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, export, distribution, wholesale and retail sale of medicines (including biologicals and complementary medicines), medical devices and in vitro diagnostic (IVD) medical devices (together 'Health Products') is governed by:

- the Medicines and Related Substances Act, 101 of 1965 (the 'Medicines Act') and the various regulations issued in terms of that Act;
- the Pharmacy Act, 53 of 1974 (the 'Pharmacy Act') and the rules and regulations issued in terms of that Act;
- the Hazardous Substances Act, 15 of 1973 and relevant regulations issued in terms of that Act; and
- the Customs and Excise Act, 91 of 1964, and related rules and regulations issued in terms of that Act.

The relevant regulatory bodies and competent authorities are:

- the South African Health Products Regulatory Authority (SAHPRA), which regulates Health Products;
- the South African Pharmacy Council (SAPC) and national/provincial health departments, which regulate pharmacy premises and the professional conduct of pharmacists and pharmacy support personnel;
- South African Revenue Service (SARS) Customs (with Port Health and SAHPRA at the border), which is responsible for enforcing customs law, verifying permits/licences, detaining/seizing goods and preventing unlawful import/export;
- the International Trade Administration Commission (ITAC), which administers export/import permit regimes activated for specific products; and
- Directorate: Radiation Control (within the National Department of Health (NDoH)), which regulates radiation-emitting devices and hazardous substances.

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?

Medicines

Medicines are regulated through a scheduling system (set out in the Medicines Act) and are controlled as follows:

- Schedule 0 substances ('unscheduled medicines') can be sold in an open shop;
- Schedule 1–2 substances are dispensed by a pharmacist, without a prescription;
- Schedule 3–8 substances are dispensed by a pharmacist, pursuant to a valid prescription; and
- Schedule 5 and 6 substances are subject to tighter controls;
- Schedule 7 substances may be imported pursuant to a specific exemption or permit (eg, for analytical/research purposes); and
- Schedule 8 substances are 'controlled drugs' (eg, certain narcotic or psychotropic substances), to which even stricter requirements apply.

Manufacturers, importers, exporters, distributors and wholesalers of Health Products require a licence from SAHPRA to conduct the manufacture, import, export, distribution and wholesale (each a 'Regulated Activity' and together the 'Regulated Activities') of Health Products.

Medicines that are subject to registration must be registered with SAHPRA prior to sale in South Africa and a registered medicine can only be sold at its registered single-exit price (SEP); this applies other than for sales to the state. Medicines are subject to requirements with respect to labelling, advertising and marketing, and bonusing and sampling (among others).

Unregistered medicines may be imported into South Africa with specific approval from SAHPRA.

From a clinical trial perspective, an application for the registration of a medicine entails an assessment of quality, safety and efficacy. Clinical trials require prior SAHPRA and ethics approval.

Medical devices

Medical devices and IVD medical devices (together 'devices') are classified on the basis of risk, as follows: Class A (low risk), Class B (low–moderate risk), Class C (moderate–high risk) and Class D (high risk).

The manufacturer or distributor of a device is responsible for determining the relevant classification using a set of classification rules supplied by SAHPRA, based on:

- the manufacturer or distributor's intended use;
- the level of risk to patients, users and other persons;
- the degree of invasiveness in the human body; and
- the duration of use and exposure.

Different requirements apply based on the class classification.

Save in respect of Class A devices that are neither sterile nor have a measuring function, only appropriately licensed manufacturers, importers, exporters, distributors and wholesalers of devices can conduct any Regulated Activity in relation to devices in South Africa.

Currently, devices need not be registered with SAHPRA. However, SAHPRA is in the process of developing a phased approach to the registration of devices. Pending the implementation of a registration system, SAHPRA may require that a device should comply with such requirements as SAHPRA may determine in order to ensure that the device meets the Essential Principles of Safety and Performance, determined by SAHPRA, which includes compliance with ISO 13485.

Devices are not yet subject to price regulation, and are currently exempt from the restriction on bonusing and sampling. Devices are subject to rules regarding labelling and advertising.

From a pre-market authorisation perspective, SAHPRA expects the manufacturer of a device to have demonstrated, using appropriate conformity assessment procedures, that the device complies with the Essential Principles of Safety and Performance of Medical Devices.

Devices must be sold in a pharmacy and, for some lower-risk devices, general retailers.

Where devices emit radiation or involve hazardous substances, additional licensing under the Hazardous Substances Act applies.

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?

As mentioned above, in order to conduct a Regulated Activity, a SAHPRA licence is required. The licence is activity-based and must list the scope of products and activities in respect of which the licence holder is authorised.

In addition to a licence under the Medicines Act, in terms of the Pharmacy Act, a wholesaler is required to obtain a 'wholesale pharmacy' licence from the NDoH for the premises from which it operates. In this regard, the wholesaler must register its pharmacy premises and appoint a responsible pharmacist (RP) who must be registered with the SAPC.

For distributors and wholesalers, SAHPRA requires compliance with Good Distribution Practice (GDP), aligned with World Health Organization (WHO)/Pharmaceutical Inspection Cooperation Schemes (PIC/S) principles (SAHPRA is a participating authority in PIC/S).

For devices and as mentioned above, SAHPRA expects an establishment quality management system that supports safe distribution. ISO 13485 certification is commonly used as evidence of suitability for device distributors. However, the exact requirements depend on the scope of activities conducted by the wholesaler.

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?

All pharmacies, including community and internet pharmacies/mail-order pharmacies, must be licensed and registered under the Pharmacy Act and operate under an RP, complying with Good Pharmacy Practice (GPP). The RP is accountable for legal and quality compliance, among other things.

For mail order/courier pharmacy services, GPP requires, among other things, that:

- the medicine is packaged in such a manner that it will guarantee the safety, quality and efficacy of medicines in accordance with the medicine's registration requirements, throughout the delivery process;
- control systems must be implemented to detect and correct a delay in the delivery process; and
- a report back system to identify problems with delivery must be implemented.

Medicines to be stored in conditions under 8ºC cannot be delivered in this way unless cold chain

management is ensured.

Pharmacies must also adhere to the rules regarding the supply of scheduled medicines as set out above, must observe the price controls applicable to medicines and must keep appropriate records and registers (as required by GPP).

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

The Medicines Act and Pharmacy Act apply in the same way to internet sales as they do to in-store sales.

Schedule 1 and above medicines cannot be sold over the internet. Pharmacies may sell medicines online provided the online operation is a registered pharmacy service under the supervision of an RP and complies with GPP.

From a social media, advertising or market-place perspective, it is possible to advertise Schedule 1 and Schedule 2 substances to the public (but, as above, these cannot be sold over the internet). Schedule 3 and above substances can only be advertised to registered healthcare professionals.

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)?

While SAHPRA regulates the import and sale of Health Products in South Africa, the NDoH issues permits for certain controlled substances, and SARS administers customs, tariffs and border requirements, often working with Port Health and SAHPRA for risk-based inspection and release at ports of entry.

SARS has the power to detain, seize, forfeit and sell or destroy goods that are brought into South Africa in the absence of the required permits. Forfeited goods are stored in the State Warehouse at the owner or importer's cost, and if not released in terms of the applicable customs processes, are typically destroyed. SARS may also apply penalties in lieu of the forfeiture of goods that are entered in contravention of the Customs and Excise Act. The applicable penalty may be up to four times the dutiable value of the goods (although, in practice, it is typically no more than 100 per cent of the value of the goods).

An importer of Health Products requires an import licence from SAHPRA. The licence will specify the products that the importer is authorised to import, the activities that the licence holder is permitted to conduct and the sites at which it is licensed to do so. Depending on the activities conducted by the importer, the importer may also require a wholesale pharmacy licence from the SAPC.

SAHPRA/Port Health is responsible for reviewing documentation, licences, permits and authorisations relating to consignments of Health Products.

SARS is responsible for customs compliance, for example, the classification of products, valuations, origin of products, duties/VAT payable in connection with the products, and verification of any other documentary evidence and controls. Where product categories require health authority oversight, SARS will refer the consignment to SAHPRA or Port Health, who may inspect documents (and where necessary the goods), verify cold-chain data and confirm permit conditions.

Imports are generally subject to VAT at the added-tax value (ATV) for all products originating outside of the Southern African Customs Union (SACU). This is an uplift on the prevailing rate, which is currently 15 per cent in South Africa. The ATV is calculated as (customs value + ten per cent + the value of any duties) × 15 per cent.

Rebates may apply on a case-by-case basis, for example, in relation to certain public sector imports (like approved donations, emergency/public health measures and clinical-trial materials).

From a customs document perspective, the following is typically required: invoices, packing lists, waybills, Harmonized System (HS) classification support, proof of origin and evidence to support the valuation of the products; registrations; and any permits or authorisations required for the importation of the goods. In addition, technical/quality agreements and standard operating procedures (SOPs) may be required to evidence GDP/Good Manufacturing Practice (GMP) compliance for authorised storage facilities if goods move to bonded or licensed premises pending clearance.

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

Any person entering South Africa may be in possession, for personal medicinal use, of:

- a quantity of Schedule 3, 4 or 5 substances, which shall not exceed the quantity required for use for a period of six months; or
- a quantity of a Schedule 6 substance, which shall not exceed the quantity required for use for a period of 30 days.

Such person must have:

- the original prescription for such medicine;
- a certified copy of such prescription; or
- a certificate or letter issued by the person who prescribed or dispensed such medicine, certifying that the medicine and quantity concerned was prescribed for the person entering South Africa, and including the name, physical and email address of the person who prescribed or dispensed the prescription concerned.

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?

In short (and save for Schedule 0 substances), no. All Health Products must be imported into South Africa by a licensed importer and before any person can conduct a Regulated Activity, that person must be properly licensed by SAHPRA.

Schedule 1 and 8 substances can only be sold/dispensed in a pharmacy and Schedule 3–8 substances can only be accessed pursuant to a valid prescription.

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 of medicines is permitted if:

- the medicine is being sold outside South Africa with the consent of the holder of the patent of such medicine;
- the medicine is imported from a person licensed by a regulatory authority recognised by SAHPRA;
- the person desiring to import such medicine is in possession of a permit issued by SAHPRA; and
- if required, the medicine is registered with SAHPRA.

In addition to proving the requirements set out above, an applicant for a parallel importation permit must provide documentary proof showing:

- the lowest price at which the medicine is sold in South Africa;
- the price at which the medicine will be sold in South Africa; and
- that it can comply with GMP/Good Warehousing Practice (GWP).

The applicant must also provide an undertaking that it will ensure the continued safety, efficacy and quality of the medicine.

In the case of a parallel import, the professional information leaflet must contain, among other things, '… the name and business address of the holder of the parallel importation permit'.

Medicines supplied to the South African market must carry South African-compliant patient information leaflets and labelling approved with the product registration. Any over-labelling or repackaging must be approved by SAHPRA. Over-stickering of devices to add the local importer/distributor details and South African-required information is possible, but must be approved by SAHPRA and controlled under the importer's quality system.

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?

Health Products may be exported by an authorised exporter with a valid SAHPRA export licence.

Products like narcotics/psychotropics and certain biologicals are subject to quantity controls and additional permits, restrictions and requirements.

ITAC may administer temporary export controls in circumstances where there are product shortages or other emergencies.

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?

South Africa permits the manufacture and export of Health Products that are not authorised for sale in South Africa, provided the manufacturer and any exporter holds the appropriate SAHPRA licences/permits and complies with applicable GMP standards, as well as destination-appropriate labelling of products.

There is no special 'dual-labelling' marketing authorisation; rather domestic marketing and sale remains prohibited if the medicine is required to be registered locally but is not. Products for export also need to be kept separate from products for use in the local market.

Devices for export must include manufacturer details, traceability details, as required by the

export destination, and instructions for use (IFU) in the language of the export 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?

Medicines placed on the South African market must bear Medicines Act/SAHPRA-compliant labelling and include a SAHPRA-approved patient information leaflet. A label must contain, among other things, the proprietary and approved names, dosage form/strength, active ingredients, scheduling statement, pack size, route of administration, warnings, storage conditions, expiry date, batch/lot number, registration holder and importer details, and the registration number, where applicable.

Device labels and IFUs must identify the manufacturer, product name/model, intended purpose, applicable warnings/precautions, lot/serial number and date of manufacture/expiry, where relevant. Labelling and IFUs must be in English and suitable for the intended user. Symbols should conform to recognised standards.

Medicines must be able to be fully traced by batch/lot and, for devices, where applicable, by serial/ Unique Device Identification (UDI). While SAHPRA requires compliance with GDP/GMP/ISO 13485 traceability requirements, South Africa has not yet implemented a universal medicines serialisation/pack-authentication mandate, although South Africa is aligning with the international UDI principle. From a device perspective, S1 identifiers are widely used and may be requested in applications or tenders.

Any changes from the SAHPRA approved labelling requires prior regulatory variation/approval.

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?

South Africa has a system of price regulation and a manufacturer, importer, distributor, wholesaler or retailer may not charge any fee or amount other than the SEP in respect of the sale of medicines to persons other than the state.

The SEP is made up of the manufacturer price, a logistics fee and VAT.

South Africa's pricing regulations empower the Minister of Health to determine and publish a methodology for making the manufacturer price conform with international benchmarks. This methodology must take into account the price, and factors that influence the price, at which the medicine or scheduled substance, or a medicine or scheduled substance that is deemed equivalent by the Minister, is sold in benchmark countries.

In this regard, draft regulations were published for comment in 2010, and they propose Australia, Canada, New Zealand and Spain as benchmark countries. It is not clear if, and if so when, these regulations would come into effect, although, in practice, we understand that SAHPRA considers the cost of medicines in other countries when setting the SEP for a medicine. Each year, the Minister publishes an annual increase in the SEP and it is possible for a manufacturer or importer

of a medicine to apply to increase the SEP of that medicine with the approval of the Minister.

The logistics fee (a component of the SEP) is currently determined by agreement between the importer/manufacturer and logistics service provider. However, draft regulations were issued in 2012 that seek to cap the logistics fee. These regulations are not in force and it is not clear if, and if so when, they will come into effect.

A pharmacist may charge a fee for dispensing medicines and the fee is limited to a statutory maximum, which is also subject to an annual increase by the Minister.

Discounts, rebates and other forms of bonusing or sampling in respect of medicines are prohibited.

Devices are not subject to any statutory price regulation, and they are currently exempt from the restriction on the supply of devices according to a discount, rebate or other incentive scheme.

As mentioned above, the SEP does not apply to supplies to the state; rather the state procures products principally through national or coordinated tenders run by the NDoH for medicines (often via the Affordable Medicines Directorate) and by National Treasury transversal contracts or provincial tenders for medical devices/IVD medical devices. Pricing in the public sector is governed by the tender process.

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?

SAHPRA and the NDoH have the power to enter licensed premises at reasonable times to:

- inspect facilities, processes and records;
- examine, sample and test products; and
- review licences, SOPs, and batch and distribution records.

In addition, they have the power to take samples for analysis (and detain consignments pending test results); and seize or seal products suspected to be unregistered, misbranded, falsified, expired, diverted, or handled in breach of licence conditions. SAHPRA and NDoH can also order the quarantine of stock or suspension of specified activities in certain circumstances.

Port Health/SARS has the power to withhold the release of goods until health authority clearance. The SAPC has the power to conduct GPP inspections, as well as to investigate the professional conduct of pharmacists.

In addition to their powers above, SAHPRA can:

- issue warning letters and compliance directives in relation to, for example, Corrective and Preventive Action (CAPA), process changes or third-party audits;
- impose additional licence conditions, change the scope of licensed activities or add additional reporting obligations;
- suspend or revoke licences for serious or ongoing non-compliance (eg, unauthorised import/sale of unregistered medicines, falsified products and systemic GDP/GMP breaches);
- mandate product recalls or endorse voluntary recalls and/or require public or customer notifications; and
- direct that products be quarantined, relabelled or destroyed.

The SAPC can impose conditions on a pharmacy practice and, in respect of pharmacists, can impose disciplinary action and, if necessary, sanctions for breaches of the rules to which they are subject and any unethical behaviour.

SARS, Port Health, ITAC can:

- impose administrative penalties and forfeiture of goods, including penalties in lieu of forfeiture, where SARS deems it appropriate;
- suspend or revoke ITAC permits and customs (import/export) licenses; and
- require heightened scrutiny and/or increase inspection rates.

In addition to the above and for statutory offences, relevant legislation provides for fines and, in extreme cases, imprisonment.

Other remedies include the ability to approach a court for an interdict and seizure order if the relevant requirements can be met, criminal sanction in the case of fraud, and a claim for damages for contractual breaches and consumer claims.

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?

From a device perspective, SAHPRA is working on its phased call-up process and a move towards UDI/traceability.

Health-regulated goods remain high-attention categories, with routine cooperation between SARS, Port Health and SAHPRA for medicines, biologicals and selected medical device/IVD medical device consignments.

We understand that:

- biologicals, cold-chain products and controlled substances seem to be subject to tighter document-heavy border reviews;
- recent SAPC inspections have focused on online pharmacies, prescriptions, scheduling controls and pharmacist oversight; and
- unlawful advertising appears to be more closely monitored.

While the National Health Insurance Act (the 'NHI Act') was signed into law on 15 May 2024, its effective date has not yet been proclaimed. The NHI Act aims to achieve universal health coverage by consolidating various sources of healthcare funding into an NHI Fund, which will be the sole purchaser and payer of healthcare services. Its implementation is on hold pending a number of legal challenges.