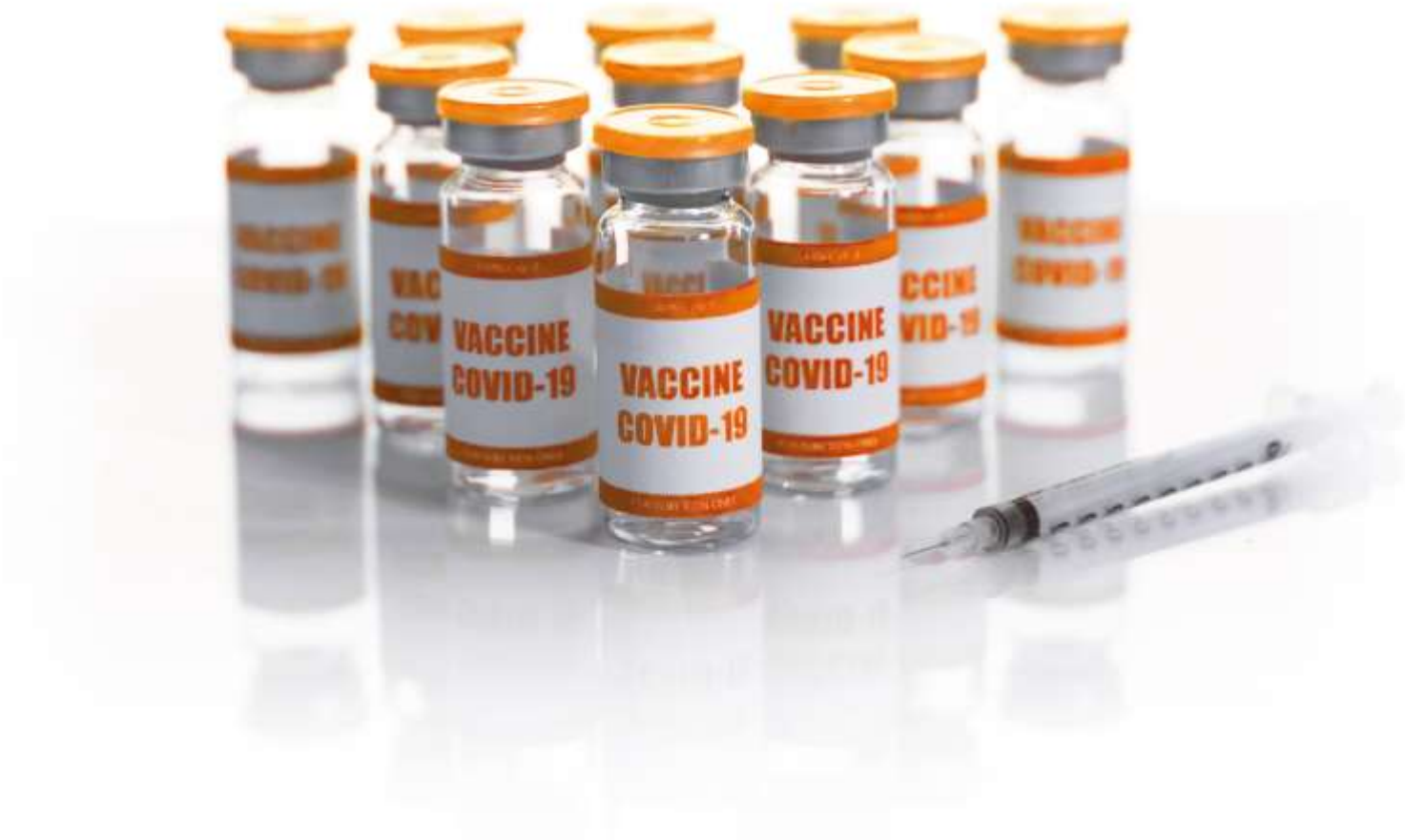
RAJAH & TANN ASIA

LAWYERS WHO KNOW ASIA

GUIDE ON COVID-19 VACCINATION: REGULATORY ISSUES



RAJAH & TANN ASIA

CAMBODIA | CHINA | INDONESIA | LAOS | MALAYSIA | MYANMAR | PHILIPPINES | SINGAPORE | THAILAND | VIETNAM

www.rajahtannasia.com

CONTENTS

Contents	2
Introduction	3
CAMBODIA	4
CHINA	6
INDONESIA	9
LAO PDR	11
MALAYSIA	12
MYANMAR	14
PHILIPPINES	16
SINGAPORE	19
THAILAND	22
VIETNAM	25
Key Contacts	27
Our Regional Contacts	30
Disclaimer	31

Guide on COVID-19 Vaccination: Regulatory Issues

Introduction

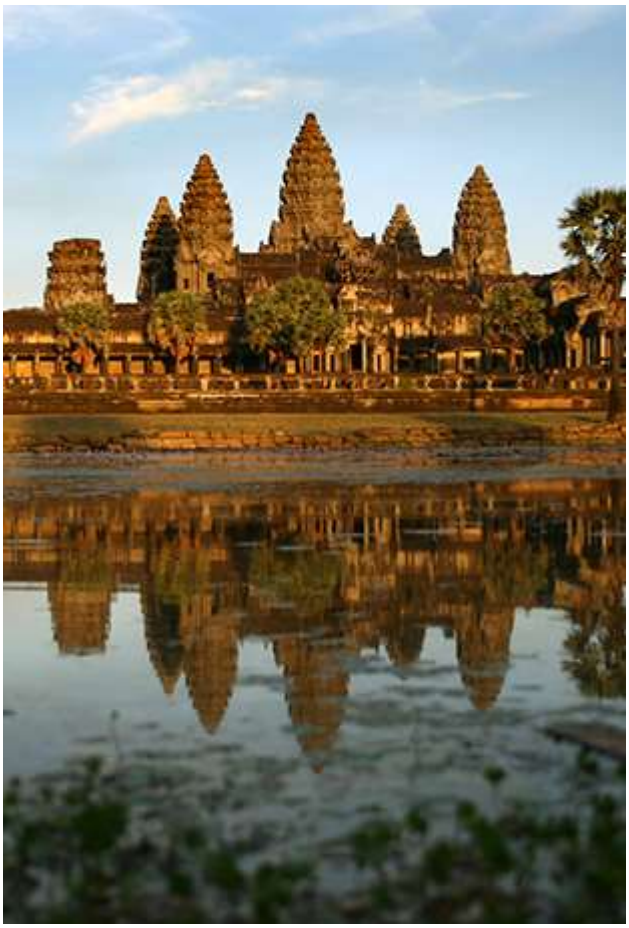
COVID-19, the disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has spread across the globe causing severe economic and social disruption worldwide. While the world continues to see the detrimental effects of COVID-19, it also begins to welcome the unfolding global endeavour of vaccine development and deployment. The global pharmaceutical industry has announced its commitment towards developing vaccines for COVID-19, and several vaccines have since been authorised by various national regulatory authorities for public use, with vaccinations taking place in several countries across Southeast Asia.

This quick guide explores the various regulatory issues arising in different parts of Southeast Asia, briefly covering vaccine registration and administration, as well as each country's regulatory framework, as of 20 April 2021.

CAMBODIA

1. Introduction

As of 20 April 2021, Cambodia has obtained COVID-19 vaccines from three foreign manufacturers: (i) Beijing Institute of Biological Products (manufacturer of the Sinopharm vaccine), (ii) AstraZeneca of Oxford (manufacturer of the Covishield vaccine), and (iii) Sinovac Biotech Ltd (manufacturer of the Sinovac vaccine). As of mid-April, more than 1.2 million people have been vaccinated**.** This figure is a combination of the number of people who received two doses of vaccines and those who received at least one dose.



Since 10 February 2021, the Royal Government of Cambodia ("**RGC**") has commenced the national COVID-19 vaccination campaign by providing the first doses of Sinopharm and Covishield on 10 March 2021 to priority groups including healthcare workers, journalists, public officials, experts of the Cambodian Mine Action Centre, frontline sub-national officials, police, and waste collection workers.

Moreover, in early April, the RGC further rolled out vaccination campaigns for the public at designated health centers.

2. Vaccine Supplies Provided to Cambodia

On 31 March 2021, the RGC obtained 700,000 doses of Sinopharm in addition to the first arrival of 600,000 doses provided by the People's Republic of China in February 2021. Besides Sinopharm, the RGC also obtained 324,000 doses of Covishield licenced from AstraZeneca of Oxford on 2 March 2021. The RGC expects to receive approximately 1.1 million Covishield doses by the end of May.

The RGC has also purchased more than 1 million doses of Sinovac. On 17 April 2020, the RGC obtained 500,000 Sinovac doses in addition to the 1.5 million doses that arrived in March.

Overall, as of 20 April 2021, Cambodia has obtained more than 3 million doses of COVID-19 vaccines.

3. Regulatory Authority and Vaccination Strategy

The Ministry of Health ("**MOH**") has full power and authority to administer and issue regulations in relation to COVID-19 vaccination and preventive measures to be complied with. Other ministries and institutions will then disseminate the MOH-issued regulations in their internal entities.

In order to roll out the vaccination program extensively and prevent the spread of COVID-19, the RGC issued Decision No. 37 on the Establishment of Covid-19 Vaccination Commission ("**Commission**") dated 17 March 2021 ("**Decision No. 37**"). The Commission consists of 21 members from diverse fields who will perform the following duties:

(a) lead and manage the work of COVID-19 vaccination throughout Cambodia;

(b) examine and prepare a plan for vaccination throughout Cambodia;

(c) train medical staff in relation to COVID-19 vaccination;

(d) transport the vaccines to the vaccination places;

(e) support funds, material and necessary equipment for COVID-19 vaccination;

(f) coordinate the vaccination work and other related work;

(g) coordinate with national and international partners including the United Nations, international organisations, non-governmental organisations, and other embassies/consulates in Cambodia for the roll-out of the COVID-19 vaccination;

(h) prepare reports relating to the COVID-19 vaccination and submit the reports to the RGC; and

(i) perform other works in relation to COVID-19 vaccination.

Decision No. 37 stipulates that the Commission may establish subordinate commissions and secretariats to support the vaccination process and smoothen the work. So far, subordinate committees have been established in the Ministry of Labour and Vocational Training, and the Ministry of Justice, among others.

While Sinopharm is provided to people aged between 18 and 59, Covishield is made available to people aged 60 or older, and Sinovac is made available to people aged 18 or older.

In order to prevent the spread of COVID-19 even after people have already been vaccinated, the RGC has enacted several laws such as: (i) the Law on Preventive Measures against the Spread of COVID-19 and other Severe and Dangerous Contagious Diseases dated 11 March 2021; (ii) Sub-decree No. 37 on Preventive Measures against the Spread of COVID-19 and other Severe and Dangerous Contagious Diseases dated 12 March 2021; (iii) Inter-ministerial No. 178 MEF on Penalties for Persons/Entities Violating the Preventive Measures against COVID-19 and other Severe and Dangerous Contagious Diseases dated 19 March 2021; (iv) Prakas No. 018 on Mask Wear and Social Distancing Obligations during COVID-19 Community Spread dated 22 March 2021; (v) Sub-Decree No. 66 on Mandatory Vaccination against COVID-19 dated 11 April 2021; (vi) Decision No. 083/21 on Extension of Imposing Curfew in Phnom Penh until 28 April 2021 dated 13 April 2021; and (vii) Decision No. 50 on Modification of Lockdown Measures in Phnom Penh and Krong Takhmao dated 17 April 2021.

4. Administration of Vaccines

On 2 March 2021, 31 March 2021, and 17 April 2021, the RGC directly received the vaccines from the COVAX Facility and the government of the People's Republic of China at the Phnom Penh International Airport. MOH is the core ministry that receives, distributes and maintains the vaccines. These vaccines have been approved by MOH for roll-out to Cambodian citizens. Moreover, MOH ensures that the appropriate vaccines are administered to eligible persons.

As of 20 April 2021, of the 700,000 Sinopharm doses available, 400,000 and 300,000 doses have been allocated for MOH and the Ministry of National Defense to administer, respectively.

Sinopharm, Sinovac and Covishield vaccines are administered to Cambodian citizens free of charge.

Importantly, there is no provision allowing the private sector such as private hospitals or companies to purchase and run their own vaccination programmes in Cambodia.

5. Conclusion

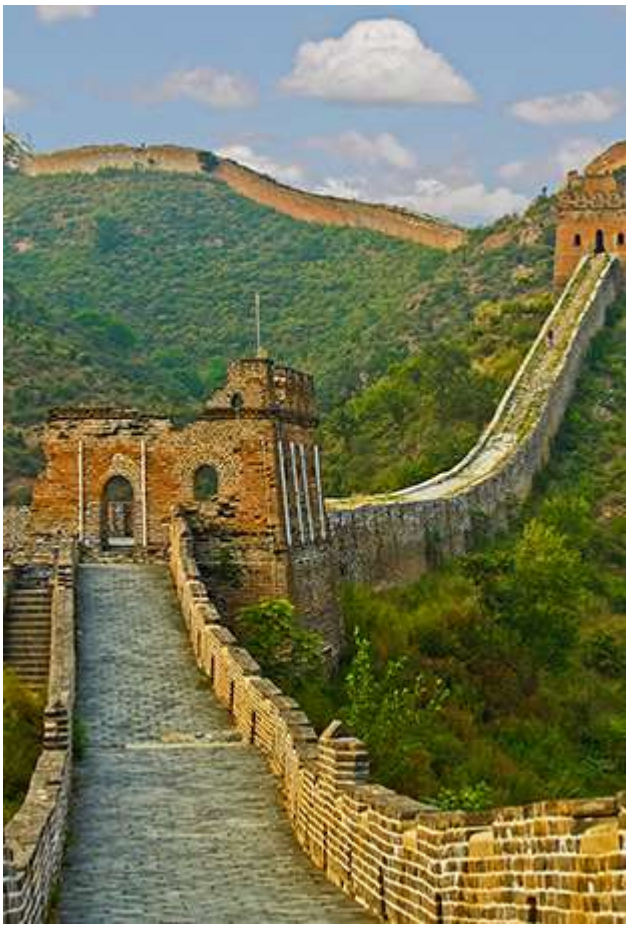
The RGC continues to enforce strict measures to manage and prevent the spread of COVID-19.

The RGC plans to provide vaccination to at least 10 million people and expects to obtain more COVID-19 vaccines. Starting from May to August, Cambodia expects to obtain approximately 7.5 million doses. Currently, Phnom Penh and Krong Takhmao of Kandal Province are under temporary lockdown due to the so-called 20-February Community Spread event.

CHINA

1. Introduction

The first vaccine manufactured by China was given conditional approval for general use on 30 December 2020. To date, there are five China-manufactured vaccines which have been approved either for general use or for emergency use. China has launched its phased plan for its COVID-19 vaccinations program since late December 2020 targeting the key groups, and now the mass vaccination for COVID-19 is being rolled out across China.



2. Vaccine Manufactured, Imported and Exported by China

As of 20 April 2021, the National Medical Products Administration of China ("**NMPA**") has approved five coronavirus vaccines, all of which are manufactured by domestic companies in China, i.e. (i) Beijing Institute of Biological Products Co., Ltd. of Sinopharm Group ("**Sinopharm Beijing**"); (ii) Sinovac Life Sciences Co., Ltd.; (iii) CanSino Biologics Inc.; (iv) Wuhan Institute of Biological Products Co., Ltd. of Sinopharm Group ("**Sinopharm Wuhan**"); and (v) Anhui Zhifei Longcom Biopharmaceutical Co. Ltd. ("**Zhifei Longcom**") and the Chinese Academy of Sciences. Save for the vaccine jointly manufactured by Zhifei Longcom and the Chinese Academy of Sciences which was approved for emergency use only, the other four vaccines have been given conditional approval for general use.

It was reported that BioKangtai and Fosun Pharma have partnered with AstraZeneca and BioNTech, respectively, to import their vaccines to China. However, to date, mainland China has not approved any overseas vaccine. The Hong Kong Special Administrative Region ("**Hong Kong SAR**") approved the BioNTech vaccine for emergency use in January 2021, while the Macao Special Administrative Region ("**Macao SAR**") granted the BioNTech vaccine special import authorisation in late February 2021. Both territories received their first batch of shots distributed by Fosun in late February 2021. The use of the BioNTech vaccine in these two Special Administrative Regions was temporarily suspended from 24 March 2021 through 4 April 2021 due to a packaging flaw in batch 210102. It is reported that both Hong Kong SAR and Macao SAR have resumed the use of BioNTech vaccine since 5 April 2021.

As of end February 2021, China has provided medical aid for vaccines to 69 countries and two international organisations worldwide, and has exported vaccines to 28 countries.

3. Regulatory Authority

Vaccines, as with other pharmaceutical products, fall under the purview of NMPA, the pharmaceutical arm of the State Administration for Market Regulation. A new vaccine needs to go through the following processes and/or satisfy the following requirements before it can be administered in China:

a. Development and Registration of Vaccines

The standard approval process for a new vaccine takes years and requires the observation of large numbers of patients over time to ensure safety and efficacy. The process includes (i) pre-clinical studies; (ii) clinical trial application; (iii) application for clinical trial institutions; (iv) clinical trial registration; (v) the authorities' review and examination of the clinical trial data; and (vi) the grant of approval for the vaccine. Once the vaccine is approved by and registered with NMPA, a Drug Registration Certificate will be issued.

b. Manufacture of Vaccines

Any manufacturer who intends to produce the vaccine is required by the PRC Vaccine Administration Law to obtain the Drug Production Permit issued by the medical products administration at or above the provincial level. A vaccine manufacturer should satisfy the following requirements in accordance with the PRC Drug Administration Law (Rev. 2019) ("**Drug Administration Law**") and the PRC Vaccine Administration Law (2019) ("**Vaccine Administration Law**"):

(a) It shall be staffed with legally certified pharmacy technicians, engineering technical personnel, as well as corresponding skilled workers;

(b) It shall have factory premises, facilities, and a sanitary environment suitable for the pharmaceutical production;

(c) It shall have an institution or competent personnel capable of inspecting the quality of the pharmaceuticals produced, as well as necessary instruments and equipment;

(d) It shall have rules and systems assuring pharmaceutical quality, and comply with the requirements of the Good Manufacturing Practices for Pharmaceuticals;

(e) It shall be equipped with appropriate scale and sufficient capacity stockpile;

(f) It shall have systems, facilities and equipment to ensure biological safety; and

(g) It shall meet the needs of disease prevention and control.

c. Lot Release System for Vaccine

Once a new vaccine is licensed, every lot shall be chemically and biologically tested before it is released along the supply chain. A lot release system for vaccines has been in place in China since the mid-2000s.

Each lot of vaccines to be sold or imported shall be examined and tested in accordance with relevant technical requirements by lot release institutions designated by NMPA. A qualified lot shall be granted a certificate for lot release of biological product, and a disqualified lot shall be given a notice of disapproval for lot release.

d. Wholesale and Retail of Vaccines

A vaccine wholesaler or retailer shall obtain the Drug Operation Permit before wholesaling or retailing the vaccine in China. A wholesaler or a retailer of vaccines as with other drugs shall satisfy the following requirements in accordance with the Drug Administration Law:

(a) It shall be staffed with legally certified pharmacists and other pharmacy technicians;

(b) It shall have business premises, equipment, storage facilities and a sanitary environment suitable for the pharmaceuticals in which it trades;

(c) It shall have a quality control organ or personnel suitable for the pharmaceuticals in which it trades; and

(d) It shall have rules and systems assuring pharmaceutical quality and comply with the requirements of the Good Distribution Practices for Pharmaceuticals.

4. Administration of Vaccines

The Vaccine Administration Law categorises vaccines into two categories: (i) vaccines under immunisation programs ("**Immunisation Program Vaccines**") and vaccines not covered by immunisation programs ("**Non-immunisation Program Vaccines**"). Immunisation Program Vaccines refer to the vaccines that shall be inoculated to residents in accordance with government provisions, including vaccines determined in national

immunisation programs, vaccines added by local governments, and vaccines used in emergency vaccinations or group preventive vaccinations organised by the governments at the county level or above or their competent health departments. In contrast, the Non-immunisation Program Vaccines refer to other vaccines voluntarily inoculated by residents. Another difference is that the Immunisation Program Vaccines are free for all the residents while the Non-immunisation Program Vaccines are not free, i.e., the residents shall pay for it.

On 31 December 2020, the National Healthcare Commission ("**NHC**") announced that COVD-19 vaccines has been categorised as Immunisation Program Vaccines which will be offered free to the Chinese citizens.

During the press conference on 15 March 2021, NHC said that China is implementing the administration of COVID-19 vaccinations in three different phases, with each phase targeting different priority groups: (i) key groups including people working in highly-exposed sectors and essential workers; (ii) high-risk groups including the elderly and people with underlying medical conditions; and (iii) other masses. The vaccination of key groups kicked off in late December 2020. Since early March 2021, China has been carrying out the vaccination campaign for other masses, which targets people aged between 18 and 59. Due to the incomplete clinical trial data for minors and the elderly, the vaccination program for minors and the elderly has not been implemented nationwide save for some cities, like Beijing and Shanghai, which have started inoculating seniors aged between 60 and 75. As of 20 April 2021, around 199 million doses of COVID-19 vaccines have been administered according to NHC.

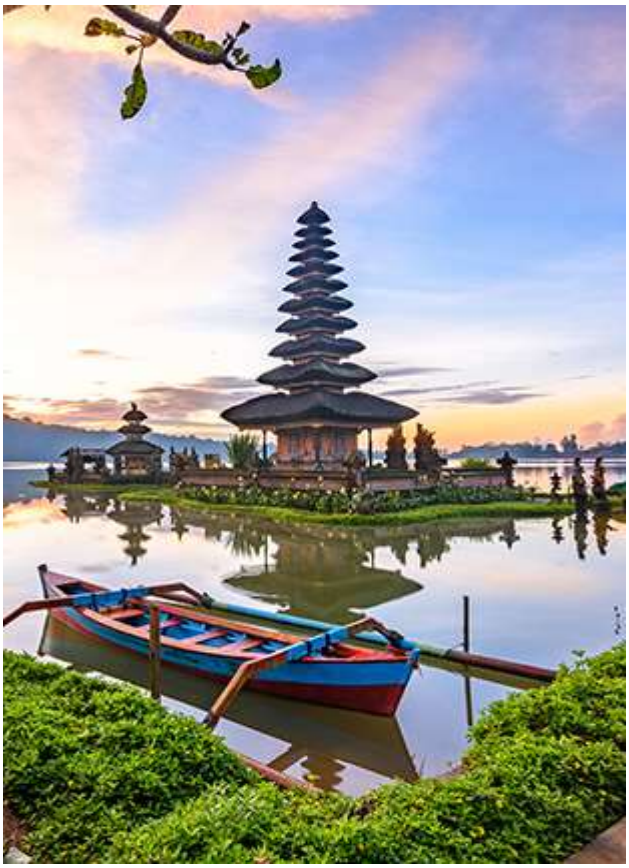
5. Conclusion

Currently, only China-manufactured vaccines can be administered in mainland China. Any vaccine, whether locally-manufactured or imported, must first be approved and registered with NMPA before it can be administered in China. In addition, manufacturers, importers, wholesalers and retailers must obtain the relevant permits and licences before they are able to manufacture and distribute vaccines within China.

INDONESIA

1. Introduction

The Government of Indonesia ("**GoI**") began its four-phase COVID-19 Vaccination Program on 13 January 2021. As is the case with other countries, healthcare workers received the first batch of vaccines, followed by public servants and then other members of the public. The GoI aims to inoculate a total of 181,554,465 people or around 66.91% of the total population by early 2022. As of late April 2021, over 19 million doses have been delivered, with 12 million people having received one dose and another 7 million having received both doses.



2. Vaccine Supplies Acquired by Indonesia

The Indonesian Ministry of Health ("**MoH**") plans to secure around 660 million vaccines both in binding and potential forms from around five different sources: (i) Sinovac, (ii) Novavax, (iii) COVAX/GAVI, (iv) AstraZeneca, and (v) Pfizer.

The supply status of each vaccine source may vary as it depends on several aspects, such as the stages of agreement and/or bureaucracy. Nevertheless, as of March 2021, the GoI has reached supply deals on more than 300 million doses of COVID-19 vaccine from various sources, including CoronaVac from Sinovac, the vaccine produced by local pharmaceutical PT Bio Farma, and AstraZeneca.

3. Regulatory Authority

The President has issued a Presidential Decree on the provision of vaccines and the implementation of vaccination program to combat the COVID-19 pandemic ("**Decree**"). It stipulates that the GoI is responsible to arrange for the provision, distribution, and administration of the COVID-19 vaccines. The Decree assigns PT Bio Farma, a state-owned pharmaceutical company, to procure the vaccine in cooperation with domestic and international institutions. Other suppliers are also allowed to procure the vaccine based on their appointment by MoH. The Decree also assigns MoH to manage vaccine distribution and the national vaccination programme.

Further, the Decree provides that the GoI will take over the legal liability of the COVID-19 vaccine suppliers in the supply of COVID-19 vaccines, including liability pertaining to the safety, quality, and efficacy of the vaccine. This take-over of liability by the GoI is subject to the vaccine supplier's compliance with good manufacturing practices and good distribution practices.

In general, vaccines are required to be registered with the National Agency of Drugs and Food Control (*Badan Pengawas Obat dan Makanan,* or "**BPOM**") before their distribution and administration in Indonesia. However, taking into account the emergency situation, the Decree allows BPOM to issue an Emergency Use Authorisation ("**EUA**") for the use of vaccines in Indonesia. The EUA issuance by BPOM must be based on the Emergency Use Listing procedure that is implemented by the World Health Organization. So far, BPOM has issued EUAs for

CoronaVac from Sinovac, PT Bio Farma, and AstraZeneca's COVID-19 vaccine in Indonesia.

BPOM will also supervise the circulation and administration of COVID-19 vaccines in the community to ensure their safety and efficacy. To support this goal, BPOM will provide an electronic reporting system where pharmaceutical firms and paramedics can report side-effects of the vaccines.

4. Vaccine Administration by the Private Sector

MoH has issued MoH Regulation No. 10 of 2021 on the execution of vaccinations in its effort to handle the COVID-19 Pandemic ("**MoH Regulation**"), which was effective from 25 February 2021. Through the MoH Regulation, companies can arrange for the vaccination of their employees. This stream of vaccination, however, requires the company to coordinate their vaccination program with the GoI and bear all costs so that recipients will not be charged at all for vaccination. Companies are not allowed to use the quota of vaccines that are used for the GoI's vaccination program. In order to streamline the process and to ensure that no GoI's vaccines are used by the companies, the procurement of the vaccines for this purpose as well as the distribution to companies will still be carried out by PT Bio Farma.

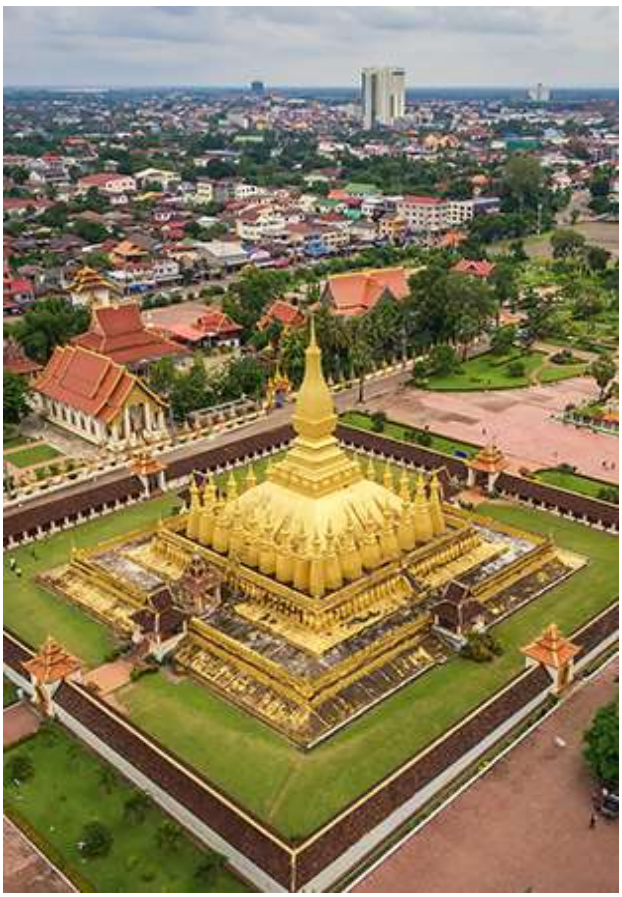
5. Conclusion

The GoI sees vaccinations against COVID-19 as a very important step for the country to emerge from the pandemic. It is determined that the vaccination must at least reach the target recipients without considering their economic background at all. Thus, the GoI also allows companies to take part in the vaccination program, but emphasising that such must be done free of charge. Nevertheless, to ensure that the vaccination will reach the desired level of efficacy without jeopardising the GoI's vaccination program, PT Bio Farma is still tasked with procuring and distributing vaccines for both the GoI's program and companies.

LAO PDR

1. Introduction

Laos has completed nationwide immunisation for front-line workers and health care workers in March 2021, and rolled out vaccination for the public on 1 April 2021. As of 20 April 2021, approximately 110,000 people have taken their first shots of vaccine, and around 50,000 people have taken their second shots.



2. Vaccine Supplies Acquired by Laos

As of 20 March 2021, Laos has acquired an aid of 1,235,000 doses of COVID-19 vaccines from (i) China's Sinopharm (1,102,000 doses); (ii) Russia's Sputnik V (1,000 doses); and (iii) 132,000 doses of AstraZeneca from Gavi COVAX Facility.

3. Regulatory Authority

While the importation of vaccines is governed by the Law on Drugs and Medical Products No. 07/NA dated 21 December 2011, the research, development, manufacture, distribution, and administration of vaccines in Laos is governed by the Law on Vaccination No. 52/NA dated 25 June 2018. The authority in charge of both normal and emergency immunisation of people in Laos is the Department of Hygiene and Health Promotion, Ministry of Health ("**DHP**").

4. The Approval Process – Import and Distribution of COVID-19 Vaccines

Currently, no entity from the private sector has filed its application for importation and distribution of COVID-19 vaccines. All available COVID-19 vaccines are being administered by DHP. The Prime Minister has announced that the government will facilitate and provide support to eligible entities from the private sector in their importation and distribution of COVID-19 vaccines.

Entities from the private sector that wish to import and distribute COVID-19 vaccines must be entities registered under Lao laws, and should have first obtained the requisite drugs importation and distribution business operation licenses from the Department of Food and Drugs of the Ministry of Health.

Prior to importation, they must also obtain a registration certificate from the Department of Food and Drugs.

5. Conclusion

Any drugs, medical products and vaccines shall be approved by and registered with the Department of Food and Drugs of the Ministry of Health before they can be imported, disbuted and administered in Laos.

The government encourages the private sector to contribute to the importation of COVID-19 vaccines for domestic distribution to achieve the goal of vaccinating at least 70% of the population by end 2021.

MALAYSIA

1. Introduction

Malaysia launched its National Immunisation Programme ("**NIP**") on 16 Febraury 2021, a few days before it welcomed the first batch of COVID-19 vaccines. More commonly known by its manufacturers, Pfizer and BioNTech, the highly anticipated Comirnaty vaccine ("**Comirnaty Vaccine**") arrived at the Kuala Lumpur International Airport on 21 February 2021.

2. Vaccine Supplies Acquired by Malaysia

As of February 2021, Malaysia had secured 66.7 million doses of various COVID-19 vaccines from five foreign manufacturers: (i) Pfizer-BioNTech; (ii) AstraZeneca; (iii) Sinovac; (iv) CanSino Biologics; and (v) Sputnik V. However, the supply and administration of such vaccines is subject to the approval of local health authorities.

3. Regulatory Authority

The Malaysian Government established the Special Committee for Ensuring Access to Covid-19 Vaccine Supply (*Jawatankuasa Khas Jaminan Akses Bekalan Vaksin Covid-19*, or "**JKJAV**"), which is co-chaired by the Minister of Health and the Minister of Science, Technology & Innovation. As its name suggests, JKJAV is tasked with ensuring timely access to the supply of COVID-19 vaccines for the country through the implementation and monitoring of the NIP. At the time of writing, JKJAV will seek to implement the administration of COVID-19 vaccinations in three different phases, with each phase targeting different priority groups.

Policy plans aside, the vaccines can only be administered to the masses if they have been given local regulatory approval. Generally, pharmaceutical product registrations fall under the purview of the National Pharmaceutical Regulatory Agency ("**NPRA**"), the pharmaceutical arm of the Ministry of Health Malaysia ("**MOH**"). On 15 December 2020, perhaps in anticipation of the NIP, NPRA issued the Guidance and Requirements on Conditional Registration for Pharmaceutical Products During Disaster ("**Conditional Registration Guidelines**"). The Conditional Registration Guidelines apply specifically to the registration of "new pharmaceutical products (including vaccines) for use during a disaster", be it products that have been imported with an intent to be distributed, or locally-manufactured products.

To date, the Comirnaty Vaccine, AstraZeneca, and Sinovac are the only COVID-19 vaccines that have been granted conditional registration by NPRA. Pursuant to the Conditional Registration Guidelines, each of the three registrations is valid only for one year from the time they are approved, after which each is subject to renewal for up to two more times. It is likely, therefore, that vaccine manufacturers granted conditional approval would apply for a full approval in due course.

Import and Distribution of Vaccines

Registered products can only be handled by licensed importers and/or wholesalers which are approved by NPRA and are subject to the principles of MOH's Good Distribution Practice Guidelines ("**GDP**"). According to the Conditional Registration Guidelines, it is the importers

and/or wholesalers (as the case may be) who are fully responsible for ensuring that all parties involved in the supply chain of the registered products are compliant with the GDP. Amongst other requirements, these include the management of time and temperature-sensitive products, such as that of the Comirnaty Vaccine which is required to be stored at -75ºC. Evidently, compliance with such requirements is paramount to the country's plans for immunisation.

Local Value-Added Manufacturing

In negotiations for the purchase of vaccines from the two Chinese manufacturers, Sinovac and CanSino Biologics, the Malaysian Government agreed to provide a value-add element to the manufacturing process, i.e., the final step of filling the vaccine into the vials. Such a proposal would enable the vaccines to be purchased in bulk, with the final manufacturing step to be conducted locally before distribution. While this would accelerate vaccine deployment, it is still subject to the approval of NPRA.

One of the many considerations of NPRA for the approval of vaccines for use in Malaysia is the local value-adding manufacturers' compliance with MOH's Good Manufacturing Practice ("**GMP**"). In the same vein as that of the GDP, the GMP seeks to ensure the quality and consistency of the vaccines manufactured. This includes a review of the manufacturing sites and information relevant to the product supply chain.

With updates of vaccine administration and immunisation plans unveiling every day, authorities have also been quick to issue warnings on "queue jumping". Such warnings were complemented with the enactment of Section 31 of the Emergency (Prevention and Control of Infectious Diseases) (Amendment) Ordinance 2021 ("**Section 31**") which allows for action to be taken for non-specified offences under the Prevention and Control of Infectious Diseases Act 1988. Under Section 31, an individual found liable for jumping the queue to receive COVID-19 vaccinations may be penalised with a fine not exceeding RM50,000, or imprisonment for a term not exceeding six months, or both. Section 31 came into effect on 11 March 2021.

4. Vaccine Administration by the Private Sector

Although the Malaysian Government initially stated that there were no provisions in place for private hospitals or companies to purchase and run their own vaccination programmes, it was clarified during a conference held on 29 March 2021 that the Government will allow private hospitals to negotiate with suppliers and purchase vaccines. However, it was made clear that vaccines procured by the private sector are only expected to arrive in the third or fourth quarter of 2021. Currently, private hospitals are only being used as vaccination centres.

It is possible, in principle, for private hospitals and companies to procure their own vaccine supply. This is because private entities are able to purchase vaccines from importers, wholesalers, or manufacturers that are licensed by NPRA, subject, of course, to the availability of such vaccines. The justification which companies use is that they need to ensure their employees are vaccinated and able to work safely, especially those in the manufacturing, construction and hospitality industry, who are not on the Government's priority list of individuals to be vaccinated. However, with only three vaccines currently registered in Malaysia, it would be practically difficult for the private sector to import vaccines into Malaysia at this point in time. There would also be the question of tracking who has been vaccinated, and the quality control of both the vaccine and administration of the vaccine itself.

5. Conclusion

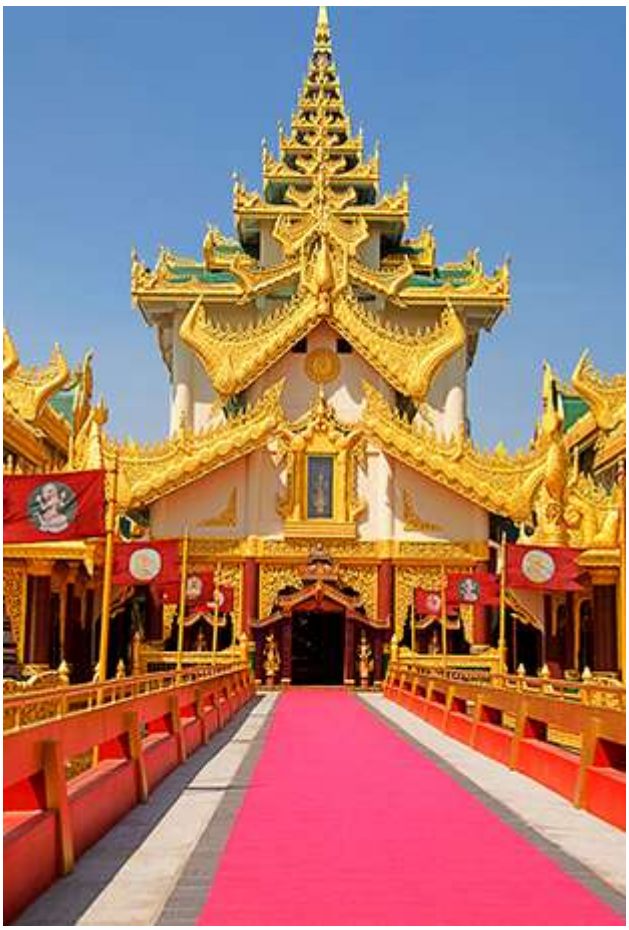
Any vaccine, before it may be administered in Malaysia, must first be registered with NPRA. In addition, vaccines can only be imported, sold wholesale, or manufactured by NPRA-approved importers, wholesalers, and manufacturers accordingly.

Malaysia is still at the initial stages of its vaccine roll-out plan, and while arrangements have been put in place to secure sufficient vaccines for the entire population, the prior approval of NPRA is required before vaccines can be imported and distributed. Therefore, the speed of any vaccination initiative, whether by the Government or the private sector, is currently still very much dependent on NPRA first approving the various types of vaccines available globally.

MYANMAR

1. Introduction

Prior to the military takeover on 1 February 2021, the Myanmar Government had planned to roll out a national immunisation programme from 27 January 2021 using the Covidshield vaccines purchased from India on 22 January 2021. After the military takeover, the Ministry of Health and Sports ("**MOHS**") announced the commencement of the immunisation program beginning 4 February 2021.



2. Vaccines Acquired by Myanmar

MOHS has already recevied a gift of 1.5 million doses of Covidshield vaccines from India. Moving forward, it is expecting 30 million doses of Covidshield vaccines purchased from the Serum Institute of India (SII) to arrive in monthly shipments, and approximately 27 million doses of vaccines from the Gavi COVAX facility from March onwards. In addition, the Commander-in-Chief of Defence Services Senior General Min Aung Hlaing, who is also the chairman of the State Administration Council, further announced on 17 April 2021 that 28 million more doses purchased from India are due to arrive in June.

3. Regulations

There is no omnibus legislation or regulations concerning the importation and handling procedures in relation to vaccines. Based on the announcement dated 4 February 2021 released by MOHS, 104,142 frontline healthcare workers have been vaccinated as of that date. MOH has rolled out a priority plan for personnel who are eligible to receive the vaccines in February as follows:

(a) Union-level government personnel, Union Ministers, Deputy Ministers, Chairmans of Regional or State Councils, Secretary of the State Administration Council and its members;

(b) Ministerial Departments and Central Committees, and civil servants from departments having a ranking of Director or higher;

(c) Persons aged 65 or older within the Stay-at-Home designated Townships; and

(d) Union Ministers, Deputy Ministers, and officials from Regional or State Governments from the pre-February government.

The same priority plan is followed for the succeeding months and it is likely that this will be implemented for the entire time while dealing with the pandemic.

Further information on vaccination plans are expected to be announced, but have not been done so at this juncture.

4. Private Sector

As of this date, the private sector has not been authorised to import vaccinations and roll out an administration plan. However, Senior General Min Aung Hlaing stated in a report dated 11 February 2021 that vaccines approved by the Food and Drug Administration Department ("**FDA**") – which include vaccines from Russia, China, and India – will soon be available for importation by the private sector in line with the COVID-19 rules and regulations. These

rules and regulations have not been enacted publicly, and no developments as to Private Sector Vaccine Administration have occurred.

5. Import Regulations

As mentioned, the country does not have omnibus legislation or regulations in relation to the importation of COVID-19 vaccines. The normal process for importation of vaccines for humans consists of: (i) registration of the drug with FDA under Section 7 of the National Drug Law of 1992; and (ii) application for an Import license under the Export and Import Law of 2012. Based on the announcement made by Senior General Min Aung Hlaing in a report dated 11 February 2012, the Government may issue rules specific to COVID-19 vaccines when the authorisation for the importation of the vaccines are extended to the private sector.

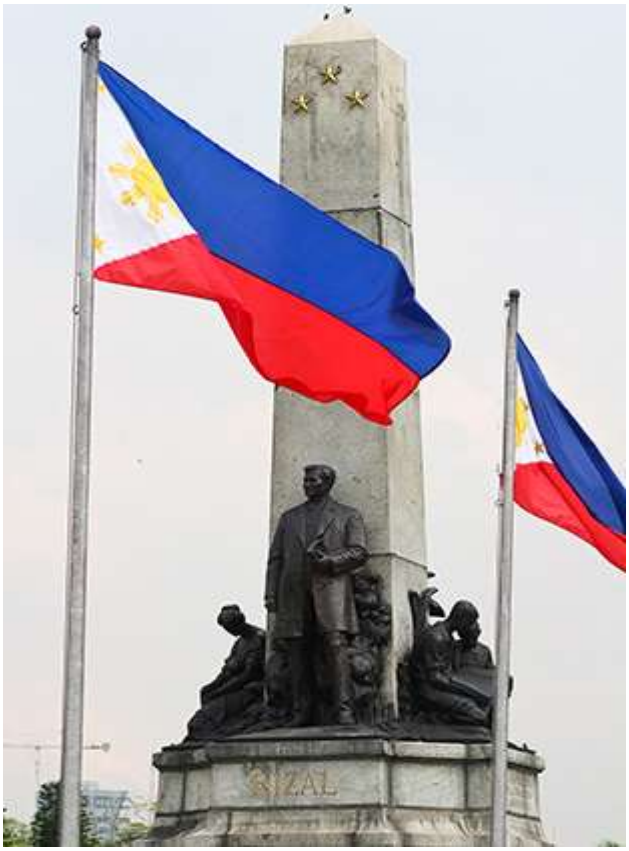
6. Conclusion

Immunisation is currently only being handled by the public sector as MOHS handles the importation and administration of COVID-19 vaccines according to its own internal guidelines. Due to the political instability of the country, it is hard to forecast whether the entire population may be vaccinated against COVID-19 within the year 2021.

PHILIPPINES

1. Introduction

On 26 February 2021, the Philippine President signed Republic Act No. 11525 or the COVID-19 Vaccination Program Act of 2021 ("**RA 11525**"). The law regulates the procurement of COVID-19 vaccines and ancillary supplies and services necessary for their storage, transport, deployment, and administration. These tasks shall primarily be carried out by the Department of Health ("**DOH**") and the National Task Force Against COVID-19 ("**NTF**"), mainly in coordination with local government units ("**LGUs**"). The COVID-19 vaccination roll-out began on 1 March 2021, with frontline healthcare workers being the first to be inoculated.



2. Regulatory Authority

The Food and Drug Authority ("**FDA**"), an agency under the Office of the DOH Secretary, through its Center for Drug Regulation and Research, is charged with regulating the manufacture, importation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of health products, including vaccines. Only COVID-19 vaccines duly registered with FDA as evidenced by a valid Certificate of Product Registration ("**CPR**") or those for which Emergency Use Authorizations ("**EUA**") have been granted by FDA may be used in the Philippines. Until a full market authorisation or a CPR is issued by FDA for a particular COVID-19 vaccine, the latter cannot be treated as a commercial product or sold to the public.

Under RA 11525, DOH and NTF, jointly or in cooperation with any national government agency or instrumentality or LGU, are authorised to procure COVID-19 vaccines and ancillary supplies and services through Negotiated Procurement under Emergency Cases as defined in the Philippines' government procurement regulations. At present, the national government, through DOH and NTF, must be involved in all negotiations and procurements of COVID-19 vaccines.

DOH and NTF shall negotiate and approve the terms and conditions, including the price and payment terms, for the procurement of COVID-19 vaccines to ensure price uniformity and prevent price competition. Once these terms have been negotiated by DOH and NTF, LGUs and other Procuring Entities may enter into supply agreements, advance market commitments, advance payments, research investments, and other arrangements as may be identified by DOH and NTF. LGUs are also authorised to directly procure ancillary supplies and services necessary for the storage, transport, deployment, and administration of COVID-19 vaccines, also through Negotiated Procurement under Emergency Cases.

RA 11525 authorises LGUs to make advance payments if required by the supplier, manufacturer or distributor of the vaccines, notwithstanding the prohibition against advance payments under the Local Government Code.

RA 11525 allows LGUs to accept donations of COVID-19 vaccines provided the latter have been authorised by FDA.

The Philippine Health Insurance Corporation is tasked with administering the COVID-19 National Vaccine Indemnity Fund to compensate any person inoculated

through the COVID-19 Vaccination Program, in case of death, permanent disability or hospital confinement for any serious adverse effects.

3. Vaccines Acquired

As of mid-April 2021, the Philippines has granted an EUA for COVID-19 vaccines from the following manufacturers: (i) AstraZeneca (United Kingdom); (ii) Gamaleya Research Center (Russia) for the Sputnik vaccine; (iii) Pfizer, Inc. and BioNtech (United States); (iv) Sinovac Biotech (China); (v) Covaxin (India); and (vi) Janssen (United States). An EUA application has not been filed for the Moderna vaccine as of mid-April 2021; however, the government has already contracted for its supply.

The Philippines so far has received around 3 million doses of COVID-19 vaccines as of mid-April 2021. Of that figure, 2.5 million were sourced from Sinovac Biotech, while approximately 500,000 were secured from AstraZeneca pursuant to the COVAX Initiative. The country expects to receive around 4.5 million doses and 117,000 doses of AstraZenera and Pfizer vaccines, respectively, in May 2021.The remainder of the vaccines are expected to become available later this year.

4. Administration of Vaccines

By the National Government

The first set of COVID-19 vaccines is primarily allocated to priority population groups as follows: (i) frontline workers in health facilities (both national and local, private and public), health professionals, and non-professionals like students, nursing aides, janitors, and barangay health workers; (ii) senior citizens aged 60 years old and above; (iii) persons with comorbidities; (iv) frontline personnel in essential sectors including uniformed personnel and those in working sectors identified by the Inter-Agency Task Force on Emerging Infectious Diseases as essential during enhanced community quarantine; (v) the indigent population; (vi) teachers and social workers; (vii) other government workers; (viii) other essential workers; (ix) socio-demographic groups at significantly higher risk other than senior citizens and indigenous people; (x) overseas Filipino workers; (xi) other remaining workforce; and (xii) the rest of the Filipino population. The list of priority groups was based on the World Health Organization's recommendation of giving priority to frontline workers in health facilities and those considered "high risk".

As of mid-April 2021, around 1.5 million doses have been administered – around 1.3 million persons have received the first dose of the vaccine while around 200,000 persons have received both doses. In Metro Manila and nearby provinces, the local government units have distributed the vaccine to healthcare workers and are now administering to senior citizens and persons with comorbidities. The Philippines has vaccinated an estimated 292,000 frontline workers. The Philippines is inoculating an average of 23,000 to 30,000 people daily and is targeting to start general public vaccinations by early May this year. The country is eyeing to vaccinate up to 70 million people by the end of 2021, and by April or May 2022 to eliminate COVID-19 in the Philippines.

By the Private Sector

Private entities may procure COVID-19 vaccines but only in cooperation with DOH and NTF through a multi-party agreement with suppliers of COVID-19 vaccines. The procurement of the vaccine, supplies, or services shall be for the sole and exclusive use of such companies, without prejudice to the multiparty agreements. Priority for the inoculation of the vaccines procured by private entities shall be given to its healthcare workers, senior citizens, economic frontliners, and essential workers. However, the chief medical officers of private entities may formulate their own vaccine recipient list and implement their own operational procedures which must be consistent with the national policies and procedures issued by DOH, if it will expediate and enhance the efficiency of the inoculation process and prevent spoilage of vaccines.

5. Conclusion

Before any vaccine can be used and administered in the Philippines, it must have an EUA or a valid Certificate of Product Registration issued by FDA. In addition, vaccines can only be manufactured, imported, sold, or advertised by importers, sellers, manufacturers or advertisers duly licensed by FDA.

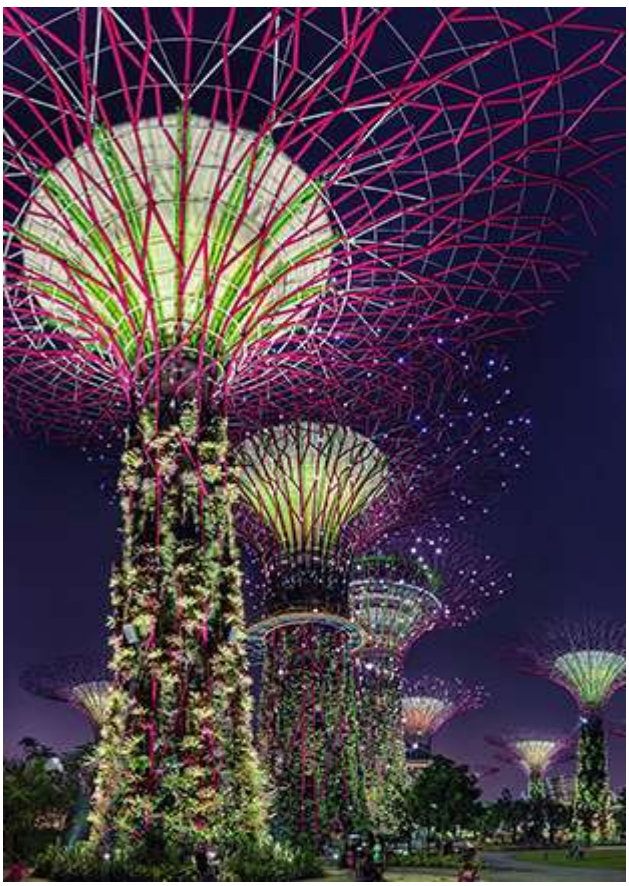
As of mid-April 2021, the Philippines is still at the initial stages of its vaccine roll-out. Although arrangements are supposedly being formulated to secure sufficient vaccines for the entire population, the requirement of FDA approval, as well as the government's practical monopoly in the negotiation and procurement of vaccines and the apparent delays in such negotiation and procurement, have resulted in the general perception that the

Philippines' COVID-19 vaccine program requires much improvement.

SINGAPORE

1. Introduction

On 30 December 2020, Singapore kickstarted its national COVID-19 vaccination programme ("**CVP**") by administering the first doses of the Pfizer-BioNTech COVID-19 vaccine to frontline healthcare workers from the National Centre for Infectious Diseases. The vaccinations were administered shortly after Singapore received its first shipment of Pfizer-BioNTech COVID-19 vaccines on 21 December 2020. The Singapore Government had set aside more than S$1 billion to secure early access to promising COVID-19 vaccines and planned to obtain enough vaccines for all citizens and long-term residents by the third quarter of 2021.



2. Vaccine Supplies Acquired by Singapore

As of 20 April 2021, Singapore has received COVID-19 vaccines from three foreign manufacturers: (i) Pfizer-BioNTech; (ii) Moderna; and (iii) Sinovac, although only the first two are approved for use by the Health Sciences Authority ("**HSA**"), which is the local regulator overseeing all health products in Singapore. The authorities did not disclose the quantity of COVID-19 vaccines ordered, save that enough has been secured for all Singaporeans and long-term residents in Singapore.

3. Regulatory Authority and Vaccination Strategy

Vaccines, as with other health products, fall under the regulatory purview of the Ministry of Health ("**MOH**") and HSA. In October 2020, MOH appointed an Expert Committee on COVID-19 Vaccination ("**Expert Committee**") to assess the safety, efficacy and suitability for use of COVID-19 vaccinations in Singapore and to advise on vaccination strategy. The Expert Committee is chaired by the Senior Advisor to the Director of Medical Services of MOH and comprises experts in diseases, immunology and other relevant fields, including senior doctors and medical consultants, medical professors, and clinical research professionals.

The Singapore Government accepted the Expert Committee's recommendations on the overall COVID-19 vaccination strategy, which include:

(a) aiming to provide vaccination to everyone residing in Singapore (including Singapore Citizens, Singapore Permanent Residents and Long-Term Pass Holders);

(b) giving vaccination priority to the following groups:

- Persons at high risk of being infected by COVID-19, including healthcare workers and workers at the frontline of the national COVID-19 response;
- Persons most vulnerable to severe disease and complications if they fall ill with COVID-19, including the elderly and persons with medical comorbidities; and

(c) setting aside 5% of available vaccine stocks for personnel involved in ensuring that nationally essential services are not disrupted.

The authorities highly encourage the public to receive vaccination, though the regime currently remains voluntary.

4. The Approval Process – Import and Distribution of COVID-19 Vaccines

Pharmaceutical products such as COVID-19 vaccines are regulated by HSA as 'therapeutic products' under the Health Products Act ("**HPA**"). While therapeutic products such as COVID-19 vaccines must typically be registered with HSA before they can be supplied in Singapore, the HSA had introduced a Pandemic Special Access Route ("**PSAR**") in December 2020 where HSA may grant interim authorisation pending full registration of the product, so as to facilitate early access to critical novel vaccines, medicines, and medical devices during a pandemic. HSA has stated that the PSAR framework is similar to emergency authorisation frameworks adopted by countries such as the United States and United Kingdom.

To obtain interim authorisation for COVID-19 vaccines under the PSAR, the applicant must be a supplier directed by the Singapore Government to supply for or on its behalf. There must be reasonable quality, safety, and efficacy data suggesting that the potential benefits outweigh the known risks when used during the COVID-19 pandemic, in addition to continuing data generated from ongoing studies to support the eventual transition of the interim authorisation to full registration.

Currently, only the Pfizer-BioNTech and Moderna vaccines have been granted interim authorisation under the PSAR. As of mid-March 2021, HSA was in the midst of evaluating the Sinovac vaccine for safety and efficacy.

Unless interim authorisation is obtained, a relevant dealer's licence (i.e. manufacturer's licence, importer's licence, or wholesaler's licence, as the case may be) must be obtained from HSA to manufacture, import and/or distribute COVID-19 vaccines in Singapore. Where licensing requirements apply and vaccines are intended for the Singapore market, both the importer and distributor will be audited for compliance with HSA's Guidance Notes on Good Distribution Practice before they may obtain their respective licences. Similarly, local manufacturers of vaccines must comply with applicable Good Manufacturing Practice ("**GMP**") standards to obtain a manufacturer's licence and overseas manufacturers intending to register vaccines in Singapore may be subject to HSA's GMP Conformity Assessment before the products can be registered.

5. Administration of Vaccines

MOH oversees the entire process of administering the vaccine to the Singapore population. It began rolling out the COVID-19 vaccination programme on 30 December 2020 for healthcare and frontline workers, while vaccinations for the elderly (aged 70 and above) commenced on 22 February 2021. Vaccination for seniors aged 60 to 69 years began from mid-March 2021.

Extent of vaccination administration in Singapore: As of 18 April 2021, more than 2.2 million doses of COVID-19 vaccines have been administered. More than 1.3 million individuals have received at least the first dose of a COVID-19 vaccine, of whom about 850,000 have completed their full vaccination regimen. As of 5 April 2021, more than 60% of eligible seniors aged 70 and above, and close to 70% of eligible seniors aged 60 to 69 have received the vaccination or booked their vaccination appointments. As of 20 April 2021, a total of 38 vaccination centres are in operation (just shy of the targeted goal of 40 centres), in addition to the 20 polyclinics and 22 Public Health Preparedness Clinics (PHPCs) in operation.

Appeal for Early COVID-19 Vaccination: On 16 March 2021, an early appeal process for Singapore Citizens and Permanent Residents was introduced, under which MOH will consider appeals from individuals to be vaccinated earlier if they fall under any of the following categories:

(a) Individuals who must take up a new job or return to employment overseas for which working from Singapore is not possible and not going overseas would result in the loss of the job;

(b) Individuals who need to travel for medical reasons or compassionate grounds; or

(c) Individuals who are required to be physically present in relation to a formal education or vocational programme overseas.

Aside from the above categories, other applications will only be considered on an exceptional basis.

Administration of Vaccination Programme: The vaccination programme is administered by the Singapore Government, and there there are currently no provisions for private hospitals or companies to purchase and run their own vaccination programmes in Singapore.

All Singaporeans and long-term residents as well as migrant workers in Singapore will be able to be vaccinated for free. The Singapore Government has also introduced the Vaccine Injury Financial Assistance Programme, which provides financial assistance to Singapore Citizens, Permanent Residents and Long-Term Pass holders if a person suffers from serious side effects arising from his or her COVID-19 vaccination.

6. Continued Management of the COVID-19 Pandemic

While the vaccination of the population is underway, the Singapore Government continues to maintain strict measures to manage the COVID-19 pandemic.

Border control measures, community safety measures, and Workplace Safe Management Measures continue to stay in place and adjusted accordingly to manage and contain the COVID-19 infections in Singaore, taking into account evolving global and domestic COVID-19 situation. Among other things, employers are urged to be prepared to implement measures such as staggered work hours and telecommuting. Employers must also ensure that a certain percentage of their employees are working from home as required by law, when there is a need to minimise the transmission of COVID-19.

Detection and contact-tracing continue to remain aggressive strategies in managing community outbreaks. To ensure rapid availability of diagnostic tests for COVID-19, HSA also expedited the approval of COVID-19 Diagnostic Tests via its Provisional Authorisation process. This process allows COVID-19 Diagnostic Tests to be made available on a short-term basis, and a summary of analytical validation and clinical data is required. As of April 2021, almost 200 COVID-19 Diagnostic Tests have been approved for provisional use in Singapore.

7. Conclusion

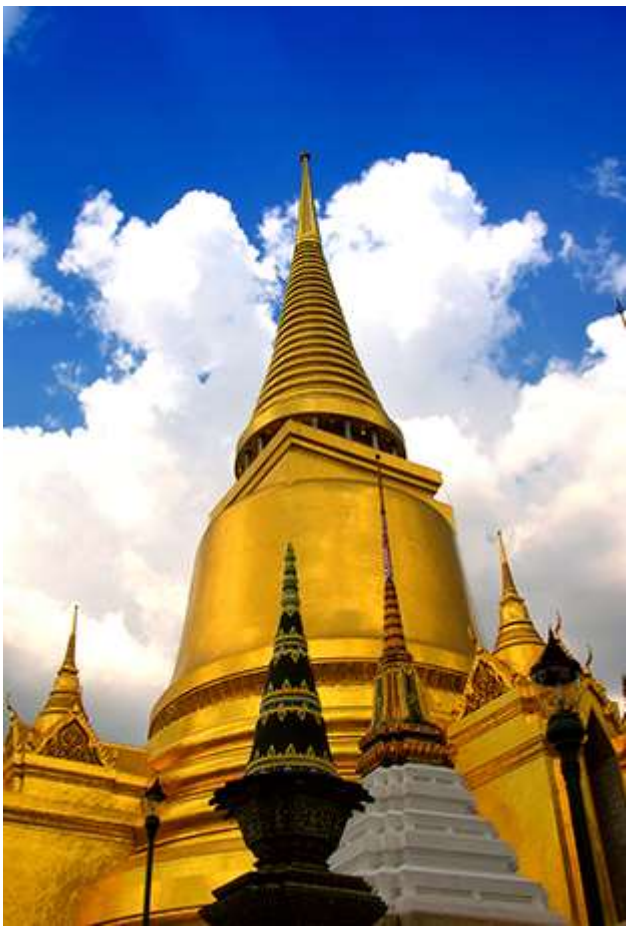
A supplier of the COVID-19 vaccine under the PSAR does so for or on behalf of the Singapore Government, and must first obtain interim authorisation by HSA under the PSAR. Without the interim authorisation, suppliers must register the COVID-19 vaccines with HSA, with the relevant dealer's licences to manufacture, import and/or wholesale.

Singapore's CVP has progressed steadily since its inception on 30 December 2020, with the Singapore Government bringing forward planned vaccination drives on several occasions. The Sinovac vaccine is awaiting regulatory approval from HSA, which will further facilitate Singapore's goal of vaccinations for all citizens and long-term residents.

THAILAND

1. Introduction

In Thailand, the two primary laws governing vaccine issues are: (i) the Thai Drugs Act B.E. 2510 (1967), as amended ("**Drugs Act**"); and (ii) the National Vaccine Security Act B.E. 2561 (2018) ("**NVSA**"). While the Drugs Act aims to regulate vaccine licensing requirements, the NVSA aims to promote and support the research, development, manufacture, procurement, and distribution of a sufficient quantity of quality vaccines for the immunisation of people both in normal and emergency situations.



2. Vaccine Supplies Acquired by Thailand

As of mid-March 2021, Thailand has secured around 63 million doses of various COVID-19 vaccines from two manufacturers: (i) AstraZeneca (61 million doses, comprising 26 million doses which will be produced locally by Siam Bioscience Co., Ltd. in partnership with AstraZeneca and another 35 million, which will be imported later this year); and (ii) Sinovac Biotech (2 million doses).

117,000 doses from AstraZeneca and 200,000 doses from Sinovac Biotech arrived at the Suvarnabhumi Airport on 24 February 2021. On 20 March 2021 and 10 April 2021, Thailand acquired an additional 800,000 doses and 1,000,000 from Sinovac Biotech, respectively. The remainder of the vaccine is expected to become available later this year. According to recent news, the Thai Minister of Public Health stated that additional vaccine purchases from other foreign manufacturers may also be made.

Thailand's COVID-19 vaccination program officially began on 1 March 2021. The first set of vaccine will primarily be given to three groups of people: (i) medical and public health personnel; (ii) individuals aged above 60; and (iii) patients with chronic diseases. By mid-April 2021, around 580,000 doses of COVID-19 vaccines have been administered, and over 70,000 individuals have been fully vaccinated. It should be noted that Thailand's vaccine roll-out plans are prepared and launched by the Sub-Committee on the administration of vaccination against the COVID-19 disease established under the Thai Communicable Disease Act B.E. 2558 (2015).

3. Regulatory Authority

Food and Drug Administration under Drugs Act

In respect of vaccine administration in Thailand, the Thai Food and Drug Administration ("**FDA**") established under the Drugs Act and chaired by the Thai Permanent Secretary of the Ministry of Public Health ("**MOPH**"), is primarily tasked with the following:

(a) Approving and registering vaccines;

(b) Issuing a license for the manufacture, import, sale, or advertisement of vaccines;

(c) Prescribing regulations, conditions, and procedures on the manufacture, sale, importation, storage, advertisement, or other relevant administration of vaccines; and

(d) Inspecting places used for the manufacture, import, sale, and storage of vaccines.

Thai National Vaccine Committee under NVSA

The Thai National Vaccine Committee, established under the NVSA and chaired by the Thai Prime Minister, has the regulatory power to propose strategic policies and plans on the administration, procurement, and distribution of vaccines or immunisation to the people, as prepared and proposed by the Thai National Vaccine Institute.

In addition, in case of emergency or necessary cause for public interest, for protection, control, cure, abatement of disease severity, or for the security of the country, the Minister of Public Health, with the consent of the National Vaccine Committee, has the power to prescribe a Notification on the following matters:

(a) Manufacture of vaccines in the prescribed type and amount;

(b) The proportion of temporary vaccine exportation, which shall be appropriate when compared with the proportion of domestic vaccine usage;

(c) Appropriate vaccine quality assurance and control;

(d) Appropriate procurement, administration, distribution, and provision of vaccine or immunisation services; and

(e) Other relevant issues relating to emergency or necessity.

Moreover, in light of the COVID-19 pandemic, MOPH issued the Notification on Procurement of Vaccines against Coronavirus Disease 2019 (Covid-19) in Case of Emergency or Necessity B.E. 2563 (2020). Pursuant to this notification, the Thai National Vaccine Institute has the responsibility to enter into agreements and collaborate with government or private entities in Thailand or from other countries in order to proceed with the procurement of COVID-19 vaccines.

4. Vaccine Administration by the Private Sector

As of mid-March 2021, the Minister of Public Health has stated that the Thai Government does not prevent the private sector from procuring and importing vaccines, and MOPH has ordered FDA to facilitate the private sector in this regard. That being said, prior to being administered in Thailand, vaccines must first be approved and registered by FDA.

In a normal situation, the process for approval and registration of vaccines usually takes up to 280 days from the submission of application for registration to complete. However, given the COVID-19 situation, FDA issued the Notification on Conditional Approval for Emergency Use of Medical Products dated 24 July 2020 to accelerate the completion of such process. As verbally informed by an FDA official, the approval and registration process could be completed within 30 days, provided that: (i) there is a certificate from an internationally-accepted medicines regulator, such as the European Medicines Agency or the U.S. Food and Drug Administration; and (ii) all requirements are met and necessary supporting documents are submitted. Note that the approval and registration of vaccines by FDA under this notification is limited to specific circumstances and purposes. Furthermore, the administration of a vaccine approved and registered by FDA under this notification is subject to certain conditions in respect of, for example, distribution, provision, storage, and reporting.

As at 16 April 2021, FDA has approved three vaccines, those from AstraZeneca, Sinovac Biotech, and Johnson & Johnson. The Sinovac Biotech vaccine is only approved for people aged between 18 and 59. The application for approval and registration of the Bharat Biotech COVID-19 vaccine has been submitted and is now pending review.

Once the vaccine has been approved for use, any private organisation, including hospitals, wishing to import, manufacture, sell, or advertise the same must first obtain a license from FDA. A licensed importer, seller, manufacturer or advertiser also has certain duties under the Drugs Act.

5. Conclusion

Any vaccine, before it can be administered in Thailand, must first be approved and registered by FDA. In addition, vaccines can only be manufactured, imported, sold, or advertised by licensed importers, sellers, manufacturers, or advertisers.

Thailand is still at the initial stages of its vaccine roll-out plan, and while arrangements have been put in place to

secure sufficient vaccines for the entire population, the prior approval of FDA is required before vaccines can be administered in Thailand. Therefore, the speed of any vaccination initiative, whether by the public or private sector, is currently still very much dependent on FDA first approving the various types of vaccines available globally.

VIETNAM

1. Introduction

To date, Vietnam has been negotiating to purchase COVID-19 vaccines from different manufacturers, such as AstraZeneca, Pfizer, Moderna, Johnson & Johnson and Sputnik V. Simultaneously, vaccines manufactured by Vietnamese manufacturers, namely Nano Covax of Nanogen Pharmaceutical Biotechnology Co., Ltd. and Covivac of Institute of Vaccines and Medical Biologicals (IVAC), are also being put into clinical testing.

On 24 February 2021, the first batch of COVID-19 vaccines from AstraZeneca has arrived at the Tan Son Nhat International Airport.

2. Vaccine Supplies Acquired by Vietnam

As of February 2021, Vietnam has secured 117,600 doses of COVID-19 vaccines from AstraZeneca ("**AstraZeneca Vaccine**"). Additionally, Vietnam has also received 1,000 doses of the Sputnik V vaccine on 16 March 2021. The supply and administration of such vaccines are subject to the guidance of the competent health authorities.

3. Regulatory Authority

The Vietnamese Government has assigned the Ministry of Health ("**MOH**") to preside over and coordinate with relevant competent authorities to purchase, import, receive aid, finance, manage, and use COVID-19 vaccines. The Minister of MOH shall decide the specific number of vaccines to be purchased and imported in each period based on the requirements for epidemic prevention.

According to Article 54 of the Law on Pharmacy, vaccines shall be required to be registered before they are administered in Vietnam. Drug registrations generally fall under the purview of the Drug Administration of Vietnam ("**DAV**") under MOH. Article 56 of the Law on Pharmacy also provides that in order for a vaccine to be registered, there must be clinical data proving its safety and effectiveness.

MOH has also issued an instruction on research, clinical testing, registration, and use of COVID-19 vaccines ("**COVID-19 Vaccines Instruction**"), which shall be applicable during the COVID-19 epidemic per Decision 3659/QD-BYT. Broadly, the COVID-19 Vaccines Instruction provides a shortened procedure for the clinical testing and registration of COVID-19 vaccines. Despite this shortened procedure, there has not been any COVID-19 vaccine registered for circulation in Vietnam up to now.

Nevertheless, Article 67 of Decree 54/2017/ND-CP provides that a vaccine can be imported if such vaccine is approved by MOH for an urgent need in disease prevention, provided that it has been registered for circulation in at least one country in the world. To date, the AstraZeneca Vaccine and Sputnik V vaccine are the only COVID-19 vaccines that have been granted conditional approval for import in Vietnam, pursuant to Decision 973/QD-BYT ("**Decision 973**") and Decision 1654/QD-BYT ("**Decision 1654**").

Importation and Manufacture of Vaccines

Articles 2.43, 6.1 and 32 of the Law on Pharmacy provides that any entity that conducts pharmaceutical business in Vietnam, including import, manufacture, and distribution of drugs for a profitable purpose, must obtain a Certificate of Eligibility for Pharmacy Business ("**CEPB**"). The Minister of MOH or the Director of the Department of Health shall have the authority to issue a CEPB, depending on the specific business activities of each entity.

Additionally, Article 54.5 of the Law on Pharmacy states that overseas manufacturers of imported drugs must be assessed for their compliance with Good Manufacturing Practice ("**GMP**") before the registration of such drugs in Vietnam. Local vaccine manufacturers are also subject to the GMP.

Distribution of Vaccines

The vaccines shall first be administered to the priority groups, pursuant to Article 2 of Resolution 21/NQ-CP. According to Decision 1467/QD-BYT ("**Decision 1467**"), in Phase 1, 117,600 doses of AstraZeneca Vaccine will be administered to: (i) the frontline anti-epidemic force, which shall include medical staff treating COVID-19 patients; (ii) participants in epidemic prevention, including the members of the Steering Committee for epidemic prevention and control at all levels, people working in quarantine areas, people in charge of tracing and epidemiological investigations, and community-based COVID-19 teams, volunteers, and reporters); and (iii) the army and police. The implementation areas shall be provinces and cities where COVID-19 transmission is widespread.

Decision 1467 states that the next phases shall be rolled out based on the actual progress of vaccine supplies, with specific instructions from MOH for each phase.

4. Vaccine Provision for the Private Sector

In Vietnam, only importers, manufacturers, or distributors with a CEPB can import, manufacture, or distribute vaccines. For unlicensed companies which intend to run their own vaccination programmes to ensure their employees are able to work safely, they must, in principle, purchase the vaccines from the licensed importers, manufacturers, or distributors.

Currently, the AstraZeneca Vaccine and the Sputnik V vaccine are the two vaccines which have been granted conditional approval for import into Vietnam. AstraZeneca Vietnam Company Limited, a subsidiary of the AstraZeneca Vaccine's manufacturer in Vietnam, is assigned to import the AstraZeneca Vaccine into Vietnam. Subject to the conditional approval of MOH on the importation of the AstraZeneca Vaccine, Decision 973 mandates that the use of such vaccine must follow the instructions of MOH. Decision 1654 on the conditional importation of the Spunik V vaccine also provides the same condition. Accordingly, it would be practically difficult for the private sector to get vaccine supplies at this point of time. There would also be the question of the quality control of both the vaccine and administration of the vaccine itself.

5. Conclusion

Any vaccine, before it may be circulated in Vietnam, must first be registered with MOH. In addition, vaccines can only be imported, manufactured or distributed by the licensed importers, manufacturers or distributors. However, a vaccine which has been registered for circulation in at least one other country may be imported into Vietnam if the vaccine is approved by MOH for an urgent need for disease prevention.

Vietnam is attempting to secure sufficient COVID-19 vaccines for the at-risk subjects. Meanwhile, the approval of MOH is required before any vaccines can be imported and circulated. Therefore, the speed of any vaccination initiative, whether by the Government or private sector, is largely dependent on MOH vaccine approval.

KEY CONTACTS

Cambodia

Heng Chhay
R&T Sok & Heng Law Office
Managing Partner

T +855 23 963 112/113
heng.chhay@rajahtann.com

Hout Sotheary
R&T Sok & Heng Law Office
Partner

T +855 23 963 112/113
hout.sotheary@rajahtann.com

China

Chia Kim Huat
Rajah & Tann Singapore LLP
Regional Head, Corporate & Transactional Group

T +65 62320 464
kim.huat.chia@rajahtann.com

Linda Qiao
Rajah & Tann Singapore LLP
Shanghai Representative Office
Senior International Counsel

T +86 21 6120 8818
linda.qiao@rajahtann.com

Indonesia

Farid Fauzi Nasution
Assegaf Hamzah & Partners
Partner

T +62 21 2555 9998
farid.nasution@ahp.id

Anastasia Pritahayu R.D.
Assegaf Hamzah & Partners
Senior Associate

T +62 21 2555 9998
anastasia.pritahayu@ahp.id

Laos PDR

Lee Hock Chye
Rajah & Tann (Laos) Co., Ltd.
Managing Partner

T +60 3 2273 1919
hock.chye.lee@christopherleeong.com

Khanti Syackhaphom
Rajah & Tann (Laos) Co., Ltd.
Legal Advisor

T +856 21 454 239
khanti.syackhaphom@rajahtann.com

Malaysia

Kuok Yew Chen
Christopher & Lee Ong
Partner

T + 60 3 2273 1919
yew.chen.kuok@christopherleeong.com

Tracy Wong
Christopher & Lee Ong
Partner

T + 60 3 2273 1919
tracy.wong@christopherleeong.com

Myanmar

Dr Min Thein
Rajah & Tann Myanmar Company Limited
Managing Partner

T +959 7304 0763
min.thein@rajahtann.com

Aung Chit Min
Rajah & Tann Myanmar Company Limited
Associate

T +959 7304 0763
aung.chit.min@rajahtann.com

Philippines

Norma Margarita (Norge) B. Patacsil
C&G Law
Senior Partner

T +632 8894 0377 to 79
nmbpatacsil@cagatlaw.com

Deborah Miriam D. Sobrepeña-Lacson
C&G Law
Partner

T +632 8894 0377 to 79
deb.sobrepena@cagatlaw.com

Singapore

Anandarajah Kala
Rajah & Tann Singapore LLP
Head, Competition & Antitrust and Trade

T +65 62320 111
kala.anandarajah@rajahtann.com

Alvin Tan
Rajah & Tann Singapore LLP
Partner

T +65 62320 904
alvin.tan@rajahtann.com

Thailand

Melisa Uremovic
R&T Asia (Thailand) Limited
Deputy Managing Partner

T +66 2656 1991
melisa.u@rajahtann.com

Supawat Srirungruang
R&T Asia (Thailand) Limited
Partner

T +66 2656 1991
supawat.s@rajahtann.com

Vietnam

Vu Thi Que
Rajah & Tann LCT Lawyers
Partner / Chairwoman

T +84 28 3821 2382
que.vu@rajahtannlct.com

Cao Dang Duy
Rajah & Tann LCT Lawyers
Special Counsel

T +84 28 3821 2382
duy.cao@rajahtannlct.com

RAJAH & TANN ASIA
LAWYERS WHO KNOW ASIA

OUR REGIONAL CONTACTS

RAJAH & TANN | *Singapore*

Rajah & Tann Singapore LLP
T +65 6535 3600
F +65 6225 9630
sg.rajahtannasia.com

R&T SOK & HENG | *Cambodia*

R&T Sok & Heng Law Office
T +855 23 963 112 / 113
F +855 23 963 116
kh.rajahtannasia.com

RAJAH & TANN 立杰上海
SHANGHAI REPRESENTATIVE OFFICE | *China*

Rajah & Tann Singapore LLP
Shanghai Representative Office
T +86 21 6120 8818
F +86 21 6120 8820
cn.rajahtannasia.com

ASSEGAF HAMZAH & PARTNERS | *Indonesia*

Assegaf Hamzah & Partners

Jakarta Office
T +62 21 2555 7800
F +62 21 2555 7899

Surabaya Office
T +62 31 5116 4550
F +62 31 5116 4560
www.ahp.id

RAJAH & TANN | *Lao PDR*

Rajah & Tann (Laos) Co., Ltd.
T +856 21 454 239
F +856 21 285 261
la.rajahtannasia.com

CHRISTOPHER & LEE ONG | *Malaysia*

Christopher & Lee Ong
T +60 3 2273 1919
F +60 3 2273 8310
www.christopherleeong.com

RAJAH & TANN | *Myanmar*

Rajah & Tann Myanmar Company Limited
T +951 9345 343 / +951 9345 346
F +951 9345 348
mm.rajahtannasia.com

GATMAYTAN YAP PATACSIL
GUTIERREZ & PROTACIO (C&G LAW) | *Philippines*

Gatmaytan Yap Patacsil Gutierrez & Protacio (C&G Law)
T +632 8894 0377 to 79/ +632 8894 4931 to 32
/ +632 8552-1977 to 78
F +632 552 1978
www.cagatlaw.com

RAJAH & TANN | *Thailand*

R&T Asia (Thailand) Limited
T +66 2 656 1991
F +66 2 656 0833
th.rajahtannasia.com

RAJAH & TANN LCT LAWYERS | *Vietnam*

Rajah & Tann LCT Lawyers

Ho Chi Minh City Office
T +84 28 3821 2382
F +84 28 3520 8206

Hanoi Office
T +84 24 3267 6127
F +84 24 3267 6128
www.rajahtannlct.com

Rajah & Tann Asia is a network of legal practices based in Asia.

Member firms are independently constituted and regulated in accordance with relevant local legal requirements. Services provided by a member firm are governed by the terms of engagement between the member firm and the client.

This publication is solely intended to provide general information and does not provide any advice or create any relationship, whether legally binding or otherwise. Rajah & Tann Asia and its member firms do not accept, and fully disclaim, responsibility for any loss or damage which may result from accessing or relying on this publication.

DISCLAIMER

Rajah & Tann Asia is a network of member firms with local legal practices in Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam. Our Asian network also includes our regional office in China as well as regional desks focused on Brunei, Japan and South Asia. Member firms are independently constituted and regulated in accordance with relevant local requirements.

Please note also that whilst the information in this publication is correct to the best of our knowledge and belief at the time of writing, it is only intended to provide a general guide to the subject matter and should not be treated as legal advice or a substitute for specific professional advice for any particular course of action as such information may not suit your specific business and operational requirements. You should seek legal advice for your specific situation. In addition, the information in this publication does not create any relationship, whether legally binding or otherwise. Rajah & Tann Asia and its member firms do not accept, and fully disclaim, responsibility for any loss or damage which may result from accessing or relying on the information in this publication.