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 regulation of therapeutic products in Ghana is principally governed by the Public Health Act, 2012 (Act 851) (the 'Public Health Act'),[1] which establishes the framework for the import, wholesale/retail distribution and export of therapeutic products.

The Public Health Act establishes the Food and Drugs Authority (FDA), the primary regulator of therapeutic products in Ghana, regulating their import, placement onto the Ghanaian market, advertisement, distribution and export. The FDA has issued guidelines (the 'FDA Guidelines') that provide detailed requirements for the registration, importation, distribution and exportation of these products. The enforcement of the Public Health Act and the FDA Guidelines is carried out by the FDA in collaboration with other regulators, including the Customs Division of the Ghana Revenue Authority, which regulates import and export at Ghana's points of entry.

In parallel, the Health Professions Regulatory Bodies Act, 2013 (Act 857) (the 'Health Professions Act') establishes the Pharmacy Council, which regulates the practice of pharmacy in Ghana. The Pharmacy Council has the mandate to license, monitor and inspect pharmacy practices where pharmaceutical care is provided, including the sale of over-the-counter (OTC) medicine, and the wholesale and retail supply of restricted medicines.[2]

The Health Institutions and Facilities Act, 2011 (Act 829) (the 'Health Institutions and Facilities Act') established the Health Facilities Regulatory Agency (HeFRA). HeFRA is responsible for the licensing and inspection of facilities for the provision of public and private healthcare services in Ghana.[3] HeFRA is also mandated to regulate and monitor activities in a practice, such as services in pharmacies,[4] to determine the adequacy and standard of healthcare provided. Certain therapeutic products are subject to additional, sector-specific regulation. For example, the

[1] Public Health Act, 2012 (Act 851).
[2] 'Restricted Medicines' include medicines classified as prescription-only medicines, pharmacy-only medicines, over-the-counter medicines and any other classification approved by the Minister.
3 Ss 3 and 4(b) of the Health Institutions and Facilities Act.
4 'Practice' includes medical and dental services, services in clinics and hospitals, services in pharmacies and chemical shops, optometry and optician services, chiropody, convalescent and nursing homes services, community health services, geriatric homes, nursing care, nursing agencies, maternity homes and occupational therapy services, physiotherapy services, dental laboratory technology services, clinical and bio-medical laboratory technology services, ophthalmic nursing services and physician assistant services.

distribution of medical devices that utilise nuclear material, radioactive material or any radiation, requires authorisation from the Nuclear Regulatory Authority (NRA),[5] in addition to the FDA registrations.

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

Pharmaceuticals

Pharmaceuticals are categorised into three classes: (1) Class A – prescription-only medicines (POM); (2) Class B – pharmacist-initiated ('P') medicines, that is, medicines that may be dispensed by a pharmacist without a prescription; and (3) Class C – OTC medicines.[6]

Premarket review and registration by the FDA are mandatory for all classes of pharmaceuticals. Registration requires the submission of a full regulatory dossier through a locally appointed agent authorised by the FDA to import medicinal products (in cases of non-resident applicants), together with samples, labelling materials and the payment of prescribed fees, following which the FDA may approve or refuse the application subject to conditions. No medicine may be lawfully traded or distributed without this approval.

OTC medicines, POM and P medicines are treated as restricted medicines.

To engage in the wholesale supply of restricted medicines, a person must hold a valid licence issued by the Pharmacy Council, which may impose limitations on the types of medicines supplied and is subject to revocation by the Pharmacy Council for non-compliance. The promotional or marketing office where a person intends to engage in the wholesale pharmacy business must be licensed and supervised by a registered pharmacist.

Similarly, in order to engage in the retail supply of restricted medicines, a person must hold a valid licence issued by the Pharmacy Council. The retail supply of restricted medicines may only be conducted from licensed pharmacy premises under the supervision of a superintendent pharmacist.

In order to engage in the retail supply of OTC medicines[7] only, a licence must be obtained from the Pharmacy Council. The Pharmacy Council must be satisfied that: (1) the person is fit to carry on the business; or (2) the area where the person proposes to carry on the business has inadequate access to pharmaceutical services.

The wholesale and retail supply of restricted medicines without the requisite licence may expose a person (and in the case of a company, its officers) to a fine of not less than GHS 3,000 (approximately US$300) and not more than GHS 60,000 (approximately US$6,000); a term of imprisonment of not more than ten years; or both the fine and term of imprisonment; and, in the case of a continuing offence, to a further fine of GHS 120 (approximately US$12) for each day during which the offence continues.

[5] S 21 of the Nuclear Regulatory Authority Act, 2015 (Act 895).
[6] See https://pcghana.org/wp-content/uploads/2025/06/GUIDELINES-ON-PHARMACY-APPLICATIONS-Pharmacy.pdf accessed 14 May 2026.
[7] S 94 of the Health Professions Regulatory Bodies Act, 2013 defines 'OTC medicine' as a restricted medicine classified as such by the FDA that, in the opinion of the Minister, can be sold or supplied to a patient or end-user other than by or under the supervision of a registered pharmacist with reasonable safety.

Medical devices

The FDA applies a risk-based classification framework aligned with the Global Medical Device Nomenclature (GMDN), categorising devices into four classes. Class I represents the group with the lowest risk and Class IV represents the group with the highest risk. Where a medical device can be classified into more than one class, the class representing the higher risk applies. The class of medical device determines the registration requirements.

Medical devices must undergo a premarket review and be registered by the FDA prior to being distributed or supplied in Ghana.

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 Practice, facility standards, personnel, insurance or financial guarantees) attach to them?

All therapeutic products (including medical devices, supplements and medicines) to be distributed wholesale must be registered with the FDA.

Additionally, a person who intends to use premises[8] for the wholesale supply or storage of therapeutic products is required to register the premises with the FDA.[9] The licence is renewable annually. The FDA requires wholesalers to comply with the FDA Guideline on Inspection of Medical Products Storage Facilities (the 'Storage Facilities Guideline') issued on 28 August 2024, which references World Health Organization (WHO) Guidelines related to Good Distribution Practice (GDP) and Good Storage Practices (GSP).

A person who uses premises for the wholesale supply or storage of therapeutic products without the premises being duly registered with and licensed by the FDA commits an offence and is liable to a fine of not less than GHS 90,000 (approximately US$9,000) and not more than GHS 180,000 (approximately US$18,000); a term of imprisonment of not less than 15 years and not more than 25 years; or both the fine and term of imprisonment.

In addition to the above, we note that there are specific requirements in relation to restricted medicines (medicines classified as POM, P, OTC and any other classification approved by the Minister of Health). A person seeking to carry on the wholesale supply of restricted medicines, must: (1) be duly registered with the Pharmacy Council; (2) hold a valid wholesale licence issued by the Pharmacy Council for the premises from which the business is conducted; and (3) have a pharmacist duly licensed to supervise the supply of restricted medicines.

The Pharmacy Council has issued guidelines for good wholesale practice for entities involved in the wholesale supply of restricted medicines. The guidelines provide that: (1) key personnel involved in the wholesaling of pharmaceutical products must be suitably trained to ensure that the products are properly handled; (2) a Restricted Medicines Record Book must be kept on the premises from where restricted medicines are supplied; and (3) a pharmacist must supervise the supply of restricted medicine.

NRA

A person must be duly authorised by the NRA in order to engage in the wholesale of medical

[8] 'Premises' has been defined to include messuages, buildings, land, easements and hereditaments of any tenure, whether open or closed, whether built on or not, and whether maintained or not under a statutory authority.
[9] S 130(1) of the Public Health Act.

devices that utilise nuclear material, radioactive material or any radiation. The person must ensure that the public and persons employed for purposes of the authorised activity or practice are protected from radiological injury.

The operator of a nuclear installation must maintain an insurance policy to cover its liability in the event of a nuclear damage proved to have been caused by the nuclear installation.[10]

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 attach to them?

Yes.

FDA

All therapeutic products to be distributed must be registered with the FDA.

A person who intends to use premises[11] for the retail supply or storage of therapeutic products is required to register the premises with the FDA.[12] An application for the registration or renewal of the registration of a premises is required to be made to the FDA in the prescribed form and must be accompanied by the prescribed fees.[13] A registration may be renewed for a period of not more than five years and the FDA must be informed of a change of the registered premises of the person.[14]

Pharmacy Council

Businesses that supply therapeutic products that are classified as restricted medicines directly to consumers must obtain a retail pharmacy licence from the Pharmacy Council under the Health Professions Act. Licensing is conditional on, among other things, the suitability of the premises, compliance with storage and record-keeping requirements, and the continuous supervision of the business by a superintendent pharmacist. A licence issued by the Pharmacy Council for the retail supply of restricted medicines is valid from the issuance date for the duration specified on the licence.

A person may opt to obtain an OTC medicine-only licence, which has less stringent regulatory conditions. Such businesses may only sell medicines expressly classified as OTC and must comply with prescribed storage requirements.

The Pharmacy Council retains enforcement powers, including inspection, closure of unlicensed premises and the imposition of sanctions for unauthorised retail supply.

HeFRA

A person is required to be duly licensed by HeFRA in order to operate a pharmaceutical facility.

A licence issued by HeFRA for a facility is valid for three years from the date of issue.[15] HeFRA may revoke or refuse to renew a licence for a practice if: (1) the state of the facility disqualifies the licensee from being granted a licence; or (2) it has reasonable grounds to believe that the

[10] S 65 of the NRA Act.
[11] See n 8 above.
[12] S 130(1) of the Public Health Act.
[13] S 130(2) of the Public Health Act.
[14] Ss 130(3) and 131(3) of the Public Health Act.
[15] S 14(4) of the Health Institutions and Facilities Act.

continued operation of the practice by the licensee will create a risk to public health, public safety or is indecent.

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

The Pharmacy Council has launched the Ghana National Electronic Pharmacy Platform (GNEPP) under its E-Pharmacy Policy to facilitate safe access to medications over the internet. The policy requires all pharmacies operating online to register with the GNEPP in addition to obtaining a licence for the retail of medicines from the Pharmacy Council.[16]

There is no express law governing the online sale of other therapeutic products. In practice, internet sales, including sales conducted through websites, social media pages and online marketplace platforms, are regulated by applying the existing rules governing the retail sale of therapeutic products.

Regulators such as the FDA and Pharmacy Council have the mandate to issue take-down notices to platform intermediaries or service providers in respect of electronically published matter that is illegal or unlawful.

The advertising and promotion of therapeutic products on social media, websites and marketplace platforms are regulated in the same manner as traditional advertising.[17]

IMPORT

6. What is 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)?

Under the Public Health Act, therapeutic products are required to be registered with the FDA prior to importation.[18] Additionally, entities intending to import therapeutic products must obtain an import permit from the FDA.[19]

In order to clear the therapeutic products from the port, the importing entity (which is duly registered with the FDA) is required to submit documents to the Customs Division of the Ghana Revenue Authority, including: (1) the bill of lading; (2) attested invoice; (3) packing list; (4) import declaration form; and (5) certificate of registration of the products and import licence issued by the FDA.[20]

All incoming consignments of therapeutic products require the submission of post-entry applications and undergo physical inspection at the approved point of entry. Physical inspection may also be conducted at the importer's premises if recommended by the Customs Division of the Ghana Revenue Authority or the FDA, or upon request by the importer.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what

[16] S E-Pharmacy Policy https://pcghana.org/newwebsite/wp-content/uploads/2024/08/EPHARMACY-POLICY.pdf accessed 14 May 2026.
[17] FDA Guidelines on the Advertisement of Regulated Products.
[18] S 118 of the Public Health Act, 2012 (851)
[19] Paras 3.1.2 and 3.2 of the Guidelines on Importation of Drugs; and para 4.0 of the FDA Guidelines on Importation of Medical Devices.
[20] The import procedures may be found online https://gra.gov.gh/customs/import-procedures/ accessed 14 May 2026.

quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?

Consumers are required to apply for a permit from the FDA and indicate 'personal effects' during the application process. Consumers must be individuals. Upon arrival, the FDA will assess the products and determine whether they qualify for personal use, taking into account the quantity of the products. Where the products do not qualify as personal effects, the importer will be required to comply with the applicable commercial importation requirements.[21] Consumers may only import personal effects up to four times per year.[22]

8. May foreign suppliers 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?

Only businesses duly licensed by the FDA as importers may distribute therapeutic products to consumers in Ghana. In order to obtain a licence, companies must present the FDA with evidence that they have been incorporated in Ghana by the Office of the Registrar of Companies. Therefore, foreign suppliers must either incorporate a local subsidiary or appoint a local agent who will be licensed on their behalf.

The foreign supplier will also require a licence from the Pharmacy Council.

In practice, these requirements may be impractical to enforce. However, the FDA/Customs may restrict the importation of the therapeutic products once they arrive in Ghana.

9. How is 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 relabelling or repackaging, and requirements to maintain original quality, safety and traceability?

Parallel importation is permitted in accordance with FDA Guidelines.

Parallel importation products must be registered with the FDA and meet the following requirements:[23]

- the registered product for which parallel import registration is sought must correspond to a product that already holds a valid registration in Ghana; and both products must contain the same active substance and share the same pharmaceutical form;
- the parallel imported medicinal product may be sourced from any country worldwide;
- the product must be covered by a valid registration from the exporting country and must have a justified shelf life based on stability studies conducted under WHO Zone IVb conditions;
- there must be no differences in therapeutic significance between the parallel imported product and the registered product in Ghana;
- a separate application must be submitted for the registration of parallel imports

[21] Personal Effect Guidelines https://fdaghana.gov.gh/wp-content/uploads/2024/09/Personal-Effect-Guidelines.pdf accessed 14 May 2026.
[22] S 3.2.5 of the FDA Guidelines on Personal Effects.
[23] Para 3.1 of Guidelines for the Registration of Parallel Imported Medicinal Products.

from each exporting country; and

- the parallel importer is responsible for notifying the registration license holder of the original product about their intention to import the medicinal product in question.

The importer must keep the FDA informed of any changes to the product, including its composition, appearance, primary packaging, manufacturer or registration license holder in the exporting country. Such changes must be approved by the FDA before importation is permitted.[24]

A parallel importer must hold a valid licence to import medicinal products. If the importer intends to undertake additional activities such as labelling or repackaging, a manufacturing licence is also required. Labelling and package leaflets of parallel imported products must not deviate from those of the reference product and must comply with FDA labelling guidelines.[25]

EXPORT

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

An export permit from the FDA must be obtained before therapeutic products can be exported from Ghana. In addition, all therapeutic products must be registered with the FDA prior to the time of export.[26]

Products intended for export must have at least 60 per cent of their shelf life remaining.

The FDA does not impose quantitative quotas on exports. However, by executive instrument, the Minister of Health may restrict the exportation a therapeutic product.[27]

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?

There is no separate 'export-only' or 'dual-labelling' authorisation regime.

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?

Labelling

All labelling and product information for any drug or medical device intended for sale in Ghana must be printed in English.[28]

[24] Para 3.5 of Guidelines for the Registration of Parallel Imported Medicinal Products.
[25] *Ibid.*
[26] Para 3.1.1 of Guidelines on Processing of Export Permit and Clearance of Pharmaceutical Products.
[27] S 116 of the Public Health Act .
[28] S 4 of the Ghana Standards Board (Food, Drugs and Other Goods) General Labelling Rules, 1992 (L.I 1541).

Medicinal products cannot be sold, distributed or imported unless the product's outer label clearly states at least the following: the name of the products; list of active ingredients and their strengths; batch or lot number; manufacturing and expiry dates; any special storage conditions or handling precautions; instructions for use (or dosage directions for medicines); the net content (quantity of product or number of doses); name and address of the manufacturer or importer; and country of origin.

Labels must be clear, legible and printed in indelible ink, without any false or misleading information. The product name, packaging or labelling must not closely resemble any previously registered product. Products not recommended for use in or by children must include the statement 'Not to be taken by children'. All drug products must bear the statement 'Keep out of the reach and sight of children'. Products intended for external use must state 'For external use only', and those intended for veterinary use must state 'For veterinary use only'.

For medical devices, labelling must include the device name, manufacturer details and manufacturing site address, along with a unique device identifier and control or batch (lot) number. It should clearly indicate the package contents, such as size, net weight, length, volume or number of units. If the device is sold in a sterile condition, the word 'Sterile' must appear, and if intended for single use, the statement 'For single use only' must be included. Labels must also display the expiry date, intended medical conditions, purposes and uses, including performance specifications, as well as any warnings, precautions, limitations and special storage conditions.

Patient information leaflets are also required for pharmaceuticals. The FDA requires that a patient information leaflet is included in English in the product packaging, detailing how to use the product, possible side effects and other user guidance.

Counterfeiting

The Public Health Act prohibits any person from manufacturing, importing, exporting, supplying, possessing or offering for sale a counterfeit therapeutic product. A product will be treated as counterfeit where, among other things, it is deliberately or fraudulently mislabelled as to its identity or source; imitates or resembles another product in a manner likely to deceive; or bears an unauthorised trademark, trade name or other identifying mark.[29]

Traceability and serialisation

Distributors and storage entities of medical devices are required to establish, implement and maintain a traceability system. Distribution records must be maintained to allow for traceability and should include the batch or serial number, manufacturing date, expiry date, name and address of the consignee, date of issue and any other records necessary to facilitate traceability.[30]

Policy

The Ghana National Pharmaceutical Traceability Strategy sets out Ghana's policy direction for the implementation of a national pharmaceutical traceability framework to strengthen the health system through improving data quality and the traceability of health commodities.[31] A central objective of the strategy is the adoption of GS1 global standards as the common framework for identifying products, locations and legal entities.

The strategy calls for a standardised product master data programme, aligning global trade item numbers with national classification codes, and for the deployment of automatic identification

[29] S 123 of the Public Health Act.
[30] Para 3.2.7.1 of the FDA Guideline for Licensing of Premises for the Storage and Distribution of Medical Devices.
[31] Ghana National Pharmaceutical Traceability Strategy.

and data capture technology to facilitate barcode scanning for data capture across the supply chain.

PRICING, REIMBURSEMENT AND MARKET ACCESS

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

Although Ghana does not impose direct government price fixing on medicines and devices, some policies influence the distribution channels and availability of therapeutic products.

Ghana's National Health Insurance Scheme (NHIS) reimburses a broad range of medicines through an NHIS medicines list, which sets out the products eligible for reimbursement and the approved reimbursement price for each product. In practice, NHIS-accredited pharmacies and hospitals are reimbursed only for medicines on the list and only at the approved reimbursement prices.[32] This may operate as indirect price control. Thus, a therapeutic product generally needs to be included on the NHIS medicine list to be reimbursable by the NHIS.

Separately, the Government of Ghana (through the Ministry of Health and public sector procurement structures) is a major purchaser of medicines and medical devices for the public healthcare system, particularly essential medicines, often through competitive tender and framework contracts. These procurement outcomes can materially shape distribution because products awarded government contracts are typically distributed at scale through the public supply chain, including regional medical stores, to hospitals nationwide, whereas products not selected under public tender or not prioritised as essential may be supplied mainly through limited private import and distribution channels.

Where a drug is not available on the market after one year of marketing authorisation, the authorisation will be cancelled.[33] In addition, the FDA may cancel an approval in respect of a registered product if the product is not made available on the market after one year of registration.[34] Where an unauthorised variation of the medicine includes mislabelling, marketing authorisation may be revoked.[35]

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 FDA has broad powers in ensuring compliance with trade and distribution rules. These include the power to: (1) inspect premises for compliance with legal requirements; (2) close down premises that fail to comply with requirements; (3) issue notices requiring compliance with requirements; and (4) revoke an entity's licence/registration.

Failure to comply with FDA requirements in respect of the registration, distribution, advertising importation and exportation of therapeutic products is a criminal offence for which an entity may

[32] National Health Insurance Scheme Medicines List, March 2025 www.nhis.gov.gh/files/2025%20NHIS%20ML.pdf accessed 14 May 2026.
[33] Para 3.2.1.2 of the FDA Guideline on Withdrawal, Suspension, or Cancellation of Marketing Authorization.
[34] S 119 of the Public Health Act, 2012 (Act 851).
[35] Para 3.2.2.1 of the FDA Guideline on Withdrawal, Suspension, or Cancellation of Marketing Authorization.

be liable on summary conviction to a fine of between GHS 90,000 (approximately US$9,000) and GHS 180,000 (approximately US$18,000). Additionally, individuals may be liable to a term of imprisonment of between 15 and 25 years.[36]

In practice, the FDA is not likely to pursue criminal conviction unless the conduct puts the public at risk. However, the FDA regularly revokes licences and closes down premises.

The Pharmacy Council and HeFRA also have similar powers in monitoring compliance with legal requirements for the distribution of pharmaceuticals.

15. Is there 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 Government of Ghana has recently announced a Ghana Medical Trust Fund, which will be passed under the Ghana Medical Trust Fund Bill. The fund aims to provide financial support for medications required by Ghanaians with chronic non-communicable diseases that are not currently included under the National Health Insurance Scheme. The initiative will improve access to healthcare. The Bill contains provisions on quality assurance and encourages the implementation of policies that will develop Ghana's healthcare system.

[36] S 129 of the Public Health Act.