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COVID-19 AND THE PHARMACEUTICAL INDUSTRY IN SINGAPORE AND MYANMAR: A Comparison of Developed and Frontier Markets

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The COVID-19 Coronavirus pandemic continues to wreak havoc and sow disruption around the world. In response, health authorities, pharmaceutical companies, life science laboratories and research centers (the "Pharmaceutical Industry") are scrambling to develop potential treatments, viable inoculations, test kits and related products (the "Products"). The efficient and speedy legal rollout of the Products will be critical. Historically, pharmaceutical products have been rolled out (since the mid-1800s) when the modern pharmaceutical industry evolved from local apothecaries distributing botanical drugs such as morphine and quinine to wholesale manufacturing. In today's interconnected markets, however, such rollouts are global in nature and must satisfy the regulatory variations and legislative nuances of numerous relevant local jurisdictions. In the midst of the current crisis, it is increasingly incumbent upon all participants to be proactive, responsive and adequately prepared for this global rollout.

This article sets out the relevant laws and processes of such legal rollouts in two Association of Southeast Asian Nation (ASEAN) jurisdictions: Singapore and Myanmar. The details of each will firstly provide a specific "how to" roadmap to complete and fully satisfy the legal requirements to sell the Products in each jurisdiction. Secondly, it will outline and contrast a prospective rollout of the Products (and pharmaceutical products generally) under a fully developed and sophisticated legal regime, as is the case in Singapore, with that of Myanmar, an emerging/frontier market, a relatively undeveloped regulatory regime with less firmly established judicial processes and administrative norms. In detailing the rollout in the two vastly different jurisdictions, this article will also touch upon the impact of less apparent societal realities between the two that may affect a legal rollout. For example, cultural attitudes toward the rule of law, the role of government and role of medical providers and medicine, is just a flavor of the underlying socio-cultural factors that may lend themselves to (or complicate) these matters. Another decisive factor in expediting any rollout is the level and condition of a country's modern infrastructure, robust supply chains and transportation networks, which Singapore has in abundance while Myanmar does not.

The types of business conducted by the Pharmaceutical Industry in various jurisdictions around the globe are also highlighted when comparing these two jurisdictions. Singapore has a very developed body of legislation (in all areas including, but not limited to, contracts, intellectual property, tort and dispute resolution), a favorable investment and tax regime, advanced infrastructure and a highly skilled workforce. As a result, not only does the Pharmaceutical Industry import and sell pharmaceutical products in Singapore but also has large onshore operations, including production. The long- established presence of pharmaceutical giants such as GSK, Roche, Abbott, Amgen, Pfizer, Novartis, Sanofi and AbbVie in the city-state attests to this. Myanmar (as is often the case with other emerging and frontier jurisdictions) currently lacks some or all of these aforementioned characteristics and thus serves mainly as an export destination for pharmaceutical companies across the world.

Given the more extensive and robust approval processes for pharmaceutical products (as discussed below), where a legal checklist approach is emblematic of the legal framework, licensing and approval in Singapore is more clear and is more easily navigated as compared to

Myanmar. The approval process is loosely more akin to that provided for by the U.S. Food and Drug Administration's New Drug Application (NDA). The legal paradigm in Myanmar is less developed, and more specifically, the codified pharmaceutical product approval processes remains antiquated (generally pre-dating the period of military junta rule 1962-2017), lacking specificity in many aspects with fewer guiding principles and ministerial directives. This often requires counsel to exercise a significant degree of flexibility and creativity in order to successfully complete the approval process. Flexibility and creativity in this context means having to discern legal solutions from a regulatory fog and/or government practices that may be contradictory, vague or non-existent. With this flexibility and creativity, in some instances, the approval process in such jurisdictions may take less time compared to a more modern jurisdiction like Singapore where the application and review process is more regimented with clearly denoted guidelines on how to procure the necessary approvals.

Due to Singapore's legislative and regulatory framework, those in the Pharmaceutical Industry not only export their products to Singapore but also use it as a manufacturing base where products are manufactured for local distribution and exported globally.

While in addition to Myanmar's relatively underdeveloped legal structure, it currently lacks the societal, cultural and physical infrastructure to be a manufacturing hub for Products. Some observers have said it has only recently begun to emerge from approximately 50 years of economically and culturally stifling military rule. One might further characterize this long period of quasi-dictatorship as having been socialist in nature, xenophobic, erratic and ultimately unsuccessful. Aung San Suu Kyi and her National League for Democracy (NLD) was democratically elected in 2017 and is well regarded by the majority of the population. However, as required by the 2008 Constitution, the military maintains 25 percent of the Parliament and thus holds veto power on all major government decisions. It also maintains direct control of a number of key ministries. The resulting power-sharing arrangement has for the most part been successful – the NLD and the military seem to recognize and abide by the principle of mutual co-existence and most importantly, the military has continued to honor the new democratic paradigm. Unfortunately, the pace of rolling out new regulations, such as a modern pharmaceutical approval process and more generally a legal regime with laws encouraging commerce and a strong rule of law, remains inadequate. On a positive note, as a former British colony the legal system is a common law jurisdiction and many of the old laws (for example the Contract Act of 1872),[1] although dated, would be familiar to lawyers from other common law jurisdictions and does provide a solid base from which future reforms can be built. While the country is moving in the right direction, many legal risks remain that do not present themselves in jurisdictions such as Singapore.

Not only do the laws (or lack thereof) in Myanmar hinder the emergence of a viable local pharmaceutical production industry; societal and cultural attitudes also discourage such industry. Its recent past has not instilled strong confidence among the populace that the government or its industries could produce safe and effective medicines. The overall manufacturing industry has stayed generally geared toward sectors such as textiles and

garments. Also, decades of economic mismanagement have resulted in underfunded state institutions, inadequate healthcare and an underdeveloped education system. This has unfortunately resulted in capacity constraints for companies to successfully implement local operations, sales and market expansion. Lastly, like some of Myanmar's neighbors, there is a cultural heritage of using "Eastern" remedies such as herbs. This does not mean that "Western" medicines are not utilized, because they are; however, the Products may not be the first approach.

Overview of the Pharmaceutical Industry in Singapore

In Singapore, the pharmaceutical industry is largely regulated by the Health Products Act (Chapter 122D)[2] administered by the Health Science Authority (HSA) under the supervision of the Ministry of Health. The regulatory approvals required for the distribution of Therapeutic Products in Singapore are as follows:

Business Activities	Registration / License Requirements	Relevant Legislation and Guidelines
Manufacture/Production of Therapeutic Products (Pharmaceutical products are generally regulated as "Health Products"[3] or more specifically "Therapeutic Products"[4] under the Health Products Act (Chapter 122D)	▪ Product registration (which requires registration of a local establishment) ▪ Manufacturer's license	▪ Health Products Act (Chapter 122D) ▪ Health Products (Therapeutic Products) Regulations 2016 (Health Products Regulations)[5] ▪ Good Manufacturing Practice (**GMP**) Standard
Exporting Therapeutic Products	▪ Wholesaler's license	▪ Good Distribution Practice (**GDP**) Standard[6]
Wholesale Import & Supply of Therapeutic Products	▪ Product registration (if the product is not already registered) ▪ Importer's license	▪ Guidance Document on Therapeutic Products in Singapore[7] ▪ Health Products (Licensing of Retail

Business Activities	Registration / License Requirements	Relevant Legislation and Guidelines
	▪ Wholesaler's license ▪ Only an import license is required (a wholesaler's license is not required) if products are imported solely for (i) export only; (ii) for supply to ships or aircraft leaving Singapore; and (iii) nonclinical use.	Pharmacies) Regulations 2016 [8]
Retail Supply of Therapeutic Products	▪ Retail pharmacy license (for Prescription-only medicines (POM) or Pharmacy-only medicines (P)) ▪ No separate license required for General Sale List medicines.	

A. Regulatory Framework for the Distribution of Therapeutic Products

The licensing framework in Singapore for Therapeutic Products is activities-based. The licensing requirements and conditions that may be applicable to a distribution chain for Therapeutic Products are as follows:

(i) Product Registration

Generally, all Therapeutic Products to be manufactured, imported or supplied in Singapore must be registered with the HSA, with limited exceptions which includes the supply of Therapeutic Product for the purpose of scientific education, research and development, or where it is supplied by a qualified medical practitioner in Singapore under prescription for a patient's use.9 Any person (or entity) who intends to supply any Therapeutic Product in Singapore must initially check through these exceptions to determine if such a product can be supplied without it first requiring a new product registration.

Only local entities registered with the Accounting and Corporate Regulatory Authority (ACRA) in Singapore can secure product registration10 and this step is mandatory for those intending to manufacture, import or sell Therapeutic Products there. Overseas manufacturers that intend to register Therapeutic Products will be subject to the GMP conformity assessment carried out by the HSA. There are two types of assessments:

(1) GMP Documentary Evidence Verification (DEVA)

Overseas manufacturers which have been previously audited and found to conform to GMP Standard by at least one Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) member authority may submit GMP evidence, such as a valid GMP certificate, for evaluation. An on-site GMP audit is not required if the submitted evidence is found to be acceptable.

However, the HSA has the discretion to conduct an on-site audit of an overseas manufacturing site, where deemed necessary.

(2) On-site GMP audit

Overseas manufacturers that do not meet the criteria above will be subject to an on-site audit by the HSA's GMP auditors to assess their compliance to the GMP Standard.

The HSA may attach such conditions to the registration of a Health Product as it deems necessary, and may periodically vary such conditions by issuing written notice to the Health Product registrant.

In considering an application for the registration of a Therapeutic Product, the HSA will also review whether the Therapeutic Product is patented under the Singapore Patents Act (Chapter 221)[11] and, if so:

(a) whether the applicant for registration of the Therapeutic Product is the owner of the patent; or

(b) if the applicant is not the patent owner, whether:

- it has consented to the granting of Therapeutic Product registration in favor of the applicant; or
- the patent is no longer valid or will not be infringed by registering the Therapeutic Product in favor of the applicant.

The Health Products Regulations outline specific requirements in this respect which must be complied with before the HSA approves the application.[12]

These requirements must be complied with before such products can be registered with the

HSA.

(ii) Manufacturing of Therapeutic Products

All local manufacturing facilities engaged in the manufacture or assembly of Therapeutic Products must obtain a manufacturer's license from the HSA as required under the Health Products Act. However, a manufacturer's license does not automatically authorize its holder to supply any Health Product that it manufactures to any other person unless the product itself is duly registered. Successful applications are further required to meet the criteria listed by the HSA including but not limited to maintenance of premises, staff, safe handling, storage, and conformity with applicable standards, as well as compliance with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide and the GMP Standard and GDP Standard.[13]

A manufacturer's license holder may not use any premises or facility to manufacture any Health Product other than that authorized for such use by the HSA or under the respective manufacturer's license.

(iii) Wholesale Import and Supply

Companies that intend to import and wholesale Therapeutic Products in Singapore are required to obtain importer and/or wholesaler licenses respectively, where the applicant is required to comply with the requirements listed under the Health Products Act (Chapter 122D) Health Products (Therapeutic Products) Regulations 2016. The requirements include provision and maintenance of premises, staff, the purpose of importing Therapeutic Products and compliance with GDP standards.

In addition, a holder of a pharmacy license may also supply Therapeutic Products by wholesale without holding a wholesaler's license, if thesupply:

(a) is to a licensed healthcare institution;

(b) is for use on a ship or an aircraft in accordance with the prescribed requirements in the Health Products Regulations respectively;

(c) is for the purpose of scientific education or research and development, or for a non-clinical purpose;

(d) is to a government department or statutory board for the provision of public services;

(e) is between licensed retail pharmacy outlets under the same management chain; or

(f) consists of the supply of registered Therapeutic Products to companies

outside Singapore for the purpose of any business or trade carried out by those companies.[14]

A manufacturer's license holder does not need to separately apply for a license to import pre cursors that it requires for further manufacturing in Singapore or to wholesale products that it has made in accordance with its manufacturing license.[15]

(iv) Retail Supply

For retail supply, Therapeutic Products may be classified into:

(a) Prescription-Only Medicines:

A drug that can only be obtained from a doctor or a dentist, or from a pharmacist with a prescription from a doctor or a dentist.[16] The medical condition to be treated for these type of medicines needs to be diagnosed and treated by a doctor.

Prescription-only medicines can also have serious side effects which require a doctor's monitoring or follow up.

(b) Pharmacy-Only Medicines:

A drug that can be obtained from a pharmacist at a retail pharmacy.[17] The medical condition to be treated can be assessed and treated by pharmacists.

(c) General Sales Listmedicines:

A drug that can be freely obtained from any retailer that can be taken safely by users without medical supervision and intended for short term self-treatment only.

These categories of medicines above are set out in the Register of Health Products kept and maintained by the HSA under the Health Products Act. The manufacture, import or supply of controlled drugs or Therapeutic Products containing psychotropic substances or codeine cough preparation may be subject to separate licensing and approval requirements.

B. Legal Rollout in Singapore

Although legal hurdles and bureaucracy generally remain stubborn impediments throughout Asia, Singapore's well-established regulatory environment and strong talent pool has made it a regional hub for the production and distribution of pharmaceuticals. For some years now, it (along with South Korea) has been a leader in the fast-tracking and approval of certain drugs.

Apart from its relatively straightforward licensing regime for Therapeutic Products (as discussed above), Singapore has been making aggressive efforts to 'flatten the curve' of the COVID-19 infection rate. In the Pharmaceutical Industry specifically, these efforts have translated into legislative changes and fast-tracked licensing processes for certain Products. For example, the Parliament successfully and swiftly passed laws in the span of weeks to empower relevant ministries and parties to carry out necessary actions to curb the spread of COVID-19.

One of these laws includes the Health Products (Import, Wholesale and Supply of Medical Devices — Exemption) Order 2020 which was passed on January 31, 2020. This exempts specified devices including particulate respirators, protective gear, surgical masks and non-touch thermometers to measure body temperature from having to be registered under the Health Products Act. The Order also exempts importers and wholesalers of those devices from any licensing requirements,[18] requiring only notification and provision of important information to the HSA.

The HSA has also announced that regulatory flexibility is to be implemented and will be periodically revised and updated based on the local COVID-19 situation. This can be seen from the HSA's dramatic acceleration of the approval process for COVID-19 diagnostic testing in Singapore via a "provisional authorization process."[19] All diagnostic test kits that have received this provisional authorization from the HSA can be supplied to any healthcare institution, private hospital, medical clinic and clinical laboratory in Singapore. This quick response was aimed at ensuring the rapid and widespread availability of such kits for COVID-19 testing in the country.

As a part of its efforts to ensure the continued availability of ventilators and related accessories (e.g. breathing circuits, filters and tubing) to meet local healthcare needs, the HSA also dispensed with particular approval requirements. This allowed healthcare institutions to put their existing anesthesia machines or positive airway pressure devices in their facilities capable of providing controlled (or assisted) ventilation into use as emergency ventilators for COVID-19 patients.

The HSA also created an alternative approval process for upgrades or modifications to registered ventilators and their associated accessories. The normal regulatory process requires registrants of these devices to submit a notification on changes to such equipment to the HSA and certain changes can only be performed subject to its approval.[20] Under the alternative process, registrants may implement modifications to the registered ventilators without awaiting HSA approval as long as they do not affect the registered performance specifications and the devices (including new accessories) continue to meet the Essential Principles of Safety and Performance as set out in the Health Products (Medical Devices) Regulations 2010. This relaxation of the HSA's standard notification process ensures that during the COVID-19 crisis, where fast action is required to combat the spread of infection and deaths, life- saving equipment can be deployed with less bureaucratic red tape and quickly put into use wherever needed to save lives.[21]

As evidenced by the steps taken by the health authorities discussed above, the regulatory flexibility and swift response demonstrated by the Singapore authorities exemplifies the government's willingness to streamline legal procedures in emergency situations. These actions are indicative of Singapore's progressive environment which would capably serve to facilitate and support any legal rollout of the Products in Singapore.

Overview of the Pharmaceutical Industry in Myanmar

The primary legislation governing pharmaceuticals is the National Drug Law (NDL), where all pharmaceutical products which are distributed in the market requires a prior approval of the Department of Food and Drug Administration (FDA). The FDA approval process is often time-consuming, with an estimated lag of six months between the date of application and finally receiving approval. In practice, the FDA exercises complete discretionary power in approving/declining pharmaceutical products. The primary legislation governing pharmaceuticals is the NDL.

The pharmaceutical companies may manufacture and distribute the Products in Myanmar or may directly distribute the imported Products. For manufacturing, a foreign pharmaceutical company must incorporate a local entity or subsidiary in Myanmar and obtain the relevant licenses, which generally includes an approval from the Ministry of Health and Sports (MOHS) and the Myanmar Investment Commission (MIC). Other sector-specific approvals such as construction permits, electricity generation permits, fire safety certificates, factory licenses and business licenses will also apply.

Manufacturing/producing the Products in Myanmar (or other frontier or emerging markets) is often not viable or advisable. Thus, the other method involves distribution either through the establishment of a wholesale/retail unit to import and distribute or via contractual arrangements with a local distributor. When a foreign pharmaceutical company intends to engage in wholesale and/or retail of its products, it would require a wholesale and/or retail registration certificate issued by the Ministry of Commerce (MoC). In general, due to various reasons including the high costs for foreigners to set up a wholesale/retail unit, foreign pharmaceutical companies have traditionally opted to export products and have them distributed through a local distributor like MEGA or DKSH.

The different types of drugs and products have not been sufficiently categorized or detailed under Myanmar laws, and thus such laws offer a more general and wider definition applicable to pharmaceuticals.[22]

As a result, in the absence of more specific definitions for various types of pharmaceutical products, vaccines, inoculations and medicines will largely fall under the category of "drug" as defined under the NDL.

A. Regulatory Framework for the Sale and Distribution of Drugs

(i) Product Registration

Generally, all drugs to be manufactured, imported and distributed must be registered and approved by the FDA under the NDL. Given the lack of enforcing rules and regulations and no specific timeframes under the NDL, the FDA approval process is relatively time-consuming.

In brief, the officially stated process of obtaining FDA approval is as follows:

- The list of Products along with the application fees must be submitted to the FDA.
- Approval will be required from the FDA for the importation of samples, together with the submission of bank receipts for payment and payment confirmation letters, along with lists and sample details of the drugs to be imported.
- Samples have to be submitted to the FDA within one week from the date of clearance at the port of entry.
- The Form I needs to be submitted and the registration has to be completed online. Upon confirmation, the FDA will request the applicant to print and submit the Form I as well as a dossier with administrative data, product information and quality information including country-specific licenses for imported products, certificates of pharmaceutical products in line with the World Health Organization (WHO) format, product information (name, strength, dosage), labeling, packaging inserts, composition, clinical particulars, blister/strips, marketing authorization, patient information leaflets and manufacturer details. The submission needs to be made within 60 days of being notified by the FDA.
- Laboratory test fees for the samples have to be paid after the dossier submission. Upon approval, the FDA will issue a letter directing the applicant to pay the registration fees within 90 days of being notified.
- The applicant (authorized company representative) must request an appointment to take possession of the drug registration certificate within 60 days of payment at the FDA office.
- The drug registration certificate is valid for five years.
- The registration process can take between two to three years depending on the documentation required. After registration, the pharmaceutical products can be sold on the market through a licensed distributor. For prescription drugs, the registration number must be stated on the box/exterior of the product packaging.

Note that the indicated dates are not in reality often indicative of actual timeframes, which can be much longer or even shorter.

(ii) Manufacturing of Products (Including Drugs and Medicines)

A foreign pharmaceuticals company must be incorporated as a private limited company under the Myanmar Companies Law (MCL) with the Directorate of Investment and Company Administration (DICA).

Foreign pharmaceutical companies would then need to obtain the relevant approvals and licenses to manufacture and produce the relevant Products. Generally, an entity in Myanmar would need approval from the MOHS and the MIC before commencing the manufacturing operations.[23]

The other sector-specific approvals such as construction permits, electricity generation permits, fire safety certificates, factory licenses and business licenses (as applicable) will apply. Upon manufacturing the Products, FDA approval as prescribed above is mandatory before the sale of the Products. The entire licensing process to establish the business and obtain the FDA approval may take from up to six to eight months.

(iii) Wholesale and Retail Import and Supply

A foreign company will be required to incorporate a private limited company with the DICA to import and distribute the Products by way of wholesale or retail in Myanmar.

For importation activities, an import registration and license from the MoC is required under the Export and Import Law. Products imported into Myanmar will also require specific clearance from the Myanmar Customs Department. Additionally, the FDA approval requirements set out above will apply and the foreign company must duly register the Products under its name with the FDA.

The newly incorporated company will need to secure wholesale or retail registration from the MoC to distribute the Products in the Myanmar market. The stipulated conditions to secure wholesale or retail registration are provided in Notification 25/2018 issued by the MoC. The investment criteria are provided in the table below:

Wholesale		Retail	
Joint Venture Companies	**Foreign Companies**	**Joint Venture Companies**	**Foreign Companies**
Investment capital (excluding rental	Investment capital, (excluding rental	Investment capital, (excluding rental	The investment capital, excluding

Wholesale		Retail	
Joint Venture Companies	Foreign Companies	Joint Venture Companies	Foreign Companies
fees) must not be less than USD 2 million. The shareholding ratio held by a Myanmar citizen or entity must be at least 20%.	fees) must be at least USD 5 million.	fees) must exceed USD 700,000. The shareholding ratio held by a Myanmar citizen or entity must be at least 20%.	rental fees, must be no less than USD 3 million.

Companies which satisfy the criteria above will then be required to apply for a Retail and Wholesale Registration certificate. Such an application would require (among other things) a recommendation letter from the relevant city development committee, for example, by the Yangon City Development Committee. Retail and/or Wholesale Registration could be obtained within three to four months from the date of submission of the application.

In Myanmar, the more common method of distribution is by way of entering into contractual arrangements with local partners in Myanmar to distribute particular Products throughout the Myanmar market. The local distribution model would involve the local distributor first importing and then selling the Products in Myanmar. The distributor must have a valid importer registration certificate and importer license for the specific shipments that are exported by the foreign pharmaceutical company. Under this model, the local distributor would be the party responsible to obtain FDA approval as required under the NDL for the Products.

B. Legal Rollout in Myanmar

Due to limited access to healthcare facilities and services, Myanmar has a high mortality rate and lower life expectancy. The Pharmaceutical Industry in Myanmar (being a frontier market) is at a very nascent stage and has a very limited presence and level of market penetration. For instance, in the case of the ongoing COVID-19 pandemic, there has been a lack of testing facilities and test kits available in Myanmar. As a result, Myanmar has so far largely been dependent on donations and resources from China, Switzerland and the United States.

While Singapore has a considerable manufacturing and industrial production base, Myanmar's levels of domestic industrial manufacturing of Products are very limited, with only a few locally

operational pharmaceutical production/manufacturing units. The pharmaceutical industry in Myanmar is thus largely driven by imports of Products, mainly from Bangladesh, China, India, Singapore and Thailand. There are hundreds of distributors of foreign drugs, importing several types of Products. Given this shortfall in local production and the rapidly growing need for Products, Myanmar thus presents itself as one of the most attractive jurisdictions for foreign pharmaceutical companies to conduct business.

Many obstacles remain, however, not least of which is the lack of well- established legal principles and high levels of bureaucratic red tape. Myanmar's pharmaceutical industry, therefore, remains at an underdeveloped stage with much room for critical improvement. The drug approval process in Myanmar is usually time-consuming and the relevant authority may lack the technical capacity and resources to fast-track the process. Furthermore, due to the COVID-19 crisis, several government offices and departments have reduced working hours with limited office staff available to help expedite the process. There has also not yet been an aggressive effort by the Myanmar government to dramatically spur the pace of legislative changes and fast-tracking of licensing and approval processes for needed or sought-after Products. Some minor relaxations which have been made now allow the authorities to accept scanned copies of documents in place of physical hard copies.

Irrespective of this, there are still concrete grounds for optimism in Myanmar. During the COVID-19 crisis, the government has been proactive and responsive in effecting several official policies. Testing facilities along with the number of tests carried out per day have been greatly ramped up. Lockdown measures have been implemented effectively in several townships and regions which had been experiencing higher rates of COVID-19 infection and/or hospitalization. The government, though treading cautiously in light of this unprecedented situation, is nonetheless always open to representations by market players. Therefore, foreign pharmaceutical companies wishing to carry out a legal rollout have the option to make official representations before the relevant authorities. On a case-by- case basis, the approval timeframes may be reduced and the legal rollout could be put into effect sooner rather than later. There have been instances in the past where (depending on the need and ease of distribution of the relevant Products), timeframes have been shortened considerably. Therefore, despite lacking clear legislation and official regulations concerning the pharmaceutical industry to-date, this in no way precludes the possibility that the entire approval process for a legal rollout in Myanmar would be far more streamlined, successful and workable than anticipated. Also, a degree of flexibility and creativity may be exercised to successfully complete the approval/registration/licensing processes. With this flexibility and creativity, in some instances, the approval process may take less time than usual.

Conclusion

The Pharmaceutical Industry in Singapore is long-established, well developed, governed by specific legislation, and guided by clearly articulated approval processes. The approval process is loosely more akin to the U.S. Food and Drug Administration's[24] NDA and overall approval process. Singapore is also one of the regional hubs for the production and export of the Products. In fact, a number of American pharmaceutical and biotech companies, such as Johnson & Johnson, Pfizer, Abbott and Amgen, have operations in Singapore.

Myanmar, on the other hand, lacks a robust legal regime and because of minimal local production the Pharmaceutical Industry exports to Myanmar pharmaceutical products, including the Products.

Given the detailed and robust legal framework, licensing and approvals, the process in Singapore is streamlined and more efficient than compared to Myanmar and other frontier and emerging jurisdictions. However, although Myanmar has fewer regulations and guidelines, with some creativity and flexibility legal counsel can still efficiently achieve approval of the Products. In such nuanced frontier and emerging markets, the speed in which the Products may actually be approved for distribution could be faster than in such developed legal jurisdictions like Singapore or the United States.

1. *See Myanmar Contract Act 1872 at: https://www.mlis.gov.mm/lsScPop.do?lawordSn=2174.*

2. *The text of the Health Products Act (Chapter 122D) can be accessed on Singapore Statutes Online's website at https://sso.agc.gov.sg/Act/HPA2007#legis.*

3. *"Health Product" refers to any substance, preparation or device (a) that (i) is represented for use by humans; (ii) whether because of its presentation or otherwise, is likely to be taken for use by humans; or (iii) is included in a class of substances, preparations or devices which are or are ordinarily intended for use by humans, solely or principally for a health- related purpose; and (b) that falls within any of the categories of health products specified under the Health Products Act (Chapter 122D).*

4. *"Therapeutic Product" is one of the various categories of Health Products regulated under the Health Products Act (Chapter 122D) and generally refers to substances intended for use by people for therapeutic, preventative, palliative or diagnostic purposes. Vaccines, for example, fall within this category. Other products in the category of "Health Products" include medical devices and cosmetic products.*

5. *The text of the Health Products (Therapeutic Products) Regulations 2016 can be accessed on Singapore Statutes Online's website at https://sso.agc.gov.sg/SL/HPA2007-S329-2016?DocDate=20190215.*

6. *The Good Manufacturing Practice Standard and Good Distribution Practice Standard*

can be accessed at the HSA's official website at https: /www.hsa.gov.sg/chinese-proprietary- medicines/dealers-licence/gmp-gdp-standards.

7. *The Guidance Document on Therapeutic Products in Singapore can be accessed at the HSA's official website at https: /www.hsa.gov.sg/docs/default-source/hprg/therapeutic- products/guidance-documents/guidance-on-therapeutic-product-registration-in-singapore_jan2019.pdf.*

8. *The text of the Health Products (Licensing of Retail Pharmacies) Regulations 2016 can be accessed on Singapore Statutes Online's website at https: /sso.agc.gov.sg/SL/HPA2007- S330-2016.*

9. *Regulation 58, Health Products (Therapeutic Products) Regulations 2016.*

10. *The guidelines on product registration in Singapore with the HSA can be accessed on the HSA's official website at https: /www.hsa.gov.sg/therapeutic-products/register/overview.*

11. *The text of the Patents Act (Chapter 221) can be accessed on Singapore Statutes Online's website at https: /sso.agc.gov.sg/Act/PA1994.*

12. *Regulation 23, Health Products (Therapeutic Products) Regulations 2016. A set of comprehensive guidance documents setting out the criteria and requirements forproduct registration is readily available on the HSA's official website: https: /www.hsa.gov.sg/therapeutic- products/guidance-documents. The HSA's product registration process has been summarized and can be accessed on the HSA's official website at hsa.gov.sg/therapeutic- products/register/overview/overview.*

13. *The guidelines that must be adhered to by Therapeutic Product manufacturers can be found on the HSA's official website: https: /www.hsa.gov.sg/therapeutic-products/dealers- licence/gmp-gdp*

14. *Regulation 49, Health Products (Therapeutic Products) Regulations 2016.*

15. *Regulations 54 and 55, Health Products (Therapeutic Products) Regulations 2016.*

16. *Prescription-only medicines can only be supplied by retail sale if the prescription-only medicine is administered by a person who is a qualified practitioner or a person acting in accordance with the instructions of a qualified practitioner; or by any person prescribed under the Third Schedule of the Health Products (Therapeutic Products) Regulations 2016.*

17. *Pharmacy-only medicines can only be supplied by retail sale if:*

    a. *the supply is made at or from a licensed retail pharmacy and by an in-store pharmaceutical officer engaged or employed by the holder of the pharmacy*

license for the licensed retail pharmacy;

b. *the supply is made, at or from a licensed healthcare institution supplying the pharmacy-only medicine, to a patient of that healthcare institution and in accordance with the written instructions of a qualified practitioner practicing in that healthcare institution;*

c. *the person is a qualified practitioner, or a person acting in accordance with the instructions of a qualified practitioner, and the supply is made to a patient under the care of the qualified practitioner.*

18. *See the HSA's official announcement at https: /www.hsa.gov.sg/announcements/regulatory- updates/import-of-hand-sanitisers-masks-thermometers-and- protective-gear.*

19. *See the HSA's official announcement at https: /www.hsa.gov.sg/announcements/regulatory- updates/hsa-expedites-approval-of-covid-19-diagnostic-tests- in-singapore-via-provisional-authorisation.*

20. *The relevant notification requirement is set out in GN-21 Guidance on change notification for registered medical devices (see guidelines at https: /www.hsa.gov.sg/docs/default- source/announcements/regulatory-updates/gn-21-r4-7-guidance-on-change-notification-for-registered-md(2dec)-for- consult.pdf).*

21. *See the HSA's official announcement at https: /www.hsa.gov.sg/announcements/regulatory- updates/hsa-regulatory-position-on-respiratory-devices- supply-for-management-of-covid-19-patients.*

22. *NDL defines a "drug" as a substance whether taken internally or externally used for the diagnosis, prevention and treatment of disease, birth control, or for any beneficial effect on individuals and animals. This expression also encompasses substances defined as a drug by the MOHS through periodic notifications.*

23. *An Investment Permit would be required if the entity would like to obtain tax incentives and long-term land leasehold rights of up to 50 years, extendable twice for 10 years each with a prior approval of the MIC.*

About the Author

William Greenlee
Partner & Managing Director, Myanmar/Singapore
william.greenlee@dfdl.com

William's practice focuses on M&A, international transactions, securities, corporate, energy, mining and infrastructure, and project finance. He has extensive experience with manufacturing, retail, banking and finance, technology, media and telecommunications (TMT), real estate development, aviation, hospitality and tourism, mining, power and the oil and gas industries throughout Asia. For over two decades William has been advising high profile clients from around the world. He has advised, among many others, on the Myingyan gas- fired power project, the first internationally tendered large-scale power project in Myanmar. He is continually involved in negotiating, structuring, documenting and managing large transactions, working with private equity firms, opportunity-fund companies and other international companies throughout Asia.

He is recognized as a leading practitioner by all of the Chambers, Asia Pacific Legal 500 and IFLR 1000. He holds a B.A. degree from the University of Oregon in Asian Studies with a minor in East Asian Literature and a Juris Doctor from the University of San Francisco, California. As well as running the DFDL Myanmar and Singapore offices, William co-heads the firm's regional China desk, which acts as a hub for Chinese investment into ASEAN. He is US-qualified attorney, licensed in California and Nevada.