

The Pharma Legal Handbook

Saudi Arabia

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

Saudi Arabia

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Saudi Arabia. It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with STA, an international law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.



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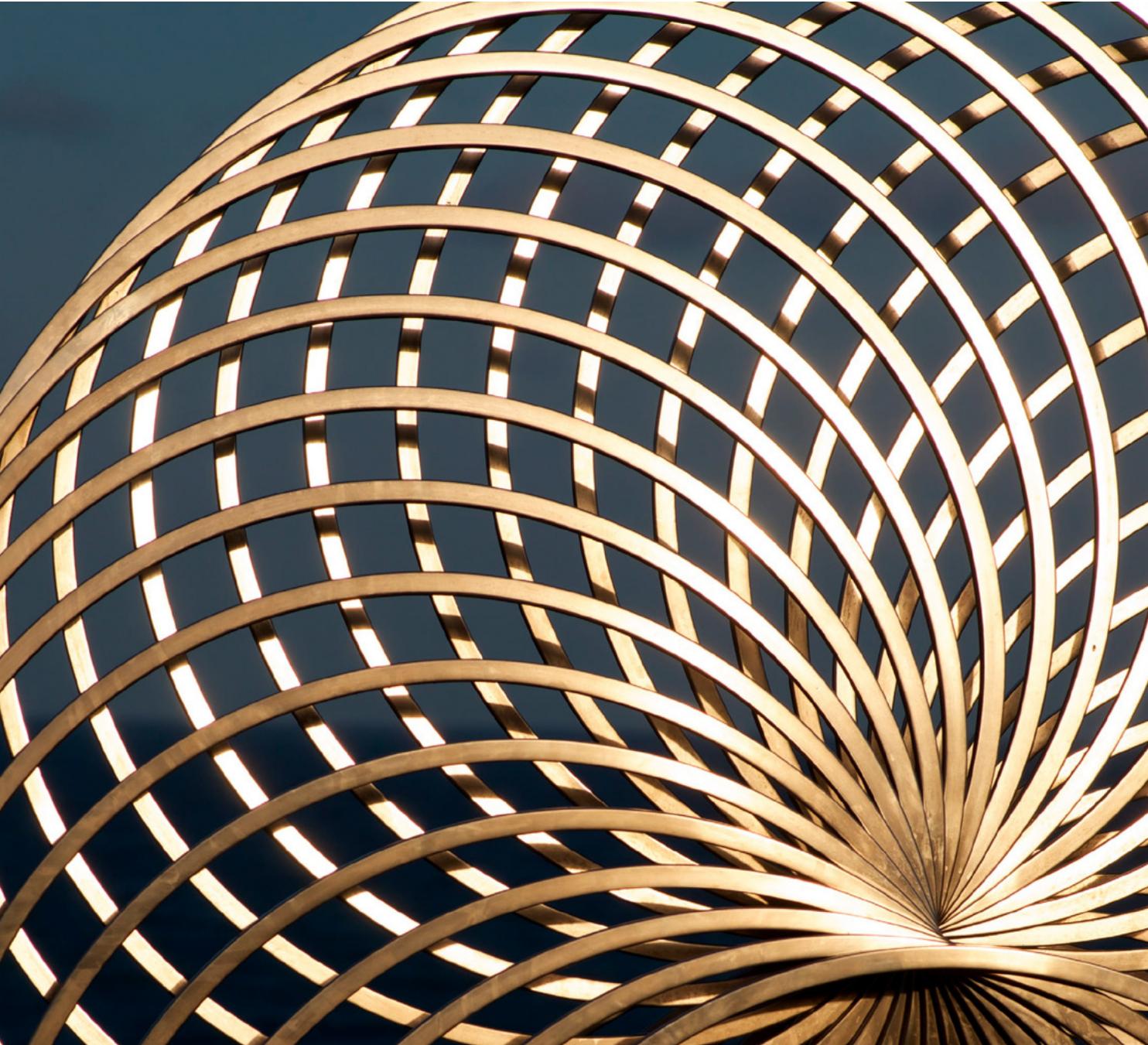
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01

REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

3. What are the steps to obtaining authorization to develop, test, and market a product?

4. What are the approximate fees for each authorization?

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

9. What is the potential range of penalties for noncompliance?

10. Is there a national healthcare system? If so, how is it administered and funded?

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The Saudi Food & Drug Authority (SFDA) is the government agency that regulates drugs and medical devices in Saudi Arabia. It is also in charge of biological and chemical substances in Saudi Arabia.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

Authorization:

The Saudi Food and Drug Authority (SFDA), the Drug Track and Trace System (RDS) track all human registered drugs that are manufactured in Saudi Arabia or imported to the country. RDS is a standardized identification system that tracks drugs from the manufacturer to the patient. It adopts GS1 standards and applies to all pharmaceutical products on the Saudi market, including over-the-counter (OTC) medicines. According to GS1, the Saudi Food and Drug Authority (SFDA) is working on similar requirements for medical devices. Saudi regulations stipulate that all drugs must be marked with a GS1 Data Matrix barcode that contains, at minimum, the GS1 Global Trade Identification Number (GTIN), the expiry date, and the batch/lot number. This information must also be printed on labels. All transactions for drug packages must be reported to a national Drug Track & Trace System (DTTS), and all manufacturers licensed by the SFDA must acquire a Global Location Number (GLN).

Pricing:

According to the new SFDA pricing guidelines, pharmaceutical products are to be priced taking into account:

- I. Therapeutic Value Add for the product (Value Add);
- II. Price of alternative products registered in KSA (Comparators);
- III. Ex-factory Price of the Manufacturer and Ex-factory to the countries where the product is marketed (Ex-f in its local currency);
- IV. Wholesaler price in the COO (WSP in its local currency);
- V. Price to Public in the COO and the countries where the product is marketed (PP);
- VI. Proposed Price to KSA (Cost, Insurance & Freight price i.e. CIF price in COO currency); CIF price to all countries where the product is marketed according to the official price certificate template. The price certificate validity has to be 6 months from the date of issuance;
- VII. The price of the product is in the adopted price references.

Reimbursement:

The Ministry of Health (MOH) is the major government agency entrusted with the provision of preventive, curative and rehabilitative healthcare for the

Kingdom's population. The Ministry provides primary healthcare (PHC) services through a network of healthcare centres throughout the Kingdom. It also utilizes a referral system that provides curative care for all members of society from the level of general practitioners at health centres to advanced technology specialist/curative services through a broad base of general and specialist hospitals. The MOH also undertakes the overall supervision and follow-up of healthcare-related activities carried out by the private sector. Therefore, the MOH can be viewed as a national health service (NHS) for the entire population.

3. What are the steps to obtaining authorization to develop, test, and market a product?

Before being sold in the Kingdom of Saudi Arabia (KSA), medical devices must receive marketing authorization from the Saudi Food and Drug Authority (SFDA) under the Medical Devices Interim Regulation (MDIR), Decree No. 1-8-1429/2008.

Step 1

Appoint a Saudi Authorized Representative (AR) to manage your device registration in the KSA. Your representative must be licensed with the SFDA. Further, the SFDA must authorize the contract between you and your AR.

Step 2

Your Saudi AR must present the authenticated AR contract to the SFDA for review and obtain a license to represent you in the KSA. The AR contract and license may be valid for 1-10 years; however, the AR license cannot be valid longer than the contract.

Step 3

Prepare the Medical Device Marketing Authorization (MDMA) application and submit it through your AR. The application includes device labelling, IFU, promotional materials, proof of regulatory approval in your reference market and quality system certification (if applicable). Labelling, promotional materials, and IFU must be in English and Arabic; English only is acceptable for professional-use devices.

Step 4

The SFDA reviews the MDMA application for completeness. Then a third-party Conformity Assessment Body (CAB) performs a detailed technical review upon payment of the application fee.

Step 5

The SFDA makes the final decision based on recommendations of the CAB. Once the device is approved, the SFDA issues an MDMA certificate that you may provide to your distributor/importer for market entry.

Step 6

Device registrations are valid for three years, or the remaining validity is in the reference country you have chosen (if less than three years).

4. What are the approximate fees for each authorization?

The SFDA will charge fees for Regulatory Services of Pharmaceutical Products, according to the following:

- I. Issuing a Certificate of Pharmaceutical Product (CPP) or a Free Sale Certificate – 200 Saudi riyal
- II. Issuing a certificate for Good Manufacturing Practice (GMP) – 500 Saudi riyal
- III. Issuing a price list of company products – 500 Saudi riyal
- IV. Evaluating product advertisement application - 14,000 Saudi riyal
- V. Inspecting a pharmaceutical consulting centre to issue a license - 1,000 Saudi riyal
- VI. Inspecting a scientific office to issue a license - 5,000 Saudi riyal
- VII. Pre-registration price estimation - 20,000 Saudi riyal.

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

Once the device is approved, the SFDA issues an MDMA certificate that you may provide to your distributor/importer for market entry. Device registrations are valid for three years, or the remaining validity is in the reference country you have chosen (if less than three years).

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

Marketing authorization for generic products is subject to the same legal process as brand-name products. Market authorizations from foreign jurisdictions are not recognized in Saudi Arabia, as all products are independently evaluated by the Saudi Food & Drug Authority (SFDA). However, importers or their agents must supply and sell pharmaceutical products from and to entities that have the applicable authorisation to deal in pharmaceutical products.

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

A product consists of two or more items that are subject to different SFDA's jurisdictions in terms of regulatory path, marketing and/or manufacturing. It includes:

A) Integrated combination product:

A product consists of two or more regulated components that are combined/integrated as a single product.

B) Non-integrated combination product:

A product consists of two or more separate items that are contained in the same package. [Co-packaged combination product].

Any regulated product packaged separately where the labelling information refers to be used with another specific regulated product where both are