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Newsletter

THAILAND AND COVID-19 VACCINES: A REGULATORY REVIEW

As countries around the world continue to battle the spread of COVID-19, an unprecedented global effort has resulted in the development of vaccination programs in a handful of countries. Three vaccines, developed by Pfizer/BioNTech SE, Moderna and AstraZeneca/Oxford University respectively, have dominated the news, in particular with the Pfizer/BioNTech vaccine receiving approval for manufacture and wider distribution in a limited amount of countries. The Thai authorities signed an advance agreement in November of 2020 to secure an undisclosed number of doses of the AstraZeneca/Oxford vaccine and authorization for local production by the Thai drug manufacturer Siam Bioscience.

The importation of and manufacture of the AstraZeneca/Oxford vaccine in Thailand will be subject to some regulatory hurdles. This briefing will discuss some of the issues that may affect the importation, manufacture and distribution of a potential COVID-19 vaccine.

Regulatory overview

The major law governing the importation, production, and sale of medicine (including vaccines) in Thailand is the Drug Act B.E. 2510 (1967) (the "**Drug Act**").

The Ministry of Public Health is the governing authority under the Drug Act and may publish and amend lists of controlled medical products, dangerous drugs and require labeling on medication. The Drug Act classifies medicines in two categories, modern and traditional drugs. Modern drugs are divided into four categories, as follows:

1. Household remedies that require no licensing;
2. Packaged medication that can be sold over the counter by medical professionals;
3. Dangerous drugs; and
4. Controlled drugs.

Less strict regulations cover traditional medicine.

Importation of medicine

Under the Drug Act, the importation of modern medicine must be preceded by the registration and licensing of the pharmacopoeia or drug formulas unless the drug is intended for use in a laboratory for the research, analysis or examination of a disease, and is not administered on human subjects.

Registration of medicine

Applications for approval of drug formulas are reviewed by the Ministry of Public Health's Food and Drug Administration (the "Thai FDA"), which may also suspend, or revoke previously granted licenses. Registration reviews may take up to 7-9 months for private entities according to the guidelines published by the Thai FDA. This process may, at the Thai FDA's discretion, be shortened or waived.

Licensing and manufacture of medicine

After the application for registration of a drug formula is approved, an importer is required to be licensed by the Thai FDA. The licensing process is shorter than that for registration of drug formulas and may take up to 10 business days as prescribed by the guidelines published by the Thai FDA. Once a drug has been registered and licensed, the licensee may import and manufacture that medication in Thailand.

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Logistics storage and distribution

The vaccine jointly developed by Pfizer/BioNTech must be stored at -70°C. Moderna's COVID-19 vaccine can be stored at 2-8°C for 30 days or-70°C for 6 months. The AstraZeneca/Oxford vaccine can be stored at 2-8°C for 6 months. Given the specific requirements for storage and transport of a COVID-19 vaccine there are specific regulations and controls, currently in force, that must be complied with.

Cold storage operations are included as restricted businesses under the Warehouse, Silo and Cold Storage Act B.E. 2558 (2015). Storage of a vaccine that requires cold storage services may only be handled by an entity licensed by the Department of Internal Trade.

Transport operators handling vaccines that are considered medication must transport the vaccine using properly licensed vehicles under the Land Transport Act B.E. 2522 (1979) and must follow the specifications provided under the Land Transport Act. The same is true for any transportation vessels falling under the Navigation in the Thai Waters Act B.E. 2456 (1913) or aircraft used for transportation under the Air Navigation Act B.E. 2497 (1954). These laws require a consideration of the cargo to be carried together with an assessment of the seaworthiness or airworthiness of the vessel/aircraft. The transport must be suitable for carrying that particular type of cargo in a safe manner.

Application of vaccine

Pursuant to the Medical Profession Act B.E. 2525 (1982), direct injections of vaccinations into human bodies may only be performed by licensed medical professionals. Therefore, the application of vaccinations to the general population must be performed by trained medical professionals. The vaccinations must be given at hospitals, clinics, or other designated places by licensed personnel who are capable of providing medical services under the Hospital Act B.E. 2541 (1998). Designated locations, other than hospitals or clinics, may include temporary medical facilities in workplaces or schools.

Conclusion

The COVID-19 vaccines being tested and which are currently in the process of formal approval by various governmental authorities around the globe represent not only a huge step in medical sciences and virology, but also may be a key factor in a return to a relative normal. Regulations controlling the import and manufacture of medicines in Thailand, much like many other countries, will play a pivotal role in how quickly a COVID-19 vaccine can be distributed to the general public. In some cases, current regulations and processes may need to be amended or replaced to facilitate access to and distribution of a vaccine.

If you would like to discuss any of the legal implications of the matters discussed above, please contact the authors listed in the right-hand column.