

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?

Therapeutic products are regulated in the Kingdom of Saudi Arabia (KSA) by the Saudi Food and Drug Authority (SFDA), which is the authority responsible for regulating and controlling drugs and medical devices. The SFDA also administers import clearances through its electronic clearance system in coordination with the Zakat, Tax and Customs Authority (ZATCA). Import clearances are required to import certain therapeutic products lawfully into KSA for wholesale distribution.

Therapeutic products are governed by separate principal statutes depending on their form. Each principal statute has a separate set of implementing regulations that provide further details on its requirements.

Pharmaceuticals (including biologics, which are regulated together as ‘pharmaceutical products’ under the SFDA framework) are governed by the Law of Pharmaceutical and Herbal Establishments and Preparations (promulgated by Royal Decree No. M/108 dated 22/08/1441H) and its Implementing Regulations (the Pharma Law). Under the Pharma Law, pharmaceutical products (including biologics) may not be manufactured, imported, marketed or distributed in KSA without prior registration with the SFDA which is documented through the issuing of a marketing authorisation.

Medical devices are governed by the Law of Medical Devices and Supplies and its Implementing Regulations (the MD Law). The MD Law restricts the distribution of medical devices without SFDA registration (documented through the issuance of a medical device marketing authorisation) and provides that medical devices and supplies may not be imported unless approved by the SFDA.

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 premarket review and approval required by a competent authority?

Pharmaceutical products

The Pharma Law does not codify legal-status classifications (such as prescription-only or over the counter). Instead, it empowers the SFDA to regulate and control pharmaceutical products through regulations and administrative decisions.

The SFDA classifies pharmaceutical products by legal status, including prescription-only medicines, over-the-counter medicines, controlled drugs (narcotics and psychotropics), and restricted or hospital-use products.

These classifications affect the trade and distribution of the product, including restrictions on points of sale, dispensing conditions, prescription requirements, record-keeping obligations, and enhanced controls for narcotics and psychotropic substances.

Premarket review and approval are mandatory. No pharmaceutical product may be imported, marketed, distributed or circulated in KSA unless it has been registered with and approved by the SFDA, and circulation of unregistered products is specifically prohibited.

Medical devices

Medical devices are regulated under the MD Law, which establishes a risk-based classification system administered by the SFDA. Medical devices are classified into four risk classes: Class A (low risk), Class B (low–moderate risk), Class C (moderate–high risk), and Class D (high risk), reflecting an approach broadly aligned with international medical device frameworks.

Premarket regulatory approval is required for all classes of medical devices, in the form of a Medical Device Marketing Authorisation (MDMA) issued by the SFDA. For lower-risk devices (particularly Class A), this may take the form of notification or listing rather than full technical review, but an MDMA remains a prerequisite to lawful importation, marketing and distribution, subject to only limited SFDA-recognised exceptions (eg, certain research or temporary-use scenarios).

The legal consequences of classification are proportionate to risk. Class A devices are subject to the lightest regulatory controls and may – depending on their intended use (as determined by the manufacturer), level of risk to patients, degree of invasiveness and duration of use – be supplied OTC. Class B devices may be OTC or restricted depending on degree of invasiveness and intended purpose. Classes C and D devices are subject to heightened regulatory oversight and are generally restricted to professional or institutional use. The approval of any classification remains subject to the SFDA’s review and discretion.

LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?

The licences and authorisations required to engage in wholesale distribution of therapeutic products in KSA depend on the role the business plays in the regulated supply chain and whether the activity relates to pharmaceuticals (including biologics), medical devices, or a combination of both.

From a corporate and investment law perspective, a foreign entity wishing to conduct wholesale distribution activities in KSA must first obtain a foreign investment licence from the Ministry of Investment of Saudi Arabia (MISA), followed by a commercial registration (CR) issued by the Ministry of Commerce.

The MISA licence and CR authorise the entity to conduct business in KSA as a matter of general commercial law, but they do not authorise the conduct of regulated pharmaceutical or medical device distribution activities.

Where wholesale distribution of therapeutic products is contemplated, the entity must obtain a separate SFDA licence for the relevant regulated activity, typically in the form of a licensed pharmaceutical warehouse or wholesale establishment.

SFDA warehousing and wholesale licences are subject to substantive compliance conditions, including facility and storage standards, compliance with Good Distribution Practice (GDP), and the implementation of approved quality and inventory control systems.

The SFDA also requires the appointment of qualified technical personnel (including for pharmaceutical establishments, a pharmacist meeting SFDA licensing criteria) and imposes ongoing obligations relating to training, supervision and record-keeping.

In addition, wholesale distributors of pharmaceutical products must comply with SFDA traceability and reporting requirements, including integration with SFDA-mandated electronic systems for monitoring product movement through the supply chain referred to as the Drug Track-and-Trace System (RSD).

While the SFDA's establishment licensing framework focuses primarily on technical, quality and operational compliance (including GDP, facilities and personnel), it does not impose a uniform statutory requirement for insurance coverage or financial guarantees across all wholesale distributors. Such protections are typically addressed through commercial arrangements or sector-specific requirements.

As a matter of market practice, international manufacturers frequently appoint KSA-licensed local distributors who already hold the necessary commercial registration and SFDA warehousing licences, thereby allocating day-to-day local regulatory and operational responsibilities to the local entity. However, the appointment of a local distributor does not, in itself, extinguish the international manufacturer's own regulatory obligations to the SFDA, including in relation to product registration, safety monitoring and product quality. While the parties may allocate responsibilities contractually as between themselves, such arrangements operate as between the parties only and do not displace or limit obligations owed to the SFDA.

KSA-owned distributors are not required to obtain a MISA licence but are required to maintain a CR and remain fully subject to SFDA licensing, GDP and distribution controls applicable to wholesale distribution of therapeutic products.

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?

Wholesale warehousing licences issued by the SFDA authorise the licence holder to store and distribute therapeutic products to other licensed entities, such as pharmacies and healthcare institutions, but do not permit direct retail supply to consumers.

Entities that supply therapeutic products directly to individual consumers, including community pharmacies and retail outlets, are subject to separate licensing regimes governed by the SFDA and, in the context of community pharmacies, the Ministry of Health (MoH) and may not operate solely on the basis of a warehousing or wholesale licence.

Under the MoH framework, pharmacies must obtain an MoH pharmacy licence prior to commencing operations and must comply with specific regulatory conditions relating to premises, dispensing practices, record-keeping and supervision which can overlap with SFDA-issued regulations particularly in the context of the therapeutic products being dispensed.

There are a number of mandatory conditions for pharmacy licensing, including the appointment of a licensed pharmacist, and other technical requirements such as the storage of therapeutic products. Additional guidance is provided by the MoH under their licensing annexes.

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

The sale of therapeutic products to consumers over the internet in KSA is only permitted within a narrow, pharmacy-led regulatory framework supervised by the SFDA and MoH.

Online sale or marketing of therapeutic products may only be conducted through a licensed pharmacy, and the electronic platform must be linked to and operated under the responsibility of that licensed pharmacy.

The pharmacy must hold a valid pharmacy licence issued by MoH and must also be commercially registered with the Ministry of Commerce, with a CR, for the relevant activity.

As a general rule, online sales by non-pharmacies are limited to non-prescription products, although licensed pharmacies may facilitate electronic ordering and delivery of prescription medicines where dispensing and prescription verification are performed in compliance with SFDA and MoH requirements. The licensed pharmacy remains fully responsible for compliance with dispensing, record-keeping, patient safety and supervision requirements, regardless of whether the sale is conducted in person or through an electronic interface.

Sales of therapeutic products through social media accounts, online marketplaces or third-party platforms that are not operated by or formally linked to a licensed pharmacy are treated as unauthorised distribution.

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)?

Therapeutic products may not be imported into or circulated in KSA unless they have first been authorised or registered with the SFDA.

For pharmaceutical products (including biologics), importation is contingent on the issuing of a marketing authorisation by the SFDA.

For medical devices, importation is similarly conditioned on prior issuing of an MDMA by the SFDA, and devices may not be cleared through customs without an MDMA.

Therapeutic products may only be imported by an entity licensed by the SFDA for the relevant activity, typically a licensed importer, warehouse or wholesale establishment, which acts as the importer of record.

Importation by any other party that does not hold the requisite SFDA establishment licence is not permitted, even where the product itself is registered.

At the border, import clearance is administered through SFDA's electronic clearance systems in coordination with ZATCA. Failure to comply with import prerequisites may result in refusal of clearance, seizure of products, or regulatory enforcement action.

Customs duties and tariff classification are administered by ZATCA under the general customs framework and are not specific to the therapeutic product regulatory regime administered by the SFDA.

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?

The permissibility of importing therapeutic products into KSA for personal use depends on the classification of the product, and such imports remain subject to oversight by the SFDA.

Narcotic and psychotropic substances are subject to the most restrictive controls and may not be imported through postal or courier services. Travellers carrying narcotic or psychotropic medicines for personal medical use must obtain prior approval through the SFDA's Controlled Drug System, and importation without such approval is prohibited.

For other therapeutic products, including prescription and non-prescription medicines, personal-use imports, whether carried by travellers or shipped by mail, must be declared and cleared through the SFDA's electronic clearance system.

Where the imported product requires a prescription, SFDA clearance requires submission of supporting documentation, typically including a valid medical prescription or medical report, proof of purchase, and shipping documentation.

Where the product does not require a prescription, clearance documentation is generally limited to proof of purchase and shipping documentation, subject to SFDA review.

SFDA applies quantitative limits to personal-use imports. For over-the-counter medicines, imports are limited to a maximum of three months' supply.

The same three-month supply limit applies to prescription medicines imported for personal use.

For controlled drugs carried by travellers, the permitted quantity is limited to three months' supply or the duration of stay in KSA, whichever is shorter, and remains subject to prior SFDA approval. The duration of stay criteria is exclusive to controlled drugs and does not apply to over-the-counter and prescription medicines.

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?

Foreign suppliers may not ship therapeutic products directly to consumers in KSA via e-commerce, social-media platforms or mail order, because importation, retail supply and dispensing of therapeutic products are regulated activities reserved for SFDA-licensed establishments in KSA.

This ban applies irrespective of whether the products are prescription-only or over-the-counter, and reflects the KSA model under which consumer access is mediated through licensed domestic pharmacies and distributors, rather than direct cross-border retail.

However, the SFDA does allow for a limited personal-use import pathway, under which individual consumers (not foreign suppliers) may import certain therapeutic products for their own personal use, subject to strict quantitative limits, prescription requirements and SFDA clearance. This is an exception for individuals, not a channel that foreign suppliers may rely on commercially.

Consequently, a foreign supplier cannot lawfully structure direct-to-consumer sales into KSA by relying on the personal-use regime, even if shipments are addressed to individuals or labelled as non-commercial.

Where online or electronic supply is permitted, it must be conducted by or through a licensed KSA pharmacy, including where delivery to the consumer occurs after lawful dispensing. The pharmacy remains fully responsible for regulatory compliance.

For medical devices, foreign suppliers are likewise banned from shipping devices directly to consumers unless the device is registered with the SFDA (and issued an MDMA) and imported and supplied through licensed local channels. Personal-use imports by individuals remain subject to SFDA control and are not a substitute for commercial distribution.

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 re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?

The parallel importation of pharmaceutical products and medical devices is subject to the SFDA's regulatory framework and is not permitted as an independent commercial distribution channel.

Therapeutic products may not be imported, distributed or circulated in KSA unless they are registered or authorised by the SFDA. Lawful marketing of a product in another jurisdiction does not permit importation into KSA. While KSA intellectual property law recognises the principle of international exhaustion, regulatory approval and authorisation by the SFDA remain the decisive prerequisites for lawful importation and distribution.

For pharmaceutical products in particular, registration is product-specific and linked to a defined authorisation structure, including ongoing obligations relating to pharmacovigilance, safety reporting and post-market surveillance. While the Pharma Law contemplates limited scenarios in which licensed wholesalers may import registered products which are unavailable from the manufacturer or non-registered products where no registered alternative exists, these remain subject to prior SFDA approval on a case-by-case basis and do not constitute a general parallel-import regime.

Medical devices are similarly regulated, with importation contingent on product authorisation and compliance with licensing requirements applicable to importers and, where relevant, KSA authorised representatives. Border clearance is dependent on satisfaction of these regulatory conditions.

Labelling and any repackaging must comply with the SFDA-approved labelling, language and product information requirements. The SFDA also requires wholesaler system integration (into RSD) to track and monitor the supply chain of the products, although this will typically be complied with by the local wholesaler rather than the foreign business.

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?

The export of therapeutic products is subject to specific SFDA licensing and administrative controls.

An entity seeking to export pharmaceuticals or controlled therapeutic products from KSA must obtain an SFDA export licence. The export licences are generally limited to local agents, licensed manufacturers and authorised wholesale warehouses.

Export licence applications must include justification, original authorisations from the destination country, manufacturing details, batch information and remaining shelf life, and are processed through the SFDA’s operations sector before actual export can occur.

The SFDA also sets conditions on remaining local supply through documentary requirements showing that local stock after export will remain sufficient for at least six months’ supply. This approach is intended to mitigate risks of domestic shortages.

Although the SFDA has not publicly identified a specific export quota, export licences are conditioned on regulatory approval and sufficiency assessments, and may be denied or qualified to protect public health interests.

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?

The SFDA has not enacted regulation around ‘export-only’ marketing authorisations that permit the routine manufacture and export of therapeutic products that are not otherwise registered for domestic marketing. Export of regulated products (including pharmaceuticals and medical devices) is governed by the SFDA’s export licensing regime, and the SFDA retains discretion to permit or restrict export even for locally manufactured products.

There is no established category of ‘dual-labelling’ authorisation that automatically substitutes for full market registration. To obtain SFDA approval for export, the entity must apply for the requisite export licence or clearance. This condition applies regardless of whether the product is intended solely for export.

When export permission is granted, the exporting establishment remains subject to the SFDA’s quality-control and traceability framework. Products exported from KSA must be manufactured in SFDA-licensed facilities and in conformity with the SFDA’s regulations. While the SFDA has not issued labelling standards which apply specifically to therapeutic products being exported outside of KSA, regulated products must meet the SFDA’s conformity and tracking requirements (RSD) as part of clearance processes. Consequently, any ‘export-only’ labelling must be managed through the exporting manufacturer’s approved quality system and SFDA-approved procedures.

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 may circulate domestically or before therapeutic products may be exported?

Therapeutic products must be registered with the SFDA prior to marketing them in KSA. For pharmaceutical products, the SFDA requires applicants to provide a Patient Information Leaflet (PIL) in Arabic and English and a Summary of Product Characteristics (SPC) in English as part of the registered product information.

In addition, the SFDA has implemented the RSD system, which is intended to follow product movement through the supply chain.

The SFDA labelling requirements for medical devices include local-language obligations that vary depending on the intended user. For devices intended for use by consumers, labelling and instructions for use must be provided in both Arabic and English. For devices intended solely for use by healthcare professionals, English labelling may be acceptable, although Arabic should be included where necessary to ensure safe and effective use. The SFDA’s device labelling rule also

addresses where the required label information must appear. On Unique Device Identification (UDI), SFDA has issued a dedicated requirements document stating that it sets SFDA requirements for UDI for medical devices and explains that the purpose is standardised device identification supporting traceability and safety initiatives. SFDA also operates a UDI system under which manufacturers and their authorised representatives are responsible for providing and maintaining UDI data (in the system).

SFDA treats export of drugs as a regulated activity and provides an SFDA-specific form and procedure for clearance (ie, export is administered through an SFDA process rather than being automatic). Where export is permitted, the local compliance obligations will still apply, including that product identity, batch and serial information and documentary traceability remain intact and auditable through the relevant SFDA-controlled quality and traceability mechanisms.

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?

Yes. In KSA, a number of pricing, reimbursement, procurement and supply-control regimes materially influence the distribution channels and availability of therapeutic products, even though they are not trade measures in the formal sense.

Pharmaceutical pricing is subject to statutory control. The Pharma Law provides that pharmaceutical products are priced in accordance with rules approved by the competent authority (ie, the SFDA), and prices may not be set or amended outside that framework. The SFDA, in its capacity as the competent authority, determines the approved price as part of the product registration process. The SFDA's price assessment relies on certain factors such as reference pricing in selected foreign jurisdictions, comparison with therapeutically equivalent products registered in KSA, and product characteristics (including strength, dosage form and pack size). The approved price becomes a condition for lawful marketing and circulation.

The SFDA's pricing rules do not regulate reimbursement as these are typically determined through commercial mechanisms which must not exceed the SFDA-approved price.

KSA's National Unified Procurement Company (NUPCO) conducts centralised procurement of medicines and medical devices for KSA government healthcare institutions. Access to public sector procurement contracts is contingent on the outcome of the submitted bids.

The SFDA enforces stock and shortage-management obligations, including requirements to maintain sufficient local supply and to notify anticipated shortages in advance, which can constrain distribution strategies and restrict exports.

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?

Non-compliance with trade and distribution rules for therapeutic products is addressed through a broad enforcement framework which combines administrative, civil and (in serious cases) criminal measures, principally exercised by the SFDA.

From an investigative perspective, the SFDA has statutory authority to conduct inspections of licensed establishments, warehouses and points of sale to review records and samples, and to

seize products suspected of non-compliance (including unregistered, falsified or improperly labelled products). These powers are exercised through scheduled and unscheduled inspections.

At the administrative level, the SFDA may impose a range of corrective measures, including warnings, product recalls, suspension or cancellation of licences, suspension of specific products, and refusal of import/export clearance.

For more serious or repeated breaches, such as circulation of unregistered products, falsification, or conduct posing a public-health risk, the regulatory framework allows for criminal referral, with penalties that may include substantial fines and imprisonment as provided under the Pharma Law and SFDA regulations; and, in exceptional cases involving fraud or intentional public-health harm, under other applicable KSA criminal statutes.

Separately, civil liability may arise in parallel, including claims for damages by affected parties or contractual consequences with procurement bodies (eg, NUPCO) or other customers.

In practice, enforcement is progressive and risk-based. The SFDA typically prioritises administrative and corrective tools and escalates to severe sanctions where non-compliance is systemic, intentional or harmful to public health.

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?

Publicly available KSA case law in this area remains limited, reflecting the fact that enforcement and interpretation of therapeutic product regulation is primarily driven by administrative practice, SFDA circulars and policy initiatives rather than reported judicial decisions.

From a legislative and policy perspective, the most notable recent development is the publication of a draft update to the SFDA's Pricing Rules for Pharmaceutical Products for public consultation. This draft signals a potential recalibration of the methodology by which pharmaceutical prices are assessed and approved, including greater clarity around reference pricing, therapeutic comparators and price-review mechanics. While not yet in force, changes in this area would have a direct downstream impact on market access, distributor margins, public procurement participation and supply strategy.

Additionally, the SFDA has issued draft guidelines addressing how the SFDA classifies a pharmaceutical product's legal and distribution status. These are not yet in force, but were open for consultation.

From an enforcement trend perspective, the SFDA has publicised circulars relating to product availability and shortages, and regulatory sanctions. Most recently, the SFDA publicised the suspension of imports of medical devices from an overseas manufacturer following quality violations, with no reference to the manufacturer's name.

Overall, anticipated reform in the short term appears focused on further enhancing the SFDA's existing regulatory framework to align further with global standards and appeal to foreign investors.