TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

1. What are the principal statutes, regulations and competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?

The principal legislation governing the import and export of goods in Myanmar is the Export and Import Law 2012. When it comes to therapeutic products, such as pharmaceuticals, biologics and medical devices, the regulatory framework is primarily established by the National Drug Law 1992.

In Myanmar, the Ministry of Commerce (MOC) serves as the principal authority overseeing the enforcement of import and export regulations for goods. However, specific oversight for pharmaceuticals, biologics and medical devices falls under the remit of the Food and Drug Administration (FDA) Myanmar, which operates within the Ministry of Health (MOH).

In accordance with the Constitution of Myanmar, legislative authority is exercised in strict compliance with the provisions set forth therein. The division of legislative powers is specified within the Constitution itself, with certain legislative competencies allocated to Self-Administered Divisions and Self-Administered Zones, as delineated in the relevant constitutional articles. At the present time, Myanmar is subject to a state of emergency. Consequently, the exercise of legislative authority continues to be governed by the Constitution, with all relevant procedures and processes being followed as stipulated by constitutional provisions.

2. How are therapeutic products classified for regulatory purposes (eg, prescription only, over the counter, hospital use, risk classes for devices, etc) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is the conclusion of a premarket review and approval process required by a competent authority?

The National Drug Law 1992 does not provide explicit classifications for therapeutic products, such as prescription-only, over-the-counter or hospital-use medicines. Instead, therapeutic products are broadly divided into two main categories: 'drugs' and 'essential drugs'. The specific status of a drug, whether it requires a prescription or can be sold over the counter, is determined in accordance with the FDA's registration guidelines, which vary based on the product's ingredients.

The term 'drug' is defined as any substance intended for use, whether internally or externally, in the diagnosis, prevention or treatment of disease, for birth control, or for any other beneficial purpose in humans or animals. This definition also extends to substances that may be designated as drugs by the relevant Ministry through an official notification from time to time. The term 'essential drug' refers to a drug determined by the Board of Authority as being crucial for the healthcare needs of the majority of the population.

Drugs that contain narcotic or psychotropic substances are classified as controlled drugs under the Narcotic Drugs and Psychotropic Substances Order 2003. With the exception of those deemed 'completely

controlled' drugs, the trade and distribution of controlled drugs are governed by the relevant Ministry's regulations and official notifications. The Ministry of Health's Notification No. 24/2025 details the different groups of controlled drugs.

Regarding medical devices, classification is determined in accordance with the Association of Southeast Asian Nations (ASEAN) Medical Device Directive, which establishes four classes based on the level of risk posed: Class A (low risk), Class B (low–moderate risk), Class C (moderate–high risk) and Class D (high risk).

Under Section 7 of the National Drug Law 1992, a person who intends to manufacture, import, export, store, distribute and sell pharmaceutical raw materials or drugs must register the relevant drugs with the Board of Authority in the prescribed manner.

In essence, this constitutes the premarket review and approval process required by the competent authorities. The specific requirements vary depending on the ingredient and type of therapeutic products involved.

LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as good distribution practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?

For retail and wholesale activities by foreign-owned companies, Notification No. 25/2018 issued by the MOC sets out the relevant requirements relating to how to import goods into Myanmar.

There are two main options for a foreign company seeking to import therapeutic products into Myanmar, as described below.

Option 1: Under Notification No 25/2018, 100 per cent foreign-owned companies are permitted to engage in retail and wholesale business activities in Myanmar. However, these companies must meet certain minimum registered capital requirements. For retail operations, the required minimum capital is US$3m for a 100 per cent foreign-owned company, while US$700,000 is required for a joint venture with at least 20 per cent of Myanmar direct ownership. For wholesale operations, the minimum capital required is US$5m for a 100 per cent foreign-owned company, while US$2m is required for a joint venture with at least 20 per cent of Myanmar direct ownership. If an investor wishes to engage in both retail and wholesale businesses through 100 per cent foreign ownership, the total required investment is US$8m.

Additionally, before conducting business, a company must register as an entity authorised to engage in international trade with the Directorate of Investment and Company Administration (DICA). All importers must obtain an exporter/importer registration certificate from the MOC in order to be eligible to import goods into Myanmar.

Option 2: As an alternative, 100 per cent foreign-owned companies and/or foreign entities may engage a distributorship model to enter the Myanmar market. This approach can reduce the relevant capital requirements and address land use constraints related to warehousing. Under this model, a foreign seller enters into an agreement with a local distributor, who must be a Myanmar citizen or a company that is 100 per cent owned by Myanmar nationals.

Once the most suitable entry option has been determined, it is essential to register the relevant therapeutic products before commencing wholesale distribution activities.

Product registration falls under the responsibility of the Drug Division of the FDA. There are five types of drug registration certificates issued by the FDA, as follows:

- drug registration certificate - import (DRC);
- drug importation approval certificate (DIAC) (for the importation and distribution of registered drugs in the country);
- one-time importation certificate (for importation for government use, samples for drug registration and donation);
- drug registration certificate - local (DRC); and
- drug local manufacturer certificate.

Medical devices are required to be registered with the Medical Device Division of the FDA. There are two types of certificates for medical device importation issued by FDA, as follows:

- one-time importation certificate for a medical device; and
- imported product certificate (medical device).

Certificates for both drugs and medical devices can be filed via the FDA's e-submission system.

4. Are there any distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies or other retailers), and what key conditions are attached to them?

The pharmaceutical sales licence is separate from the certificates referenced above. Any person or entity intending to operate as a pharmaceutical wholesaler or retailer must obtain this type of licence, which is distinct from importation, registration or manufacturing certificates. Applications for a pharmaceutical sales licence must be submitted to the FDA in line with MOH Order 6/1993. The applicant must be a local resident. In the case of a foreign company, the application must be made by its local representative and/or local establishment.

Additional requirements apply for selling controlled drugs. These substances are subject to strict regulation, and only designated hospitals and authorised private hospitals are permitted to sell them. Hospitals intending to distribute controlled drugs on a wholesale basis must obtain a specific permit for controlled drugs from the FDA in Nay Pyi Taw. For retail sales, hospitals are required to apply for a controlled drugs permit from the FDA at their respective township offices.

5. What rules govern the sale of therapeutic products to consumers over the internet (including social media and marketplace platforms)?

Beyond the previously mentioned requirements, any business engaged in selling therapeutic products to consumers over the internet, whether operating as a retailer or wholesaler, must also register as an online business. Pursuant to Notification No. 51/2023 issued by the MOC, such online businesses are obliged to register with the Department of Trade (DOT), which operates under the MOC.

IMPORT

6. What requirements are set as part of the import control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions and routine or risk-based border inspections)?

Prior to importing therapeutic products into Myanmar, it is mandatory to register them with the FDA Myanmar and obtain both a DRC and a DIAC. For medical devices, an imported product certificate (medical device) must be secured from the FDA. Subsequently, applications for import licences must be submitted to the MOC by applying through the TradeNet 2.0 online system. When applying for import licences, the submission of a DRC or DIAC is compulsory, and a recommendation from the FDA is required, depending on the type of imported product involved.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?

Under Section 23 of the National Drug Law 1992, individuals are permitted to bring drugs into the country from abroad for their personal use. However, the law does not specify any limits or requirements regarding the quantity or conditions surrounding such personal imports.

8. Are foreign suppliers allowed to ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification or labelling obligations – if any – must they satisfy?

Because the applicant for a pharmaceutical sales licence must be a local resident, foreign companies are required to appoint a local representative to submit the application on their behalf. Consequently, foreign suppliers must establish a local presence before they can officially sell and/or distribute medicinal products to consumers in Myanmar. Once products are sold in Myanmar, it is mandatory to adhere to local registration requirements and ensure that all product labelling complies with the applicable domestic regulations.

9. How is the parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging and requirements to maintain the product's original quality, safety and traceability?

Pharmaceutical products that have not been registered are treated as illegal goods, which includes parallel imports in Myanmar. All medicines brought into the country must be registered with the FDA. As part of the approval process, the FDA may require evidence that a second importer of the same product has received consent from the original registered importer prior to authorisation. The FDA is proactive in carrying out inspections and taking administrative measures against the distribution of unregistered pharmaceuticals. Nonetheless, there are presently no reported or published court cases concerning parallel imports of pharmaceuticals in Myanmar.

EXPORT

10. Are there quantitative quotas, permits or other measures that restrict or condition the export of therapeutic products (for example, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?

The export of therapeutic products from Myanmar is overseen by the MOC, with export licences being issued by the DOT within the MOC, contingent upon recommendations from the FDA. The Myanmar Customs Department (MCD) is tasked with evaluating and collecting relevant export taxes, as well as fulfilling additional regulatory and law enforcement duties associated with exports. For medicines manufactured domestically, it is necessary to obtain both a DRC and a drug local manufacturer certificate, both of which are administered by the FDA.

11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing and, if so, what standards, labelling or record-keeping obligations apply?

Current legislation does not contain any provisions regarding 'export-only' or 'dual-labelling' authorisations that would allow the manufacture and export of therapeutic products that have not been approved for sale on the domestic market.

LABELLING, TRACEBILITY AND PRODUCT INFORMATION

12. What local-language labelling, patient information, unique device identification, serialisation, anti-counterfeiting or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?

Therapeutic products offered for sale in Myanmar must adhere to local labelling regulations, as stipulated in Medicine Labelling Notification No. 7/1993 and the Consumer Protection Commission Directive 2/2019.

According to the Consumer Protection Commission Directive 2/2019, the following details must be provided on therapeutic product labelling in the local language:

- the name of the product;
- the size, quantity and net weight;
- storage instructions;
- directions for use;
- side effects; and
- warnings.

By contrast, at present, there are no specific legal requirements concerning the labelling of therapeutic products intended solely for export.

Under the National Drug Law 1992, drugs are categorised as counterfeit or falsified in Myanmar if their labels, whether in whole or in part, imitate or closely resemble another product by various means or use similar wording. This also applies if the expiry date, manufacturer, distributor, location or country of manufacture is falsely declared, or if the drug is falsely claimed to have been produced according to the formula stated at the time of its registration.

Further, the legislation prohibits the manufacture, importation, exportation, storage, distribution or sale of drugs not officially registered; drugs with temporarily revoked or cancelled registration; counterfeit drugs; drugs failing to meet the required standards; deteriorated or adulterated drugs; those produced using harmful substances; as well as dangerous drugs deemed unfit for use by the MOH.

However, there are no explicit provisions relating to patient information, unique device identification, serialisation or traceability requirements in Myanmar yet.

PRICING, REIMBURSEMENT AND MARKET ACCESS

13. Are there any price control, reimbursement, public procurement or stock/supply-related obligations that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

Myanmar does not have any specific legislation governing the pricing, reimbursement or market access of therapeutic products. Instead, pricing practices among competitors are subject to the general provisions set out in the Competition Law 2015.

ENFORCEMENT, COMPLIANCE AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions and remedial measures (administrative, civil or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

The penalties for importing unregistered drugs vary from a fine of not less than MMK 50,000 and not more than MMK 500,000 or imprisonment for a term not exceeding seven years, or both. In addition, any evidence relating to the offence shall be confiscated as public property. These rules are provided in Section 18 of the National Drug Law 1992.

Furthermore, additional penalties under the relevant laws may be imposed, depending on the specific circumstances of each case.
15. Is there any recent case law, legislative or policy developments, noteworthy enforcement trends or anticipated reforms that may significantly alter the regulation of trade, distribution or cross-border movement of therapeutic products in the future?
N/A