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?

Kenya regulates therapeutic products through multiple pieces of legislation. The Pharmacy and Poisons Act (Chapter 244, Laws of Kenya) is the primary legislation governing the manufacture, import and export, distribution, sale, advertising and use of therapeutic products. The Pharmacy and Poisons Act is supplemented by regulations made pursuant to it, which relate to the registration and importation of health products, parallel importation, pharmacovigilance and post-market surveillance, as well as the transportation of pharmaceuticals. The Pharmacy and Poisons Board, as established pursuant to the Pharmacy and Poisons Act, is the regulatory body responsible for the regulation of therapeutic products. The Pharmacy and Poisons Board issues guidelines on the the manufacture, import and export, distribution, sale and use of therapeutic products.

The Health Act (Chapter 241, Laws of Kenya) provides the overarching statutory framework for the establishment of a single regulatory body for the regulation of therapeutic products, namely the Pharmacy and Poisons Board (PPB), as established pursuant to the Pharmacy and Poisons Act. In regard to this hierarchy, the Pharmacy and Poisons Act (and its regulations) operate as the implementing legislation that gives effect to the Health Act's framework in respect of the regulation, licensing and oversight of therapeutic products, including the requirements applicable to manufacturers and distributors.

The Narcotic Drugs and Psychotropic Substances (Control) Act, (the 'NDPS Act'), on the other hand, regulates the possession, supply and administration for medicinal purposes of narcotic drugs and psychotropic substances. It also establishes a board to issue licences for the importation, exportation, diversion, sale, manufacture, production or distribution of such substances. The NDPS Act prohibits medical practitioners or dentists from prescribing, administering, selling or supplying or signing any prescription or order for the supply of narcotic drugs and psychotropic substances for non-medical purposes. It relies on the provisions set out in the Pharmacy and Poisons Act to inform the procedures related to the illicit control of narcotics and psychotropics in line with the relevant international drug control conventions to which Kenya is a signatory.

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 completion of a premarket review and approval process required by a competent authority?

Kenya classifies therapeutic products into different schedules, according to their risk–benefit profile, in relation to their intended therapeutic use, and whether their use requires professional

advice or supervision or can be appropriately self-selected. Additional factors considered include: the need for access to a therapeutic product, the potential for abuse, evidence of toxicity, the need for a medical diagnosis, monitoring and medical management by a healthcare professional and the product's proposed indication.

Medicines are classified as general sales health products (Schedule 1), pharmacy-only health products (Schedule 2), prescription-only health products (Schedule 3), controlled substances (Schedule 4), prohibited products (Schedule 6) and pharmaceutical raw materials (Schedule 7). Schedule 1 products are available for self-selection by the public from licensed pharmacies and retail outlets. Schedule 2 products can only be dispensed or supplied by a licensed pharmacy outlet or an online pharmacy and are not available for self-selection. Schedule 3 products can only be dispensed or supplied by a licensed pharmacy under the supervision of an authorised pharmacy professional to the consumer on and in accordance with a prescription issued by an authorised healthcare provider. Schedule 4 products consist of substances that have the potential to cause a psychological and physical dependence. These substances can only be dispensed or supplied by a licensed pharmacy premises under the supervision of an authorised pharmacy professional to the consumer or to certified healthcare providers and education and research institutions based on a valid prescription. Schedule 6 products consist of prohibited pharmaceutical products that are either banned products, severely restricted products or non-approved products. Schedule 7 categorises pharmaceutical raw materials that are used in the manufacture of medicines as either active pharmaceutical ingredients (APIs) or pharmaceutical excipients. Schedule 2 products can only be publicly advertised within the confines of a pharmacy. Public advertisement of controlled, narcotic and psychotropic substances is prohibited. All medicines, medical products and medicinal substances must be registered with the PPB prior to being supplied in Kenya, unless an exemption applies.

Medical devices and in vitro diagnostics (Schedule 8) are risk classified (classes A,B,C and D), with Class D presenting the highest level of risk. For use and handling of the control of sale purposes, medical devices are scheduled as: (1) general sales medical devices, which are low-risk medical devices that may be supplied or handled by licensed pharmacies, retail outlets, authorised dealers, laboratories and hospitals; (2) over-the-counter medical devices, which are medium-risk medical devices that may be supplied or handled by licensed pharmacies, authorised dealers, laboratories and hospitals; and (3) prescription-only medical devices, which are high-risk medical devices that can only be supplied or dispensed by authorised healthcare providers based on a valid prescription in licensed pharmacies and hospitals. In vitro diagnostics medical devices (IVD-MDs) are scheduled as: (1) over-the-counter IVDs, which are high-risk IVDs that can be supplied or handled by licensed pharmacies, authorised dealers, laboratories and hospitals; and (2) prescription-only IVDs, which are high-risk IVDs that can only be supplied or dispensed by an authorised healthcare provider based on a valid prescription in licensed pharmacies and hospitals. All medical devices (including IVDs) must be registered with the PPB prior to being supplied in Kenya, unless an exemption applies. Advertisements for medicines and medical devices that are subject to supply restrictions must display information on those restrictions.

The PPB conducts a premarket review of medicines and medical devices before issuing a certificate of registration for health products and technologies.

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-related requirements, insurance or financial guarantees) are attached to them?

For medicines, a PPB licence is required for wholesale distribution, and each premise in which wholesale operations are conducted requires a separate licence. Wholesale operations must comply with good distribution practice (GDP) to preserve product quality and protect the integrity of the distribution chain. The primary requirements set out in the PPB Guidelines for GDP for Medical Products and Health Technologies in Kenya include: the adoption of an appropriate organisation and management structure; the adoption of a quality management system; the employment of qualified personnel; the use of appropriate premises, warehousing and storage; the use of appropriate equipment; and suitable inventory management. All consignments of therapeutic products for import/export must be supported by the applicable import/export permit authorisations issued by the PPB.

Wholesalers and distributors of medical devices are required to ensure that the medical devices that they deal with are registered and retained annually within the PPB database of medical devices in order to maintain the relevant market authorisation status. Importers of medical devices need to secure medical device registration certificates and import permits issued by the PPB for each consignment. Medical device distribution operations are also subject to GDP requirements. The PPB Guidelines for the Registration of Medical Devices Establishments requires establishments that distribute medical devices to be registered by the PPB to ensure the safety, quality and performance of medical devices. Manufacturers based outside of Kenya must appoint local authorised representatives for the purposes of the distribution, sale, importation and registration of medical devices in Kenya.

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?

All premises used by businesses that provide therapeutic products directly to consumers are required to be registered by the PPB. General sales health products (Schedule 1) may be supplied directly to consumers by licensed pharmacies (including community pharmacies), supermarkets, general shops or kiosks. Only licensed pharmacies can supply prescription-only health products (Schedule 3) and controlled substances (Schedule 4) to consumers. The draft PPB Guidelines for Good Pharmacy Practice in Kenya provides that the scope of community pharmacies will only cover the dispensing of over-the-counter (OTC) medications and select prescription-only medicines.

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

Internet pharmacies must be registered with the PPB and must be included in the list of registered online retail sellers in Kenya. Under the PPB Guidelines on Internet Pharmacy Services, any website selling therapeutic products directly to consumers must be operated by and form part of a pharmacy licenced by the PPB. Accordingly, a website cannot supply therapeutic products to consumers independently of a pharmacy. Pharmacists must ensure that only PPB-registered and retained medicines are sold or dispensed to consumers over the internet and that prescription-only medicine is supplied in accordance with a prescription by an authorised healthcare provider. Internet pharmacies must adhere to the PPB's Guidelines for the Advertisement and Promotion of Health Products and Technologies and adhere to the data protection principles set out in the Data Protection Act (Chapter 411C, Laws of Kenya).

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)?

Kenya regulates the import of therapeutic products under the Pharmacy and Poisons Act, the Standards Act (Chapter 496, Laws of Kenya) and customs law. The PPB issues 13 types of import permits including: commercial medicine import permits; medical device import permits; narcotics, psychotropics and precursor chemicals import permits (commercial); narcotics, psychotropics and precursor chemicals import permits (raw materials); raw materials import permits; prescription drug import permits; clinical trials and research import permits; drug registration sample(s) import permits; priority import permits; donation import permits; bonded medical products import permits; promotional material import permits; and government supplies import permits. Import permits applications must be made prior to shipment.

Importers of medicines and medical devices must make a declaration to customs and PPB officials upon the arrival or expected arrival of consignments of interest. Importers are required to apply the correct harmonised code system/tariff in accordance with the applicable customs law in Kenya and may consult with the Kenya Revenue Authority (KRA) in this regard.

The PPB applies a risk-based approach (where applicable) to import permit issuance and port activities. The factors that influence the PPB's border control activities include any applicable decisions made by the PPB's quality safety efficacy (QSE) committee, GDP/current good manufacturing process (cGMP) reports issued by the PPB, PPB post-marketing surveillance/pharmacovigilance reports, World Health Organization (WHO) product advisories and any advisories issued by other national medicine regulatory authorities (NMRAs).

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 importing therapeutic products for personal use are subject to the Pharmacy and Poisons Act and the related laws and guidelines, as well as customs regulations. A prescription drug import licence is required for the importation of prescription therapeutic products. This type of permit is intended for returning patients who have been receiving treatment abroad or are undergoing long-term treatment and must continue to receive refills of the relevant medicinal products subject to their doctor's review. A patient, guardian, doctor or healthcare facility must appoint a licensed pharmaceutical company to apply for the licence.

Travelers are generally required to declare any restricted items (including medicaments), with supporting documentation, to customs on arrival. The PPB's guidance on the import and export of health products and technologies underscores its collaboration with the KRA at ports of entry to ensure only authorised, safe and high-quality therapeutic products enter the country.

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?

Therapeutic products are subject to import licence and product registration requirements set by the PPB. The supply of therapeutic products via e-commerce can only be facilitated by a website that is operated by and constitutes part of a pharmacy licensed by the PPB. Internet websites cannot

operate independently of a registered pharmacy and, therefore, they must have a physical presence in Kenya. Only PPB-registered and retained therapeutic products can be supplied to consumers over the internet. Foreign suppliers cannot bypass these requirements in order to ship therapeutic products directly to Kenyan consumers.

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?

The parallel importation of therapeutic products is permitted in Kenya but is subject to the Pharmacy and Poisons (Parallel Imported Medicinal Substances) Rules to ensure the safe use of such therapeutic products and their traceability. Parallel importers are required to obtain a parallel importation licence and must ensure that the therapeutic products have valid marketing authorisations in the country of origin. The parallel importation of therapeutic products in Kenya is subject to GDP and GMP requirements, as well as labelling and packaging guidelines issued by the PPB, which cover the form and content of the package insert, the form and content of the patient information leaflet, the labelling of the parallel imported therapeutic product and any other necessary information. Where imported therapeutic products are to be re-packaged in Kenya, the re-packaging must be conducted at a site approved and licensed by the PPB for that purpose. Licensed parallel importers must register the relevant therapeutic products on the PPB's tracing system.

EXPORT

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

Kenya does not impose general quantitative quotas on the export of therapeutic products. Exports are regulated through a permit system. Export consignments must be accompanied by export licences from the PPB. Kenya's pharmaceutical trade continues to expand in a way that favours imports, resulting in an import–export imbalance. As a result, the government conducts export promotions and is incentivising the local manufacture of therapeutic products to improve export numbers.

The PPB is required to ensure that all therapeutic products exported from Kenya conform to the prescribed quality, safety and efficacy standards. To achieve this, the PPB conducts document verification and consignment inspections. The PPB has the power to withdraw permits granted to exporters and to investigate conduct related to the export of therapeutic products. It also has the power to enforce the prescribed quality, safety and efficacy standards in regard to therapeutic products exported out of Kenya. The exportation of therapeutic products is limited to authorised ports of exit that are equipped to handle these types of products.

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

Therapeutic products that are not manufactured for the local market also require an export licence. For the issuance of an export licence for 'export-only' therapeutic products, the PPB may require

either or some of the following certificates to be held by the entity: (1) a free sale certificate (medical devices/borderline products/food supplements/cosmetics/herbal products); (2) a certificate of a pharmaceutical product (COPP) (in the case of pharmaceuticals); (3) import authorisation from the foreign NMRA or national competent authority; and/or (4) a certificate of exportability. Marketing authorisation holders or their local technical representatives are responsible for obtaining the required export permits.

Exporters of therapeutic products are required to retain records for a period of five years from the date of exportation, and the premises must be easily accessible for any post-export audit or investigations by the PPB.

LABELLING, TRACEABILITY 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 are allowed to circulate domestically or before therapeutic products are allowed to be exported?

Under the PPB Guideline on the Summary of Product Characteristics, Patient Information Leaflets and Labelling, the labelling of therapeutic products must be, at the very least, in English and any other language that the PPB may prescribe. Where more than one language is used, all of the text must be in each language, and the overall readability of the information must not be compromised. The PPB also prescribes the content and format of the patient information leaflet, which covers elements such as the product name and its use, how to take or use the product, the possible side effects and how to store the product. The PPB is in the process of piloting a Pharmaceutical Authentication and Traceability Program (PATP). The PPB is also in the process of developing the Standards for the Authentication and Traceability of Health Products and Technologies.

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?

There are no defined formal price controls for therapeutic products. Prices are dictated by market forces in a free-market economy. Therapeutic products that are not included in the Kenya Essential Medicines List and the Kenya Essential Diagnostics List are excluded from reimbursement by the social health insurance fund, established by the Social Health Insurance Act 2023.

The Kenya Medical Supplies Authority (KEMSA) is the primary supplier of essential medical supplies to public health facilities. National and county health facilities must prioritise procuring medical supplies from KEMSA and may source medicines and medical devices from other suppliers if KEMSA lacks the required medical supplies. KEMSA is financed by the national government and through donations.

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 PPB is responsible for post-marketing surveillance in Kenya, as per the post-marketing surveillance system established by the Pharmacy and Poisons (Pharmacovigilance and Post-Market

Surveillance) Rules. It conducts regulatory inspections of operations in the therapeutic product supply chain to ensure that such operations are in accordance with the Pharmacy and Poisons Act, the PPB guidelines and the relevant approved standards.

Non-compliance with trade and distribution rules attracts fines, prosecutions and criminal liability for those found guilty. The PPB may suspend or revoke licences and close distribution premises. If a therapeutic product does not meet the required standards or specifications or if it poses a risk to public health and safety, the PPB may recall the product temporarily or permanently. The PPB also issues public notices on sub-standard and falsified medical products.

15. Is there any recent case law, legislative or policy developments, noteworthy enforcement trends, or anticipated reforms that may significantly alter the regulation of the trade, distribution or cross-border movement of therapeutic products in the future?

The Kenya Health Products and Technologies Regulatory Authority Bill (National Assembly Bill No. 54 of 2022) is intended to establish a new regulator, the Kenya Health Products and Technologies Regulatory Authority, to regulate, investigate, inspect and approve health products and technologies, among other functions. It seeks to harmonise the regulation of pharmaceutical practices, medical products, therapeutic cosmetics, medical devices and related items that are currently regulated by fragmented legislation, including the Pharmacy and Poisons Act and the NDPS Act. These Acts establish two separate regulators with similar and overlapping mandates, hence the need to harmonise the regulatory framework. As of the date of publication of this Q&A, the Bill is working its way through the legislative process before the Senate, after which it may be passed into law.