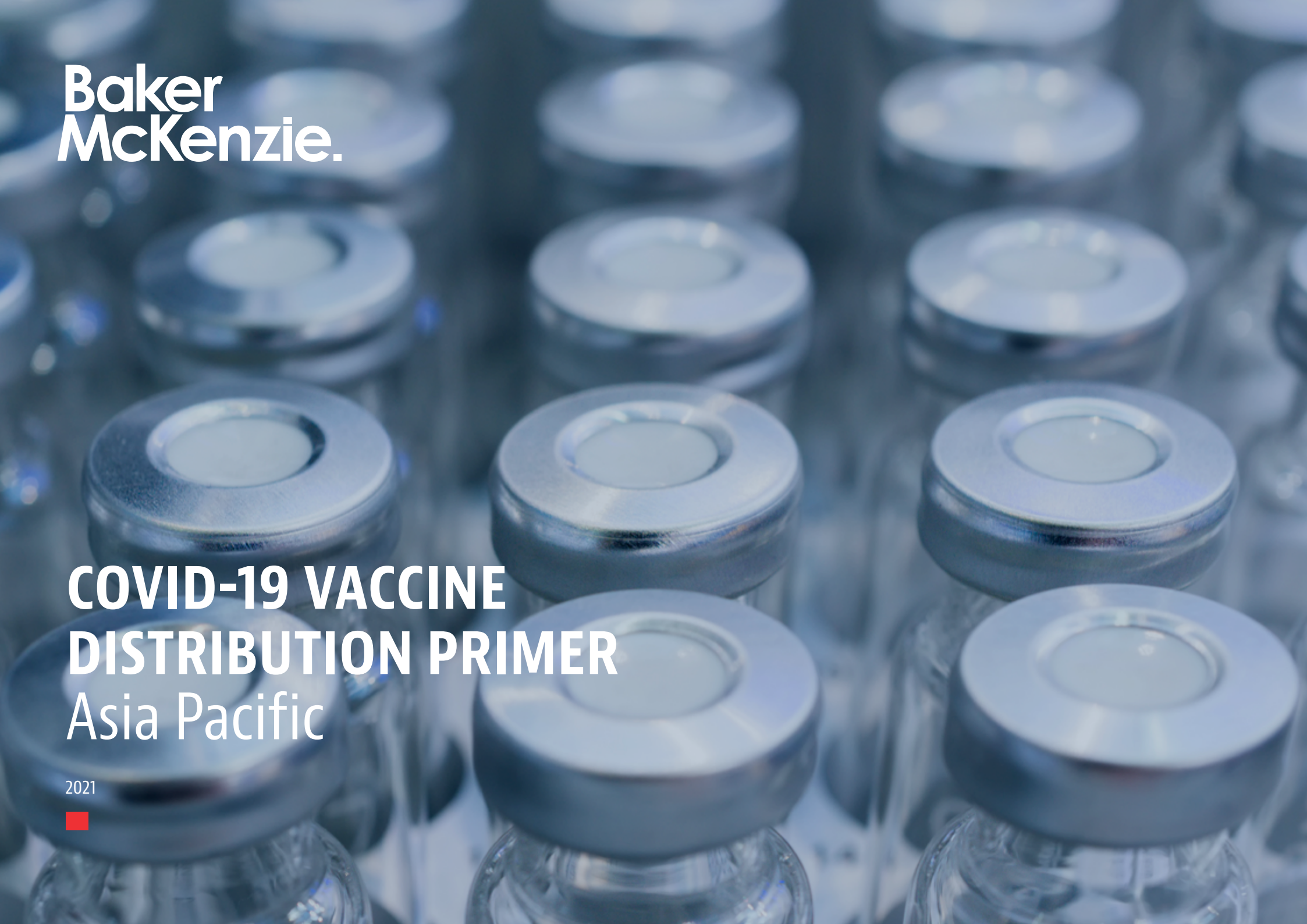

Baker McKenzie.

COVID-19 VACCINE DISTRIBUTION PRIMER

Asia Pacific

2021

INTRODUCTION

Welcome to the Asia Pacific Healthcare & Life Sciences' COVID-19 Vaccine Distribution Primer.

As the world prepares for the roll-out of the COVID-19 vaccine, manufacturers, governments, and clients in the logistics sector are looking into various structures and arrangements that will help bring the vaccine to the public as soon as possible.

Our Primer focuses on key legal issues and high level considerations on topics such as the procurement framework, regulatory approvals, and contractual stipulations relating to the supply and distribution of the COVID-19 vaccine across 14 Asia Pacific jurisdictions.

This guide has been prepared for the general information of clients and professional associates of Baker McKenzie. The content of this guide is current as of 27 May 2021. It is not legal advice and should not be regarded as a substitute for legal advice.

If you have questions or would like to discuss any of the topics raised in this Primer in more detail, please do get in touch.

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1	**What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**	▪ The key requirements are as follows : ▪ COVID-19 vaccines must be registered before they can be supplied in Australia. ▪ Businesses must apply for product regulatory approval (i.e., product registration) in order to import, manufacture, export and supply COVID-19 vaccines in Australia. ▪ When marketing COVID-19 vaccines, businesses must comply with the relevant provisions under Australia's Therapeutic Goods Act 1989 (Cth), which governs the advertising and promotion of therapeutic products, and other government campaigns regarding vaccination.
2	**Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?** **- If yes, what are the requirements and conditions?**	▪ There is currently none. However, we understand that the Therapeutic Goods Administration (TGA) and Human Research Ethics Committees would generally prioritize any clinical trial application involving COVID-19 vaccines.
3	**Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?** **- If yes, what are the requirements and conditions?**	▪ There is currently none. However, the TGA is prioritizing any registration application regarding treatment of COVID-19.

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Australia

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ At the time of writing, the TGA has granted provisional determination for three COVID-19 vaccines in Australia (to Janssen Cilag Pty Ltd, AstraZeneca Pty Ltd and Pfizer Australia Pty Ltd). This means that an application for provisional product registration can be made (if the pharmaceutical company chooses to proceed). ▪ The provisional pathway allows for provisional registration of medicines on the basis of preliminary clinical data and a clinical study plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of a maximum period of six years (starting on the day that provisional registration of the medicine would commence if the Secretary were to provisionally register the medicine). However, the TGA requires comprehensive non-clinical data on safety, quality and compliance with Good Manufacturing Practice. These requirements are the same as in the standard registration process for prescription medicines. ▪ TGA guidance does not expressly state what stages of clinical trial data would be considered. Applications should include clinical analysis, interpretation and justifications based preliminary data.
5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?** **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ **Public procurement laws** The application of public procurement rules, which include requirements for governments to conduct open or select competitive procurement processes subject to exemptions, will depend on how the government chooses to obtain the vaccine. For example, programs funded by grants are regulated by rules for awarding grants instead of procurement. In limited instances, procurement rules may allow government agencies to enter into single source supplies, such as where determined necessary for protection of human health. ▪ **Competitive bidding requirements and exceptions** See previous point. ▪ **Foreign equity restrictions or other regulatory requirements** There are no applicable foreign equity restrictions. The usual regulatory requirements discussed in questions 1-4 above apply equally to supplies of COVID-19 vaccines to the government. ▪ **Advance purchases** Yes. ▪ **Supplying logistics/distribution/warehousing storage services** Yes.

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Australia

6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ For prescription medicines such as a COVID-19 vaccine, importers and a wholesalers need to have a medicines wholesale license before they can store and supply the vaccine or other prescription medicines to the government, or any other party for that matter. ▪ The government has to date not imposed any statutory requirements for storage, warehousing, transport and logistics services for COVID-19-related equipment/supplies. Storage, warehousing, transport and logistics services should be done in line with the product's recommended storage and transport instructions.
7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Yes, notwithstanding future legislative enactments by the government and/or contractual arrangements between the manufacturer and the government.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ No.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No. However, manufacturers may include such indemnities in their contractual arrangements (if it can be negotiated).
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ Yes. Holding professional indemnity insurance is part of the criteria for a doctor's professional registration in Australia.

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1	**What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**	▪ A vaccine must be approved by the National Medical Products Administration (NMPA) and obtain marketing authorization before it can be marketed in China. The steps involved are as follows:
		  ▪ Application of Clinical Trial Approval (CTA)
		  ▪ Conducting phase I, II and III clinical trials (it is possible to only conduct registration trials for imported vaccines that are already approved in another country)
		  ▪ Application for registration (marketing authorization)
		▪ In addition, domestic manufacturers of vaccines must comply with Good Manufacturing Practice (GMP) requirements and obtain a Drug Manufacturing License.

2	**Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?** **- If yes, what are the requirements and conditions?**	▪ None. However, if the NMPA and the Centre for Drug Evaluation (CDE) consider the drug to be urgently needed, expedited CTA can be granted on a case-by-case basis.
3	**Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?** **- If yes, what are the requirements and conditions?**	▪ Under the PRC Vaccine Administration Law, the NMPA should conduct priority review for the registration of vaccines that are urgently needed for the prevention or control of diseases,. However, there is no interpretation on how a vaccine can be considered as urgently needed, and the NMPA will determine this on a case-by-case basis. ▪ Further, it is possible to obtain conditional approval for vaccines used in relation to major urgent public health events and other vaccines determined by the National Health Commission (NHC) if the benefits are determined to outweigh risks.

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China

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ In the case of conditional approval, late-stage trials and racial difference trials to be completed after the vaccine is approved. In this case, certain clinical trials can be delayed and the NMPA does not require final phase III clinical trial results before approving the vaccine.
5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?** **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ For vaccines that are listed in the national immunization programs, national centralized procurement mechanisms organized by the NHC (such as centralized tender and bidding or centralized price negotiation) are applicable. For other vaccines, procurement is conducted at a provincial level, and depending on the specific vaccine, competitive bidding or other mechanisms such as individual negotiation are applicable . ▪ There are no foreign equity restrictions per se. As discussed, imported vaccines must also obtain marketing authorizations from the NMPA before they can participate in the procurement process. For imported vaccines, the importer (acting as the agent of the overseas marketing authorization holder) would participate in the procurement process on behalf of the overseas marketing authorization holder. ▪ There is no basis for advance purchase agreement, but it is still possible if the government finds it necessary. ▪ Typically, the marketing authorization holder is responsible for the logistics/warehousing/storage of the vaccine it supplies to the government. It is not common for it to provide such services separately. However, licensed third-party logistics service providers can provide such services separately to marketing authorization holders or the government (the local Centres for Disease Control or CDCs).

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China

6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ Under the PRC Vaccine Administration Law, manufacturers should supply vaccines to the government (CDCs) directly without engaging any distributors. For imported vaccines, the importer as the agent of the overseas marketing authorization holder should supply the vaccines to CDCs directly. The importer must be GSP-compliant and obtain proper Drug Distribution License. ▪ In supplying the vaccines, the marketing authorization holders can engage qualified third-party logistics service providers to conduct storage, warehousing, transport and other logistics services. The logistics service providers must comply with GSP requirements to maintain a quality management system and obtain a proper drug 3PL license.
7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Under the PRC Vaccine Administration Law, manufacturers can only supply vaccines to the government.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ Yes. Death and injuries, including severe disability and organ damage caused by vaccines within the list maintained by the NHC will be compensated by the provincial government. ▪ The PRC Vaccine Administration Law also encourages the engagement of commercial insurers to compensate persons that suffer vaccine related injuries.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No. However, manufacturers of COVID-19 vaccines may be able to negotiate relevant indemnity terms when entering into supply contracts with the government/hospitals.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ No.

Hong Kong

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1	**What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**	▪ COVID-19 vaccines are prescription-only medicine and therefore subject to the current pharmaceutical product regulatory framework. In short, a vaccine must be registered with the Pharmacy and Poisons Board before it can be sold, offered for sale, distributed or possessed for distribution/sale in Hong Kong. ▪ The importer/distributor should hold a wholesale dealer license.
2	**Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?** **- If yes, what are the requirements and conditions?**	▪ Yes. The Drug Office has issued a special notice stating that applications relating to the drugs used for prevention or treatment of COVID-19 will be handled with priority and the evaluation process will be expedited. There are no additional requirements or conditions.
3	**Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?** **- If yes, what are the requirements and conditions?**	▪ Yes, as with item 2. There are no additional requirements or conditions as well.
4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ The Pharmacy and Poisons Board may conditionally approve a registration pending final phase III clinical trial results.

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Hong Kong

5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?** **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ The Hong Kong Hospital Authority contracts as a commercial entity and has discretion to enter into special supply arrangements. Most supplies are fulfilled through open/limited tenders, and public procurement laws can apply depending on the value of the supply. ▪ There are no foreign equity restrictions. A vaccine should be registered with the Pharmacy and Poisons Board before they can be supplied to the government, but conditional approval of registration may suffice for a COVID-19 vaccine. ▪ Tender terms specific to each tender provides for supply conditions. Most product owners supply to public hospitals through local distributors who handle related services in order to fully comply with the tender terms.

6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ A non-manufacturer wishing to supply COVID-19 vaccine to the government should have a wholesale dealer license and comply with the requirements under the Pharmacy and Poisons Ordinance (Cap. 138) and the Code of Practice for Holder of Wholesale Dealer Licence. In relation to vaccines, the requirements include the following, among others:
		  ▪ Regulatory approval of storage facilities of vaccine
		  ▪ Cold room or refrigerator with an alarm or alert system
		  ▪ Appropriate arrangement with transportation agents to ensure that the vaccine will be kept in appropriate storage conditions during transportation, such as cold chain management

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Hong Kong

7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Yes.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ No.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No. Unlike in the United States, there are no laws that protect vaccine manufacturers. While the laws allow for contractual indemnity from the government in case of product liability claims, it is not common practice in Hong Kong.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ No.

India

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1 **What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**

- The key regulatory requirements are as follows:
  - Ethics Committee approval to conduct clinical trials under the New Drugs Clinical Trials Rules 2019 ("**NDCT Rules**")
  - Permission to conduct Clinical Trials from the central drug regulator (CDSCO[1])
  - Approval from the CDSCO to import, manufacture and sell based on clinical trial data that is submitted
  - License to manufacture for sale (under the Drugs and Cosmetics Act, 1940 read with the Drugs and Cosmetics Rules 1945 ("**D&C Act and Rules**")) obtained from local state CDSCO divisions; such license is based on approval granted as above.
- Further, the Ministry of Science & Technology, through its Office Memorandum dated 26 May 2020, published a **Rapid Response Regulatory Framework** to deal with applications for COVID-19 Vaccine Development.[2]

1 Central Drugs Standard Control Organisation - the statutory body that grants approvals for the import, manufacture and sale of drugs in India.
2 Source **here**.

2 **Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?**

- If yes, what are the requirements and conditions?

- The NDCT Rules provide for approval for permission to conduct clinical trials which may be given in a period of 90 days if the drug is already approved and marketed in a country outside India.[3]

3 Rule 24 read with Rule 101 of the NDCT Rules. Application disposed of within a period of 90 days.

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India

3 **Is there a fast-track approval process to obtain a marketing authorization[4] or registration for a COVID-19 vaccine?**

If yes, what are the requirements and conditions?

- Yes. The NDCT Rules provide for an Accelerated Approval Process[5] for expedited approval of import/ manufacture of 'new drug' for sale/ distribution.[6]
- The following conditions and requirements need to be satisfied:
  - There should be a demonstration of a positive surrogate end point in the clinical trial data over standard outcome measures such as survival or disease progression.
  - Data should be reasonably sufficient to predict clinical benefit or a clinical endpoint.
  - Positive results/data should be measurable earlier than irreversible morbidity or mortality and reasonably likely to predict clinical benefit.
  - Post approval marketing trials shall be required to validate the anticipated clinical benefit.
- Further, the Rapid Response Regulatory Framework as discussed above would also be applicable.
- The CDSCO, through their notification dated 15 April 2021,[7] declared that foreign-produced vaccines that have been granted emergency approval for restricted use by foreign regulatory bodies such as the US FDA, the EMA, the UK MHRA, and the Japan PMDA or that are listed in WHO emergency use listing may be granted emergency approval in India, provided that the vaccines undergo a post-approval parallel bridging clinical trial. Notably, it was also mandated that the first 100 beneficiaries of the vaccines would be assessed for seven days for safety outcomes prior to the vaccines being rolled out for a further immunization program.

4 The term "marketing authorization" is assumed to include approval for manufacture, import, stocking, distribution and sale of the pharmaceutical products in India.
5 NDCT Rules, Second Schedule.
6 Accelerated approval process may be allowed for drugs intended to be used in life-threatening or serious and rare disease conditions, as well as for drugs intended to be used for diseases of special relevance in the Indian scenario or for unmet medical need in India, disaster or special defense taking, into account the severity, rarity or prevalence of such disease, and the availability or lack of alternative treatments, provided that there is a prima facie case of the product being of meaningful therapeutic benefit over existing treatment.
7 Source **here**.

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India

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ For 'consideration of data on clinical trial,' the guidance note in the Rapid Response Regulatory Framework states that: Phase I, Phase II or Phase III multicentric study on statistically significant sample size may be considered by the regulatory authorities based on, initial safety studies, proof of concept and dose finding data. That said, the NDCT Rules also provide that if remarkable efficacy is observed with a defined dose in the Phase II clinical trial of the investigational new drug for unmet medical needs of serious and life threatening diseases in the country, it may be considered for grant of marketing approval by the Central Licencing Authority based on Phase II clinical trial data. In such cases, additional post licensure studies may be required to be conducted after approval to generate the data on larger population to further verify and describe the clinical benefits, as per the protocol approved by the Central Licencing Authority. ▪ Furthermore, as stated above, the CDSCO, through their notification dated 15 April 2021, declared that foreign-produced vaccines that have been granted emergency approval for restricted use by foreign regulatory bodies such as the US FDA, the EMA, the UK MHRA, and the Japan PMDA or that are listed in WHO emergency use listing may be granted emergency approval in India, provided that the vaccines undergo a post-approval parallel bridging clinical trial. Notably, it was also mandated that the first 100 beneficiaries of the vaccines would be assessed for seven days for safety outcomes prior to the vaccines being rolled out for a further immunization program.
5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?** **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ Yes, however, the government has an overreaching power under the provisions of the Epidemic Diseases Act (1897), to take procurement decisions in the interest of the general public. ▪ Exceptions to the competitive bidding requirement may be made depending on specific facts, such as vaccine safety, efficacy protocols and the emergent need for the vaccine in the country. Any deviations from standard procurement protocol would need to be supported by reasoned orders and may also be subject to judicial review if challenged. ▪ Applicable restrictions on foreign investment under the existing Foreign Direct Investment Policy of India would apply. Any vaccine that is imported into India requires approval from the CDSCO. ▪ Yes, provided public procurement rules are followed or dispensed with. ▪ A marketing authorization holder may sell, stock, exhibit or offer for sale a drug and will be required to fulfil the conditions specified under the D&C Rules in relation to such services, including logistics. That said, vaccine distribution logistics may be outsourced to third parties that meet standards set by regulatory authorities in this regard.

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India

6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ A non-manufacturer will have to follow storage, warehousing, transport and logistics conditions as set out by the government and/or as identified to the manufacturer/marketing authorization holder as terms of such marketing authorization.
7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Yes. Through its notification dated 21 April 2021,[8] the Ministry of Health and Family Welfare declared that for Phase III of the vaccination drive in the country, the National Vaccination Strategy has been modified to allow for liberalized vaccine pricing and the scaling up of vaccine coverage - the same would come into effect from 1 May 2021. In addition, vaccine manufacturers would be free to supply 50% of their vaccine doses to state governments and in other than government of India channel (which includes private hospitals and industrial establishments that through their hospitals may procure vaccine doses). The vaccine manufacturers would be free to determine the price at which they supply 50% doses of vaccines. ▪ Furthermore, the ready-to-use imported vaccines would be allowed to be utilized entirely in the other than government of India channel.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ There is no specific vaccine compensation system, but any vaccine-related injuries would be actionable under the Consumer Protection Act, 2019, which provides for payment of compensation to consumers. Compensation is payable by the manufacturer and/or the marketing authorization holder of the vaccine. Trial participants are eligible for compensation under the provisions of the NDCT Rules.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No. However, manufacturers may choose to include such indemnities in their respective contractual arrangements with the government (subject to the government agreeing to the inclusion of the said indemnity clauses).
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ No.

8 Source **here**.

Indonesia

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1 **What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**

- All COVID-19 vaccines must be registered at the Drug and Food Monitoring Agency ("BPOM") to obtain an emergency use authorization or marketing authorization before they can be procured and/or consumed.
- After the marketing authorization or emergency use authorization is obtained, COVID-19 vaccines must also fulfil certain requirements relating to safety, quality and efficacy.
- Local private parties and international bodies/institutions may be involved in the procurement of COVID-19 vaccines under MOH Regulation 28.
- For the distribution of the COVID-19 vaccine, the appointed business entity may cooperate with a wholesale pharmaceutical company that has obtained a wholesale pharmaceutical distribution certificate and a good distribution practices certificate.

2 **Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?**

- If yes, what are the requirements and conditions?

- Yes. The evaluation and approval process for clinical trials for a COVID-19 vaccine will receive a fast-track approval with a timeline of four business days instead of the usual 20.

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Indonesia

3	**Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?**
	
	- If yes, what are the requirements and conditions?
		▪ Yes.
		▪ An emergency use authorization granted under BPOM Regulation No. 27 of 2020 on the Procedure of Drug Registration allows the drugs to be distributed and consumed by patients during a health emergency without first having to obtain a marketing authorization. The holder of the emergency use authorization will be responsible for the following:
		  ▪ Quality of the drug.
		  ▪ Conducting further clinical trials of the drug if it is still undergoing clinical trials to ensure its effectivity and safety.
		  ▪ Conducting pharmacovigilance monitoring and reporting of any side effects of the drug to BPOM.
		  ▪ Reporting the realization of the importation, production and distribution of the drug to BPOM.

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ Procurement of vaccines that are still in the early stage of development can be conducted before the emergency use authorization or marketing authorization is issued; however, these vaccines can only be consumed or used after the emergency use authorization or marketing authorization for these vaccines has been issued. Development stage means the completion of a second phase of clinical trials for the relevant vaccine, i.e., anything less will render the vaccine not qualified for procurement.
5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?**	▪ Yes, existing public procurement laws will generally apply to the supply of a COVID-19 vaccine to the Indonesian government, as the new COVID-19 vaccine regulations do not provide specific rules on this matter. However, the government will directly appoint Bio Farma or its subsidiaries, or directly appoint local pharmaceutical manufacturing companies to procure the COVID-19 vaccine. Additionally, public procurement regime is heavily driven by government unwritten policies; therefore, discretions may be made by the government on case-by-case basis for their selection regarding the supplier for COVID-19 vaccine. ▪ A local business entity (e.g., 100% Indonesian-owned, or a foreign-owned company in Indonesia) may be appointed by the government for the procurement of COVID-19 vaccines. Locally produced COVID-19 vaccines will be prioritized in the procurement process. ▪ Yes, the government can enter into advance purchase agreements for COVID-19 vaccine.

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Indonesia

	- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?	▪ The scope of procurement of COVID-19 vaccines by the supplier includes: (i) the supply of COVID-19 vaccines and supporting equipment and logistics for vaccination; and (ii) the distribution of COVID-19 vaccines until the delivery points determined by the MOH. The procurement of the supporting equipment and logistics for vaccination can be supplied by the supplier of the vaccine or by a different third party provider. If COVID-19 vaccine and the supporting equipment and logistics for vaccination are all supplied by the same supplier, that supplier should offer a competitive price as set out in the e-catalogue. The distribution of COVID-19 vaccines along with the supporting equipment and logistics for vaccination should be addressed in the procurement contract, and the provider will be responsible for the distribution of the COVID-19 vaccine.
6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ Transport, logistics and/or distribution services for COVID-19 vaccines may be conducted by a local business entity, which is required to be a wholesale pharmaceutical company that has obtained a wholesale pharmaceutical distribution certificate and a good distribution practices certificate.
7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Generally, no, except, where the government has appointed a private local pharmaceutical manufacturing company to help with the procurement. For locally manufactured vaccine, a local pharmaceutical manufacturing company appointed by the government may supply the vaccine to other third party private pharmaceutical wholesalers.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ None.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No. However, manufacturers may include such indemnities in their contractual arrangements with the government.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ We understand that there are no specific regulations that impose the obligation to provide liability insurance for doctors in public hospitals. However, under Article 46 of the Hospital Law (Law No 44 of 2009), hospitals will generally be liable for all losses incurred due to the negligence of their medical personnel.

Japan

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1	**What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**	▪ A COVID-19 vaccine must be approved as a drug by the Ministry of Health, Labour and Welfare. ▪ A person who markets vaccines in the Japanese market (whether manufactured in Japan or imported into Japan) must be licensed as a Marketing Authorisation Holder (**MAH**). An MAH may apply for approval of a COVID-19 vaccine as a drug. ▪ In marketing a vaccine, the MAH must comply with the provisions of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("**PMD Act**") and regulations and guidelines thereunder.
2	**Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?** **- If yes, what are the requirements and conditions?**	▪ No.

3	**Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?**
	
	- If yes, what are the requirements and conditions?
		▪ There is a fast-track product approval procedure under the PMD Act, and it is available for a COVID-19 vaccine under the following circumstances:
		  ▪ (i) The vaccine is needed to prevent the spreading of COVID-19, and there are no appropriate alternative measures available.
		  ▪ (ii) The vaccine has been approved in a jurisdiction with a system of product approval that is considered to be at the level equivalent to that of Japan's in terms of ensuring quality, efficacy and safety.

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Japan

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ There is no rule or practice one way or the other relating to the acceptability of mid-phase III clinical trial results. Clinical trial requirements will be determined on a case-by-case basis.
5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?** **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ Yes, public procurement laws will apply, which basically requires competitive bidding. ▪ There are a number of exceptions to the requirement for competitive bidding, notably in cases where urgency is required so that going through a bidding process would not be appropriate. ▪ A foreign manufacturer of a drug may apply for a product approval but will need to designate a licensed MAH ("**Designated MAH**") in Japan as the importer of the drug. A drug must be approved for marketing in Japan before it is imported. ▪ Yes, the government may enter into advance purchase agreements for COVID-19 vaccines. ▪ Being an MAH of itself does not allow the MAH to provide logistics, distribution, warehousing or storage service. See 6.
6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ A manufacturing license, which is different from a license as MAH and is granted in respect of each site where such work is carried on, is required.

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Japan

7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ A licensed manufacturer may supply drugs only to an MAH or another licensed manufacturer. An MAH, meanwhile, may supply drugs to other parties, including a pharmacy, another MAH, a licensed manufacturer or a licensed distributor.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ There is a relief program for health injury by vaccination, which applies to injuries caused by vaccination of diseases designated under the Vaccination Act. Although COVID-19 is not a disease designated under the Vaccination Act, a bill was passed by the Diet on 2 December 2020 to allow COVID-19 to be covered by the Vaccination Act. ▪ The government pays the compensation.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ The bill to amend the Vaccination Act (referred to in 8) contains provisions that permit the government to enter into an agreement to indemnify an MAH for losses incurred by it for compensation of injuries cause by vaccination.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ No.

Malaysia

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1 What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?

- The key regulatory steps are as follows:
  - COVID-19 vaccines must be registered via the National Pharmaceutical Regulatory Agency (NPRA).
  - Businesses must apply for the relevant licences in order to manufacture, import and/or supply by wholesale COVID-19 vaccines in Malaysia.
  - When marketing COVID-19 vaccines, businesses must comply with the relevant provisions under the **Medicines (Advertisement and Sale) Act 1956** and the **Guideline on Advertising of Medicines and Medicinal Products to General Public**.

2 Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?

- If yes, what are the requirements and conditions?

- Yes. Fast track review for clinical trial import licence application is available to shorten the review period from the standard 45 working days to 22 working days.
- The requirements are as follows:
  - The product is an investigation product used for treatment/prevention in pandemic/epidemic situations in the interest of public health; and
  - The product does not involve new active substance under development to be administered to human for the first time i.e., First-in-Human (FIH) clinical trials.

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Malaysia

3	**Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?**
	
	- If yes, what are the requirements and conditions?
		▪ Yes. Fast track conditional registration is available to shorten the review period from the standard 245 working days to 120 working days.
		▪ The requirements are as follows:
		  ▪ The product is intended for disease which is serious or immediately life threatening and has the potential to cause an outbreak, epidemic or pandemic;
		  ▪ Existing registered products have not been successful in eradicating the disease or preventing outbreak, epidemic or pandemic;
		  ▪ The product is in an ongoing Phase III clinical study, with at least one well-planned Phase III clinical study that clearly demonstrates the safety and efficacy of the product; and
		  ▪ The product is registered or has been given emergency use authorisation by any of the following:
		  ▪ National regulatory authorities of country of origin
		  ▪ European Medicines Agency
		  ▪ United States Food and Drug Administration
		  ▪ World Health Organisation
		▪ An even shorter review period of 90 working days is also available via abbreviated and verification review, provided that the product has been evaluated and approved by both the European Medicines Agency and the United States Food and Drug Administration.

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ Yes. COVID-19 vaccines may be conditionally registered based on an ongoing Phase 3 clinical study with preliminary data on safety and efficacy. There should already be at least one well-planned Phase 3 clinical study that clearly demonstrates the safety and efficacy of the product.

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Malaysia

5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?** **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ Yes. However, we understand that special supply arrangement is possible for COVID-19 vaccines. ▪ There are no foreign equity restrictions, but COVID-19 vaccines should be registered via the NPRA before they are supplied to the government. ▪ The government may enter into advance purchase agreements for COVID-19 vaccines. ▪ Product registration holders (previously known as marketing authorisation holders) may supply logistics, distribution, warehousing and/or storage services as well as related equipment/supplies to the government together with the supply of the vaccine.
6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ Non-manufacturers may be required to have a wholesaler's licence or an import licence from the NPRA, which necessitates compliance with, among others, the Guideline on Good Distribution Practice. ▪ Some other key documents with relevant requirements include the Guidance on the Requirement to Import, Handle, Store and Distribute COVID-19 Vaccines in Malaysia, the Guidance Document for Biological Products Lot Release in Malaysia, and the Guidelines on Management of Cold Chain Products in MOH Facilities.
7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Yes.

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Malaysia

8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ No.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No. Unlike in the US, there are no laws that protect vaccine manufacturers. However, it is legally possible to obtain contractual indemnity from the government in case of product liability claims.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ No.

Myanmar

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1	**What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**	▪ COVID-19 vaccines must be registered with Myanmar's Food and Drug Administration (FDA) before they can be marketed in Myanmar. ▪ Businesses must apply for the relevant licenses to import, manufacture, distribute and sell vaccines. ▪ When marketing COVID-19 vaccines, businesses must comply with the National Drug Law (1992) and Regulations of National Drug Law.
2	**Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?** **- If yes, what are the requirements and conditions?**	▪ Under the COVID-19 Economic Relief Plan (**CERP**), the importation process of COVID-19-related medical products should be expedited, and there is a waiver of import license and FDA requirements as long as the products have been approved by an FDA-equivalent body in the country of origin. The implementing bodies are the Ministry of Commerce (**MoC**) and the Ministry of Health and Sports (**MoHS**). However, no specific directives or guidelines relating to the expedited processing or approval of vaccines for local distribution or for conducting clinical trials for vaccines have been issued by the authorities.
3	**Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?** **- If yes, what are the requirements and conditions?**	▪ Please see response to question 2.
4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ Please see response to question 2. ▪ We await further guidance by the relevant government authorities to be able to comment on whether mid-phase clinical trial results would suffice for vaccine registration.

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Myanmar

5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?**	▪ No. The CERP states that COVID-19-related medical products may be imported without going through a lengthy procurement process. The MoHS as implementing body may be exempted from complying with the public procurement guidelines.
	- If yes, are there exceptions to the competitive bidding requirement?	▪ **Public procurement** A foreign body corporate not incorporated in Myanmar may participate in bidding, but it must incorporate a company in Myanmar prior to entry into a contract.
	- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?	▪ **Foreign equity restrictions or regulatory requirements** Yes if the supplier intends to import the vaccine into Myanmar directly. Foreign-owned Myanmar companies are required to obtain a retail/wholesale registration certificate from the MoC before they can apply for an importation license. However, if the vaccine is imported by the government directly, such requirement is waived and the usual regulatory requirements discussed in 1 and 2 above apply.
	- Can the government enter into advance purchase agreements for COVID-19 vaccine?	▪ Generally, yes.
	- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?	▪ Generally, yes, but subject to compliance with competition laws.
6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ There are no specific requirements as yet. We await the issuance of further guidelines by the relevant government authorities regarding this.
7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Yes.

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Myanmar

8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ No.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No. However, manufacturers may include such indemnities in their contractual arrangements with the government.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ No.

Philippines

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1 What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?

- The following are the key requirements:
  - The manufacturer, importer or distributor of the vaccine in the Philippines must be registered to engage in business in the Philippines and be a holder of a license to operate (**LTO**) from the Philippine Food and Drug Administration (**FDA**).
  - The vaccine must be registered with the FDA, or covered by an Emergency Use Authorization (**EUA**) from the FDA.
- As will be discussed in item 5 below, there are additional requirements for the supply of the vaccine to the Philippine government, such as the conduct of a health technology assessment (**HTA**) and inclusion of the vaccine in the Philippine National Formulary (**PNF**).

2 Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?

- If yes, what are the requirements and conditions?

- Yes, as stipulated under FDA Circular No. 2020-020 on "Guidance on Applications for the Conduct of COVID-19 Clinical Trials".
- The following are the key requirements:
  - Entities that intend to conduct clinical trials must obtain an LTO as a sponsor or a contract research organization (**CRO**) before it can apply for a license to conduct clinical trials in the Philippines.
  - All applications for a COVID-19 clinical trial shall be submitted to the Vaccine Expert Panel (**VEP**) of the Department of Science and Technology (**DOST**) and simultaneously reviewed by the designated ethics board for a period of 14 calendar days. If the application has merit, it will be submitted to the FDA for evaluation.
  - If the application is meritorious, the FDA shall issue the import license and clinical trial a pproval within eight calendar days.
- The FDA may exempt a vaccine from the requirement of a local clinical trial prior to issuance of an EUA, if the same complies with the requirements under the EUA Guidelines (discussed below).

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Philippines

3	**Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?**
	
	- If yes, what are the requirements and conditions?
		▪ Yes. The DOH-issued Administrative Order No. 2020-0045 on "Establishing Facilitated Registration Pathways for Drug Products including Vaccines and biologicals" provides for the following registration pathways and specific eligibility criteria for each pathway: abridged review, verification review and collaborative procedure. A potential COVID-19 vaccine may avail of any of these facilitated registration routes subject to compliance with the applicable eligibility criteria.
		▪ In addition, the FDA has issued Circular No. 2020-036 entitled "Guidelines on the Issuance of EUA for Drugs and Vaccines for COVID-19" (**EUA Guidelines**), which authorizes the issuance of an EUA for a COVID-19 drug or vaccine. The conditions and requirements for issuance of an EUA include:
		  ▪ Based on the totality of evidence, it is reasonable to believe that the drug or vaccine may be effective to prevent, diagnose, or treat COVID-19;
		  ▪ The known and potential benefits of the drug or vaccine, outweigh the known and potential risks, if any;
		  ▪ There is no adequate, approved and available alternative to the product for diagnosing, preventing or treating COVID-19; and
		  ▪ Applicant submits a list of the countries where an EUA covering the drug is approved by the relevant NRA, reports on the actual use of the vaccine from the issuance of the EUA to the time of filing of the EUA with the FDA, and a risk management plan, among other requirements.
		▪ The EUA shall only be valid within the duration of the declared public health emergency due to COVID-19 or upon issuance of a full marketing authorization or certificate of product registration.

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ Under the Bayanihan to Recover as One Act, the requirement of Phase IV trials for COVID-19 medication and vaccine is waived to expedite procurement, provided that these products are recommended and approved by the World Health Organization (**WHO**) and/or other internationally recognized health agencies. ▪ There is currently no regulation for waiver of final Phase III clinical trial results. However, based on the EUA Guidelines, the FDA may waive a local clinical trial in the Philippines, provided that the applicant submits clinical trial data with racial distribution including Filipinos and Asians, and complies with other requirements for EUA.

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Philippines

5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?** **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ Yes, public procurement laws will generally apply. However, the requirement for competitive bidding may be dispensed with, and the government may procure vaccine through a negotiated procurement in emergency cases such as a pandemic. ▪ As a rule, only Filipino citizens or corporations that are at least 60% Filipino-owned may supply goods, including vaccines, to the Philippine government. However, a foreign corporation may supply to the government in the absence of suppliers that meet the nationality requirements and/or in the case of a reciprocity provision between the Philippines and the country of the supplier. ▪ The president recently announced that he will approve advance purchase agreements and advance payments for the purchase of the vaccine. To address legal risks, it may be necessary to waive or amend certain provisions in Philippine procurement laws and the requirement for an HTA if the advance purchase agreement will cover a vaccine that is still in development and has not obtained regulatory approval. ▪ Yes, provided that the additional services can be reasonably justified as "incidental services" for the supply of the vaccine and expressly covered by the bid documents. In the absence of public bidding, there may be a higher threshold to justify inclusion of incidental services in a negotiated procurement for the vaccine due to emergency cases, as this would be an exception to the general requirement for public bidding.

6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ The following are the key requirements:
		  ▪ It must have a registered entity in the Philippines.
		  ▪ It must be at least 60% Filipino-owned, unless the foreign supplier is a citizen/corporation of a country that grants reciprocal rights/privileges to Philippine nationals.
		  ▪ It must undergo competitive public bidding, unless the circumstances permit the supplier to avail of exemptions from public competitive bidding.
		  ▪ It must secure an LTO from the FDA and appropriate product registration/notifications that the goods are medical devices.

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Philippines

7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Yes, subject to compliance with applicable regulatory requirements for private distribution of the vaccine and rules on the sale of prescription drugs.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ No.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ There is no legal protection under local law. ▪ The Philippine government may provide contractual indemnities, provided that the terms of such indemnification are not contrary to mandatory laws, morals, good customs, public order or public policy, such as in case of willful injury to a person or property, future unlawful acts, gross negligence, intentional misconduct, and acts of bad faith. However, it is not common for the government to grant such indemnities. Furthermore, to enforce a claim against the government, there must be an appropriation of funds to cover the claim.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ No. There is currently no such requirement.

Singapore

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1 **What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**

- The key requirements are as follows (see **here**):
  - COVID-19 vaccines must be registered before they can be supplied in Singapore.
  - Businesses must apply for the relevant licenses in order to import, manufacture and supply COVID-19 vaccines in Singapore.
  - When marketing COVID-19 vaccines, businesses must comply with the relevant provisions under Singapore's **Health Products Act (Cap. 122D) (HPA)** and the **Health Products (Advertisement of Therapeutic Products) Regulations (TPR)**, which govern the advertisement and promotion of therapeutic products.

2 **Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?**

- If yes, what are the requirements and conditions?

- There is currently no official fast-track approval process to obtain a license to conduct clinical trials. Based on our anonymous call with the Health Sciences Authority of Singapore (HSA), however, we understand that the HSA would generally prioritize any clinical trial application involving COVID-19 vaccines.

3 **Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?**

- If yes, what are the requirements and conditions?

- There is currently no official fast-track approval process for registration. We understand, from our anonymous call with the HSA, that prioritizing any registration application requires a case-by-case assessment.

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Singapore

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ There is no official position suggesting so. ▪ However, as remdesivir (Veklury®) was recently conditionally approved based on preliminary clinical data from two phase III trials (see **here**), the HSA may accept mid-phase III clinical trial results but impose restrictions and conditions on their use (see **here**, in particular "Restrictions on the use of remdesivir (Veklury®)").
5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?** **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ **Public procurement laws** Yes. ▪ **Competitive bidding requirements and exceptions** Yes. Competitive bidding must also adhere to Section 34 of the Singapore **Competition Act (Cap. 50B) (CA)**, which prohibits bid-rigging as they are agreements which have the object of restricting competition. Yes, there are exceptions to the Section 34 prohibition. ▪ **Foreign equity restrictions or other regulatory requirements** None. For completion's sake, the usual regulatory requirements discussed in 1-4 apply equally to supplies of COVID-19 vaccines to the government. ▪ **Advance purchases** Yes. ▪ **Supplying logistics/distribution/warehousing storage services** Generally, yes. However, a marketing authorization holder that makes the purchase of the vaccine conditional on the purchase of logistics/distribution/warehouse/storage services may be viewed as engaging in tying. Tying agreements made by dominant market authorization holders may in turn constitute unilateral abuse, which is prohibited under **Section 47 of the CA**.
6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ For COVID-19-related goods, such as equipment and supplies, non-manufacturers will typically require an importer's and wholesaler's license before they may be supplied locally to the government, or any other party for that matter. ▪ The government has to date not imposed any statutory requirements for COVID-19 storage, warehousing, transport and logistics services.

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Singapore

7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Yes, notwithstanding future legislative enactments by the government and/or contractual arrangements between the manufacturer and the government.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ No.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No. However, manufacturers may include such indemnities in their contractual arrangements with the government.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ Not at present.

South Korea

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1 **What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**

- Importing manufacturing and/or selling vaccines, like other pharmaceutical products, requires the following licenses from the Ministry of Food and Drug Safety ("MFDS"):
  - Import license, if importing vaccine into the country
  - Manufacturing license, if manufacturing vaccine for sale in the country
  - A separate license for selling products that are made by way of consignment manufacturing
- Licensed vaccines are subject to a "lot release" requirement, i.e., final review and authorization from the MFDS prior to commercial launch to ensure the quality of vaccines authorization from the MFDS prior to commercial launch to ensure the quality of vaccines authorization from the MFDS prior commercial launch to ensure the quality of vaccines.

2 **Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?**

- If yes, what are the requirements and conditions?

- Yes. The MFDS has formed a specialized team for fast-track review and approval of clinical trial applications for COVID-19 vaccines ("**COVID-19 Review Team**"). Additional information on that team's process can be found at the MFDS **website** (in Korean) or by email inquiry to **covid19drug@korea.kr**.
- The Ministry of Health and Welfare has also formed a task force to assist in processes for clinical trials.

3 **Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?**

- If yes, what are the requirements and conditions?

- Yes.
  - A product may be eligible if developed to prevent or treat an infectious disease that threatens serious harm to public health, where either there is no existing treatment, or the product's mechanism is new (compared to any existing treatment) or shows a substantial increase in efficacy of treatment.
  - An applicant should request prior consultation with the MFDS, and apply for fast-track review in line with an **MFDS Guide** (in Korean) on considerations in applying for fast track review of pharmaceutical products. The process requires various product and treatment data.
  - With respect to the lot release requirement, the MFDS has announced that COVID-19 vaccines will be granted an expedited review.

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South Korea

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ In case of confirmed efficacy and provided that the design and purpose of the phase II clinical trials are similar to those of phase III, the MFDS may take phase II clinical trial results for review and possible approval (subject to the condition of phase III results being submitted in due course).

5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?**
	
	- If yes, are there exceptions to the competitive bidding requirement?
	
	- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?
	
	- Can the government enter into advance purchase agreements for COVID-19 vaccine?
	
	- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?
		▪ Yes, this is subject to the Act on Contracts to Which the State is a Party ("**Public Contracts Act**"), along with several enforcement decrees (primary implementing regulations) and further regulations, including rules when foreign bidders are involved.
		  ▪ Competitive bidding is required, in general, but there are exceptions. Among these, a contract may be negotiated, without bidding, in an emergency such as to prevent spread of infectious diseases.
		  ▪ There are no regulations specifically prohibiting the government from entering into an advance purchase agreement or provisional contract. But such arrangements may impinge on constraints under other laws such as the Pharmaceutical Affairs Act.
		  ▪ Marketing license holders may supply additional services, as part of the vaccine supply (or separately), if so requested by the government, or as negotiated.

6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ Non-manufacturers must obtain a wholesale pharmaceutical product distributor license (from a public health center) to provide COVID-19-related logistics and equipment/supplies to the government.

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South Korea

7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Yes.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ Yes. Under the Infectious Disease Control and Prevention Act, the government is to provide compensation for vaccine-related injuries, subject to certain standards. The government gets subrogated to rights against the vaccine maker.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No. There are no special rules exempting COVID-19 vaccine makers as such from liability or furnishing indemnity. In case of harm caused by a vaccine, the maker would generally face liability under the Product Liability Act. However, vaccine suppliers may seek contractual indemnity clauses.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ No.

Taiwan

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1 What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?

- The key requirements are as follows:
  - COVID-19 vaccines must be registered with the Taiwan Food and Drug Administration (TFDA) or imported or manufactured under a special permit from the TFDA before they can be marketed in Taiwan.
  - The supplier of COVID-19 vaccines must hold a pharmaceutical manufacturer or dealer license in order to import or manufacture and supply COVID-19 vaccines into/in Taiwan.
  - When marketing COVID-19 vaccine, the pharmaceutical company must comply with the relevant provisions under the **Pharmaceutical Affairs Act** (PAA) and the supplementary regulations that govern the advertisement and promotion of pharmaceutical products.

2 Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?

- If yes, what are the requirements and conditions?

- There is currently no fast-track approval process specifically for clinical trial for COVID-19 vaccines. However, we understand that the TFDA would generally prioritize any clinical trial application involving COVID-19 vaccines or related treatments, irrespective of whether the requirements for fast-track process are met.
- Nonetheless, we set out below the two fast-track approval processes and requirements to obtain a license to conduct clinical trials for any investigational new drug (IND).
- **For clinical trial approved to be conducted in the US**
  If the clinical trial for IND has been approved by the US FDA, the fast-track approval process to obtain a license to conduct the clinical trial of the same protocol for conducting in Taiwan is applicable.
- **For multi-national and multi-center clinical study**
  Fast-track approval process is applicable: (1) if the study is conducted in any of the A10 countries, i.e., Germany, USA., UK, France, Japan, Switzerland, Canada, Australia, Belgium and Sweden; and (2) if at least one medical center in Taiwan will be the site of the study.

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Taiwan

3 Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?

- If yes, what are the requirements and conditions?

- There is currently no fast track approval process specifically for granting the marketing authorization to a COVID-19 vaccine. However, we understand that the TFDA would generally prioritize any new drug application (NDA) involving COVID-19 vaccines or related treatments, and the review and approval process would be faster than any existing type of fast-track process.
- Below are existing fast-track approval processes that may be applied to an NDA for COVID-19 vaccine, provided that the TFDA's prior permission is obtained:
- **Priority review (about 240 days)**
  - a. The product to be registered is a new drug defined under the PAA.
  - b. The product to be registered is indicated for serious disease in Taiwan.
  - c. The product to be registered would satisfy unmet medical needs.
- **Quick review (about 240 days)**
  - The product to be registered is a new drug defined under the PAA.
  - Any of the following conditions is met:
    - The product to be registered is indicated for serious disease in Taiwan and it would satisfy unmet medical needs.
    - It is an orphan drug designated by any of the A10 countries.
    - It is not designated as an orphan drug in Taiwan but would meet unmet medical needs and is difficult to be manufactured or imported.
- **Simplified review**
  - Type 1 (about 180 days): New drug having a new chemical entity/entities or a biologic that is registered in any two of the FDA (USA), EMA (EU) and MHLW (Japan), and there is no ethnic difference.
  - Type 2 (about 120 days): New drug having a chemical entity/entities or a biologic that is registered, based on chemical manufacturing control (CMC) data, in the FDA (USA), EMA (EU) and MHLW (Japan), and there is no ethnic difference.

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4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ There is no written ruling or guideline on this issue. ▪ Nevertheless, the TFDA may accept and even approve an NDA (with or without condition(s)), provided the submission dossiers can support the safety and efficacy of the product to be registered even if phase III clinical trials have not been completed..
5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?** **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ **Public procurement laws** Yes. ▪ **Competitive bidding requirements and exceptions** The competitive bidding requirements under the Government Procurement Act (GPA) will apply to the supply of COVID-19 vaccine. The exception is that if any of the situations specified in Article 22 of the GPA occurs, the limited tendering process, under which two or more suppliers are invited to compete or only one supplier is invited for tendering without public notice, will be applicable. The possible situations under which the limited tendering process might apply are when: (1) no bidder or no qualified bidder attended the public tender process; (2) an unforeseeable emergency occurs, which impedes the public tendering process; or (3) special approval from the competent authority (Public Construction Commission) is secured. ▪ **Foreign equity restrictions or other regulatory requirements** Normally, a COVID-19 vaccine supplier should be a local entity holding pharmaceutical manufacturer or dealer license. There is no foreign equity restriction on such a local entity. This local entity can be a 100% subsidiary or a Taiwan branch of a foreign entity. ▪ **Advance purchases** Advance purchases are not typical under the GPA. The Center for Disease Control (CDC) is still discussing and planning whether advance purchases can be applicable to COVID-19 vaccines. ▪ **Providing logistics/distribution/warehousing storage services** This depends on the procurement agreement entered into by the CDC. Taking the template procurement agreement for influenza pandemic vaccine as an example, the supplier of vaccine should provide the logistics, warehousing, storage services together. The service fees are included in the total purchase price. It is likely that the CDC would use the similar template agreement because in common practice, the government agency usually uses the standardized government procurement agreement and is not willing to make material changes to avoid issues.

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6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ A non-manufacturer wishing to supply COVID-19 vaccine to the government should hold a pharmaceutical dealer licence and be certified by the TFDA for its compliance with the Good Distribution Practice (**GDP**).
7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Yes.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ Yes. A no-fault Vaccine Injury Compensation Program ("Program") has been in place in Taiwan for about 30 years. A victim who suffers injury after receiving a vaccine supplied based on a marketing authorisation or a special import/manufacturing permit may file a claim to the Program. A working group of the Program will review the victim's claim and decide whether to grant compensation. The Program sets out a range of compensation for death and each type of injury. The victim's medical expenses and funeral expenses can also be compensated by the Program. ▪ The funds for the Program to compensate the patients are primarily contributed by the manufacturers and the importers of vaccines based on the volume of vaccines they supply to the market and the CDC.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No. While the laws allow for contractual indemnity from the government in case of product liability claims, it is not a common practice in Taiwan. The CDC typically procures vaccines from manufacturer with a standardized government procurement contract, leaving little room for a manufacturer to negotiate an indemnity from government in such case.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ No.

Thailand

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1 **What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**

- A COVID-19 vaccine would be considered a "drug" under the Drugs Act B.E. 2510 (1967) ("Drugs Act"). Accordingly, the key requirements are as follows:
  - COVID-19 vaccines must be registered as a new vaccine with the Thai Food and Drug Administration (FDA) before they can be manufactured or imported and distributed in Thailand.
  - Businesses must apply for a modern drug import license in order to import and distribute a COVID-19 vaccine in Thailand.
  - Businesses must obtain Good Manufacturing Practices (GMP) clearance.
  - Any third-party distributor must obtain a drug selling license.
  - When marketing a COVID-19 vaccine, businesses must comply with the relevant provisions of the Drugs Act.

2 **Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?**

- If yes, what are the requirements and conditions?

- Yes. On 16 March 2020, the FDA announced the new procedure, format, and documents for the fast-track approval of the clinical trial application for drugs urgently needed during a public health emergency. The approval timeline may be reduced to 10 days.

3 **Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?**

- If yes, what are the requirements and conditions?

- Yes. On 28 April 2020, the FDA announced that screening validation for the product registration application of a COVID-19 vaccine is reduced to 10 to 25 working days from 120 working days. However, the timelines for the other product registration steps (i.e., scientific review, approval) remain the same.
- On 1 June 2020, another FDA announcement provided for the simplification of the GMP clearances for local and overseas manufacturers of COVID-19 vaccine.

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Thailand

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ No. The FDA requires the final and complete phase III clinical trial results for COVID-19 vaccine registration.
5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?** **- Can the government enter into advance purchase agreements for COVID-19 vaccine?** **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ Generally, public procurement laws prevent the government from procuring COVID-19 vaccine that has not yet been developed. However, based on the Notification of the Ministry of Public Health re: Sourcing of Coronavirus Disease 2019 or COVID-19 Vaccines in Emergency Situations or as a Necessity, B.E. 2563 (2020), the National Vaccine Institute is authorized to enter into an advance market commitment arrangement in order to procure COVID-19 vaccine in advance. This is similar to the arrangements entered into with the COVAX platform.

6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ The key requirements are as follows:
		  ▪ Drug selling license from the FDA
		  ▪ Upon the FDA's implementation of Good Distribution Practice (GDP), a GDP certificate from the FDA and compliance with the GDP
		▪ The government has to date not imposed any statutory requirements specifically for COVID-19 storage, warehousing, transport and logistics.

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Thailand

7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ Yes.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ No.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ No.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ No.

Vietnam

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1	**What are the key regulatory steps or requirements to market a COVID-19 vaccine in your jurisdiction?**	▪ COVID-19 vaccines must be registered with the Drug Administration of Vietnam (DAV) under the Ministry of Health (MOH) before they can be supplied in Vietnam. ▪ Part 1: Administrative documents (e.g., application form, letter of authorization, business licenses of the applicant, product label, CPP, product characteristic summary, patent, document assessing GMP conformity) ▪ Part 2: Quality documents (e.g., release certificate, certificate of analysis, ACTD technical documents, stability data, manufacturing process evaluation, analysis method evaluation) ▪ Part 3: Pre-clinical documents ▪ Part 4: Clinical document
2	**Is there a fast-track approval process to obtain a license to conduct clinical trials for a COVID-19 vaccine?** **- If yes, what are the requirements and conditions?**	▪ None, as stipulated under Decision No. 3659/QD-BYT ("**Decision No. 3659**") dated 21 August 2020.

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Vietnam

3	**Is there a fast-track approval process to obtain a marketing authorization or registration for a COVID-19 vaccine?**
	
	- If yes, what are the requirements and conditions?
		▪ Yes.
		▪ Besides the standard requirements, such as administrative, quality, pre-clinical and clinical documents, the DAV allows an applicant to supplement the following time-consuming documents after submitting the registration application:
		  ▪ Test report, quality standards and testing methods certified by the Institute of Vaccine and Medical Biologicals, which can be supplemented when the results are available
		  ▪ Study data of stability of active ingredients and finished products with registered expiry date, which can continue to be updated during the application review
		  ▪ Clinical trial results, which can continue to be updated during the application review
		▪ The DAV shall issue the marketing authorization for the COVID-19 vaccine within six months from the date of receipt of a complete application, instead of 12 months under the normal procedure.

4	**In the application for COVID-19 vaccine registration, does the regulatory agency accept mid-phase III clinical trial results or does it require final phase III clinical trial results?**	▪ The regulatory agency accepts mid-phase III clinical trial results on safety and immunogenicity for COVID-19 vaccine registration.
5	**Will public procurement laws or competitive bidding requirements apply to the supply of COVID-19 vaccine to the government?** **- If yes, are there exceptions to the competitive bidding requirement?** **- Are there foreign equity restrictions, or other regulatory requirements before a COVID-19 vaccine can be supplied to the government (e.g., whether the drug should already be registered with the relevant regulator)?**	▪ The supply of COVID-19 vaccine to the government must go through the public procurement process and there is no exception in this regard. ▪ However, since there are not many bidders for COVID-19 vaccine supply, the government may apply the direct appointment of the bidder, instead of open bidding. ▪ The vaccine must be approved by the DAV before it can be supplied to the government. ▪ A foreign-invested company in Vietnam is not permitted to directly sell the vaccine to public hospitals under the government.

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Vietnam

	- Can the government enter into advance purchase agreements for COVID-19 vaccine? **- Can the marketing authorization holder supply logistics/distribution/warehousing/ storage services to the government separately or together with the supply of the vaccine?**	▪ Yes, the government can enter into advance purchase agreements for COVID-19 vaccine. ▪ If the marketing authorization holder is a foreign-invested company in Vietnam, they are not permitted to provide such services to public hospitals under the government.
6	**What are the key requirements for non-manufacturers to supply COVID-19 storage, warehousing, transport and logistics services, as well as related equipment/supplies to the government?**	▪ If the non-manufacturers are a foreign-invested company in Vietnam, they are not permitted to provide such services to public hospitals under the government.
7	**Can a manufacturer supply COVID-19 vaccine to parties other than the government?**	▪ There is currently no regulation preventing a manufacturer from supplying COVID-19 vaccine to parties other than the government.
8	**Is there a vaccine compensation system to protect persons that suffer vaccine-related injuries?** **- If so, does the government pay the vaccine compensation?**	▪ Yes. The funding resource for this vaccine compensation system comes from the state budget. ▪ The state compensates an aggrieved party that has been vaccinated under an expanded immunization program or a vaccination program against epidemic, and only when either: a) serious injuries that lead to disabilities; or b) death occurs.
9	**Do local laws protect manufacturers of COVID-19 vaccine or allow for contractual indemnity from the government in case of product liability claims?**	▪ Yes.
10	**Is liability insurance for doctors operating in public hospitals compulsory?**	▪ Yes, as stipulated under Article 16 Decree No. 102/2011/ND-CP).

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