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 import, wholesale distribution, retail sale and export of pharmaceutical products and medical devices ('therapeutic products') are primarily regulated by Republic Act (RA) No. 3720 (the 'Food, Drug and Cosmetic Act'), RA 9711 (the 'FDA Act') and RA No. 7394 (the 'Consumer Protection Act'). The Department of Health (DOH) administers all laws, rules and regulations relating to, among others, drug safety. The Food and Drug Administration (FDA), an office within the DOH, is tasked with the implementation of the FDA Act and its rules and regulations. The DOH and FDA issue standards and authorisations for establishments, facilities and medical products, with the FDA serving as the lead agency responsible for inspections, licensing and monitoring of such products and activities.

Other principal statutes include RA No. 10918 (the 'Philippine Pharmacy Act'), RA No. 9502 (the 'Cheaper and Quality Medicines Act') and RA No. 6676 (the 'Generics Act').

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?

Generally, pharmaceutical products are classified according to the safety of the active pharmaceutical ingredients (APIs) contained within the finished product itself, and how these products may be accessed by patients and consumers.[1] APIs refers to the substances in pharmaceutical products that have a direct impact on the diagnosis, cure, mitigation, treatment or prevention of disease or to have a direct impact in terms of restoring, correcting, or modifying the physiological functions of the body. The FDA provides and publishes an updated list of APIs, with the corresponding pharmaceutical product classifications.

Pharmaceutical products are primarily classified based on the classification of the APIs. Broadly, they are classified as either prescription pharmaceutical products and non-prescription pharmaceutical products.

For medical devices, the Philippines has adopted the regionally accepted rule-based classification system developed by the Association of Southeast Asian Nations (ASEAN) Consultative Committee on Standards and Quality-Medical Device Product Working Group, where the FDA issues a guidance document containing a list of medical devices, along with the corresponding classifications, based on the relevant level of risk posed.[2] Medical devices are classified as Class A for low risk, B for low–moderate, C for moderate–high and D for high risk. [3] The class determines the type of authorisation that must be secured.

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

[1] DOH Administrative Order No. 2024-0013, (c)(2).
[2] Annex A, FDA Circular No. 2020-001
[3] FDA Circular No. 2020-001.

conditions (such as good distribution practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?

Businesses (referred to as 'establishments' in DOH/FDA rules) seeking to engage in the wholesale distribution of both pharmaceutical products and medical devices must secure a licence to operate (LTO) from the FDA before engaging in importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship activities. Moreover, establishments must secure the relevant market authorisations, ie, a certificate of product registration (CPR) for pharmaceutical products and medical devices categorised as Class B, C or D or a certificate of medical device notification (CPN) for Class A medical devices (collectively, 'product market authorisations').[4]

Further, all such establishments are required to retain a qualified person, ie, an organic or full-time employee with technical competence related to the establishment's activities and health products due to their profession, training or experience.[5] All drug establishments, including drugstores, must be supervised by a registered pharmacist when operating or open for business.

The Philippines has adopted, and the DOH and FDA conduct their inspections of drug establishments and retailers based on, the World Health Organization's 'Annex 5 Guide to Good Distribution Practices for Pharmaceutical Products' and 'Annex 9 Guide to Good Storage Practices for Pharmaceuticals'.[6]

4. Are there 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?

Philippine regulations require all manufacturers, wholesalers, retailers, drug outlets and retail outlets, among others, dealing with pharmaceutical products[7] to secure an LTO and the relevant product market authorizations, as applicable.

To maintain a licence, all establishments must ensure that each retail outlet employs at least one qualified person who will supervise the operations and appropriate storage facilities (including cold-chain management for vaccines and biologicals)[8]. All establishments must display all of the FDA-required information, education and communication campaign material in the establishment's conspicuous area.[9]

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

Online selling of therapeutic products is not allowed under the existing laws, rules and regulations.[10] The FDA also prohibits the online selling of medical devices absent the required authorisations from the FDA.[11] However, the online ordering of therapeutic products and medical devices requires compliance with the provisions set out in the Consumer Protection Act,[12] which provides that persons are prohibited from manufacturing, selling, offering for sale, importing, exporting, distributing or transferring any drug or device unless they have filed the required application for licensing and registration with the DOH. Online ordering and delivery are additional drugstore activities that require the applicant to provide specific processes, the website where the orders will be made and the placement of the LTO details on that website.

[4] FDA Circular No. 2020-001.
[5] DOH Administrative Order No. 2020-0017.
[6] DOH Administrative Order No. 2013-0027.
[7] Defined as 'drugs, medicines, biologicals, pharmaceutical and biopharmaceutical products/specialties. It is the finished dosage form that contains an [active pharmaceutical ingredient], generally, but not necessarily in association with other active or inactive ingredients.' (DOH AO No. 2024-0013).
[8] DOH Administrative Order No. 2016-0003.
[9] DOH Administrative Order No. 2024-0015.
[10] FDA Advisory No. 2019-154.
[11] FDA Circular No. 2020-010.
[12] Joint DTI–DOH–DA Administrative Order No. 01, series of 2008.

Engaging in the online sale of therapeutic products is considered to be a 'variation', ie, an additional drugstore activity, for the purposes of securing an LTO. This requires the applicant to provide documents, as part of its application, showing its standard operating procedure, the website link and a website screenshot showing the ordering system and placement of the applicant's LTO details.[13]

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)?

Importers of therapeutic products are required to be accredited with the Bureau of Customs (BOC) as an importer.[14] The BOC requires that the necessary authorisations, depending on the class of medical device involved, must be presented for the release of imported products under the jurisdiction of the FDA.[15] As a general rule, the LTO is required by the BOC and, in certain cases, the CPR, the certificate of medical device notification or the certificate of medical device registration. Notably, the BOC may require a special certification for new technologies, such as test kits for Covid-19.[16] Applicable tariff rates are published by the Philippine Tariff Commission, which adopts the ASEAN Harmonised Tariff Nomenclature for 2022.

The BOC performs routine inspections of imported goods pursuant to its risk management policies and may require the submission of documents and the issuance of statements, affidavits and attestations, as it deems necessary.[17] The BOC is provided with random samples taken from every incoming shipment of, among others, drugs and devices, which are being imported or offered for import into the Philippines, with notice to the owner and consignee, for inspection.[18]

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?

Consumers are permitted to import FDA-regulated therapeutic products for personal use and without prior FDA clearance, provided that such products are brought into the Philippines in a passenger package, *balikbayan* boxes or in parcels sent through the mail or via delivery services, and only in the quantities allowed. Some of the limits are: 50g for over-the-counter drugs; the volume or quantity indicated in a physician's prescription, or its equivalent for prescriptions issued by foreign physicians, for prescription drugs; one piece of each type of medical device; and up to 100 pieces for medical devices used as maintenance and sold in packs. Any quantity of the covered products beyond the specified limits will be seized and forfeited in favour of the government.[19]

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?

Subject to the discussion above on the importation of therapeutic products for personal use, foreign suppliers are barred from directly shipping such products to Philippine consumers. Under the current FDA rules, all establishments must first secure an LTO and the corresponding product market authorizations for specific products prior to, among others, importing such therapeutic products. Moreover, a foreign supplier who seeks to sell its products to Philippine consumers online will be deemed to be conducting business in the Philippines and must secure the authority to do so from the Philippine Securities and Exchange Commission. Such registration will require the registrant to identify a local address. Moreover, a foreign supplier needs

[13] FDA Circular No. 2020-030.
[14] BOC Administrative Order No. 07-2022
[15] BOC Memorandum Circular No. 166-2024
[16] *Ibid.*
[17] Customs Administrative Order No. 9-2020
[18] EO 175 s. 1987, section 23
[19] BOC Memorandum dated 9 July 2015, referring to DOH–FDA–BOC Joint Circular No. 1, dated 22 June 2015.

to secure the relevant product authorisation from the DOH/FDA and, thus, must maintain some form of local presence.

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?

Parallel importation is regulated in the Philippines and is authorised in certain circumstances. Section 72 and 74 of the Intellectual Property Code (the 'IP Code'), as amended by the Cheaper and Quality Medicines Act, provides for parallel importation by the Philippine government or any private third party once a patented drug or medicine has been introduced in the Philippines or anywhere in the world by the patent owner or by any party authorised to use the invention. Thus, a compulsory licence may be issued by the Intellectual Property Office of the Philippines (IPOPHL) to authorise the exploitation of a patented invention, without the permission of the patent holder, either through the manufacture or parallel importation of the product in the following circumstances:

- there is a national emergency or other circumstances of extreme urgency;
- public interest, in particular, national security, nutrition, health or development of other vital sectors of the national economy, as determined by the appropriate agency of the Philippine government;
- where a judicial or administrative body has determined that the manner of exploitation by the patent owner or a licensee(s) is anti-competitive;
- public non-commercial use of the patent by the patentee absent a satisfactory reason;
- the patented invention is not being used in the Philippines on a commercial scale, although it is capable of being used in this way, without a satisfactory reason, provided that the importation constitutes such a use of the patent; or
- where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the DOH secretary.[20]

Except for th first, third, fourth and sixth bullet points, a licence will only be granted after the petitioner has made efforts to obtain authorisation from the patent owner on reasonable commercial terms and conditions, but such efforts have been unsuccessful within a reasonable period of time.[21]

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?

Exporters in general are required to register with the BOC's Client Profile Registration System (CPRS) and to lodge an export declaration, containing information on their export transaction through the CPRS. [22]

There are currently no quantitative quotas or quantitative permits for the exportation of therapeutic products and those which are duly authorised by the FDA for local use are generally authorised for export, subject to the importing country's regulations authorising local use, as may be implemented by the importing country's local national drug regulatory authority and the FDA's authorisation for exportation.[23]

In case of a declared public health emergency in the country or anticipation of an actual critical shortage of therapeutic products which are authorised for export only, the same shall be allowed for local distribution. Furthermore, the DOH and FDA reserve the right to suspend export-only authorisation in order to prioritise the country's supply of therapeutic products.[24]

[20] Intellectual Property Code, as amended; DOH–DTI–IPO–BFAD Joint Administrative Order No. 01-08.
[21] *Ibid.*
[22] BOC Administrative Order No. 08-2020.
[23] DOH Administrative Order No. 2024-0013.
[24] DOH Administrative Order No. 2024-0012.

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?

Yes, therapeutic products may be authorised for export-only activities. These products are wholly and locally manufactured by licensed pharmaceutical manufacturers and are exclusively intended for foreign markets. Export-only activities require the firm to secure an LTO and an export-only authorisation, as well as a valid certificate of good manufacturing compliance, from the FDA. The therapeutic product should be wholly manufactured in the Philippines and must not include bulk or semi-furnished therapeutic products imported for the purpose of filing, packing, re-packing, altering, ornamenting, finishing and/or labelling.

It must be noted that an export-only authorised therapeutic product is not automatically authorised for local distribution. As such, these products may not be exported and re-imported back into the Philippines and/or re-labelled for the same purpose.[25] Moreover, local pharmaceutical manufacturers and traders seeking to engage in export-only activities must submit an affidavit to affirm that their product: (1) is intended solely for export; (2) conforms with the specifications in the country of destination; (3) is not in conflict with the laws of the country to which it is intended for export; and (4) is labelled on the outside of the shipping package to show that it is intended exclusively for export and is manufactured in the Philippines.[26]

All export-only authorisation holders are required to maintain records of all their export-only transactions and countries of destination and to retain samples of all therapeutic products exported. The FDA must also be notified of any updates to the exported products in the country of destination.

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?

At a minimum, the following mandatory information must appear on the labelling materials accompanying a drug product: the product name; dosage form and strength; pharmacologic category; formulation/composition; indication(s); dosage and mode of administration; contraindication(s), precaution(s) and warning(s), if applicable; interactions; adverse drug reaction(s) (ADR); overdose and treatment; storage condition(s); net content or pack size; name and address of the market authorisation holder; name and address of the manufacturer; RX symbol and caution statement for prescription drugs; ADR reporting statement; registration number; batch number and lot number, if any; expiration date; and the date of manufacture. The generic name must also be indicated with the brand name, must appear prominently with an outline box and shall have prominence over other information. If the product has a brand name, the generic name must be in an outline box and must always appear immediately above the brand name. The DOH also issues guidelines on how the other mandatory information should be indicated on labels, such as those relating to the order such information appears or the metric unit such information should be expressed in.[27] If the price of a therapeutic product is the subject of any maximum drug retail price controls, the same must be indicated.[28] All information on the product's label must be in English and/or Filipino and should be readable with normal vision without straining.

All LTO certificates are issued with a security code provided in the form of a unique quick response (QR) code or a sequence number located at the bottom right corner of the certificate. This is required for subsequent renewals and for the purposes of verification of the said LTO in the FDA database.[29]

In an application for an LTO, applicants must declare the list of sources/authorised suppliers, respective types and names of the finished products, semi-finished, raw materials, APIs and excipients relevant to the

[25] *Ibid.*
[26] DOH Administrative Order No. 2024-0012.
[27] DOH Administrative Order No. 2016-008.
[28] *Ibid.*
[29] DOH Administrative Order No. 2024-0015.

activity applied for. For this purpose, the applicant shall provide a copy of the contract of agreement between the applicant and its client/supplier.[30]

However, the DOH has specifically exempted therapeutic products manufactured for export from the above requirements.[31] Also exempted are low importations of therapeutic products, ie, importations of less than 12,000 units per year, with units being the number of individual dosages or finished packed products.[32]

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?

Yes, there are laws and regulations that may materially influence the distribution channels or availability of therapeutic products in the Philippines. Under the Cheaper and Quality Medicines Act, the Philippine president, upon a recommendation from the DOH secretary, has the power to impose a maximum retail price for specified drugs subject to price regulation, subject only to the Supreme Court's power to issue a temporary injunction against such a decision. Drugs subject to such a price cap include drugs for the treatment of chronic illness and life-threatening conditions, the prevention of diseases, or the prevention of pregnancy; anaesthetic drugs; IV fluids; drugs included in the Philippine National Drug Formulary Essential Drug List; and all other drugs as may be determined by the DOH secretary to be in need of price regulation.[33] It is unlawful for any retailer to sell covered drugs at a price exceeding the price cap.[34]

In terms of government procurement, the Implementing Rules and Regulations (IRR) of the Cheaper and Quality Medicines Act mandates that only drugs and medicines included in the latest edition of the Philippine National Drug Formulary (PNDF) may be procured by government agencies or reimbursed by the Philippine Health Insurance Corporation ('PhilHealth').[35] Under the IRR, the DOH secretary is authorised to implement cost containment measures, which the government may avail of to effectively reduce the cost of drugs and medicines, in the context of competitive bidding, price volume negotiations, consignment and other appropriate mechanisms that influence supply, demand and expenditures on drugs and medicines.[36] Government agencies and local government units are also limited to procuring drugs and medicines from suppliers that are registered with the DOH.[37] For the procurement of drugs and devices by the government for the purposes of RA No. 11223 (the 'Universal Healthcare Act'), such activities must be guided by price reference indices, following centrally negotiated prices by the Price Negotiation Board and sold within prescribed maximum mark-ups.[38]

Meanwhile, under the Generics Act of 1988, drug manufacturing companies operating in the Philippines are required to produce, distribute and make available to the general public the medicine it produces in the form of generic drugs, ie, drugs not covered by patent protection and which are labelled solely by their international non-proprietary or generic name. This policy aims to ensure the adequate supply of drugs with generic names at the lowest possible cost and to make the same available for free to indigent patients, under certain conditions and requirements provided under the law.[39]

ENFORCEMENT, COMPLIANCE AND RECENT DEVELOPMENTS

[30] *Ibid.*
[31] DOH Administrative Order No. 2016-008.
[32] *Ibid.*
[33] Cheaper Medicines Act, section 17.
[34] I*bid*, section 19.
[35] IRR, Rule 6, section 3.
[36] IRR, Rule 38.
[37] *Ibid.*
[38] Universal Healthcare Act, section 28.
[39] Generics Act, sections 2 and 8.

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 FDA is authorised to investigate and inspect any establishment, including any vehicles used to transport any therapeutic products and collect and test samples of therapeutic products and/or raw materials and/or packaging materials.[40] Criminal and administrative actions may also be instituted separately and independently of each other. For this purpose, the FDA is authorised to issue subpoenas (*duces tecum* and *ad testificandum*),[41] cease and desist orders based upon a verified complaint and other post-marketing surveillance activities.[42] The FDA Act provides for penal sanctions for violations thereof. A person may, thus, be imprisoned or subjected to a fine, or both, upon conviction, for violations of the FDA Act. Products found in violation of the FDA Act and other relevant laws, rules and regulations may also be seized upon a finding that these may cause injury or prejudice to the consuming public. Administrative sanctions also include the cancellation or suspension of any FDA-granted authorisation, the imposition of an administrative fine, the destruction or disposition of the product and/or closure of the establishment.

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?

The FDA has circulated a draft of its guidelines on the importation and exportation notification for pharmaceutical products and raw materials, which aim to ensure that the public receives only quality-assured therapeutic products and to prevent the infiltration of substandard and counterfeit therapeutic products into the supply chain. If enacted and duly issued, the draft guidelines will require establishments to give notice to the FDA of each importation/exportation within 30 days prior to the arrival or departure of the shipment to or from the Philippines. The imported/exported products may only be channelled exclusively through established and identified BOC ports.[43]

The FDA has also recently modernised the regulatory framework with FDA Administrative Orders No. 2024-0015 and 2024-0016, which streamline the relevant processes and extend the validity period of the corresponding licences.[44]

[40] IRR of the FDA Act, section 2.
[41] FDA Act, section 30.
[42] IRR of the FDA Act, section 2.
[43] FDA draft guidelines www.fda.gov.ph/draft-for-comments-guidelines-on-the-importation-and-exportation-notification-for-pharmaceutical-products-and-raw-materials/last accessed on 12 May 2026.
[44] FDA Administrative Order No. 2024-0015 and 2024-0016.