilities of the parties in a supply chain contract, there may inevitably be other factors at play in determining the allocation of liability and legal risks. Other issues that are relevant in the circumstances would include the following:

**Diplomatic relations** – Rather than being a purely commercial engagement, the transport of vaccines may also attract geo-political considerations. With global demand continuing to exceed the available supply, the sharing and availability of vaccines has also taken on an element of diplomacy, in which the obstacles in the distribution journey are reflective of the impediments in country-to-country relations. Such obstacles may arise at the supply stage or at the import/export stage.

- Supply chain partners should be aware of the diplomatic climate of the intended route and account for such factors in their planning and drafting.

**Price differentials** – Much like any limited commodity, vaccines will follow the supply-demand model. As such, the price of vaccines may be driven up by nations that are more able to afford the financial load of buying vaccines in substantial bulk, leaving developing countries (which may ironically be in greater need of vaccines) with a shortage of supply.

- This would affect the consistency and viability of certain routes, which would then in turn take a toll on the business of operators along such routes, raising issues of payment capability and the fulfilment of other obligations.

**Spikes and variants** – The COVID-19 virus has been notoriously unpredictable. Countries have gone through multiple waves of spikes in infections, and this has been exacerbated by the emergence of new variants such as the Delta variant and the Omicron variant (and sub-variants).

- This has led to shifts in national vaccination programmes, which causes uncertainty in the supply chain. However, an increase in demand would also be countered by an increase in the practical obstacles of supply and transportation, such as border restrictions and manpower shortages.

**National policy** – The adoption of a vaccination policy by any nation is potentially a politically charged decision. While the politics of COVID-19 function at a level above the authority of supply chain partners, the effects of such policies will certainly be felt at all levels. Operators will have to be aware of any changes in policy and be able to adapt to any required changes in operation.

## CONCLUDING WORDS



The global pandemic may have accentuated the barriers and distance dividing countries, but with nations pursuing vaccination programmes, supply chain partners are playing a key role in breaking down these barriers and crossing the divide.

The cross-border nature of vaccine transport and distribution means that supply chain partners must be aware of the specific legal and practical issues that exist at each point of the journey, and local legal regimes. It is not enough for one's regulatory knowledge to be confined to one's own jurisdiction.

In this regard, Rajah & Tann Asia has Regional Offices across the Asian region, capable or working together to provide a comprehensive and seamless legal advisory experience. Rajah & Tann Asia is well placed to advise on the applicable legislation, regulation and guidelines in the various jurisdictions in Asia, as well as the relevant on-the-ground issues that supply chain partners should be cognizant of.

## About the Regional Shipping Group

Managing a complex portfolio of high-end shipping work throughout the region, in both "wet" and "dry" contentious matters, as well as in ship finance and other non-contentious matters, our shipping practice is quite simply the dominant force in Asia within this highly specialised area.

With varied areas of expertise and a wealth of experience, coupled with keen commercial acumen, our shipping partners are endorsed by *Chambers Global* and *The Legal 500 Asia Pacific* as leading practitioners and experts in the shipping arena. Collectively and individually, we have won testimonials as Asian counsel of first resort in shipping and trade-related work.

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Find out more about our Regional Shipping Group [here](#).

If you would like to find out how we may assist you, do touch base with us at [shippinglaw@rajahtann.com](mailto:shippinglaw@rajahtann.com) or our team members below.

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