The Pharma Legal Handbook

United Arab Emirates

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

PHARMA BOARDROOM

United Arab Emirates

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in the United Arab Emirates.
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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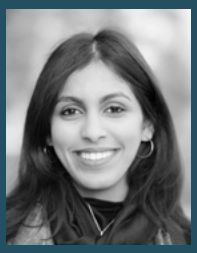

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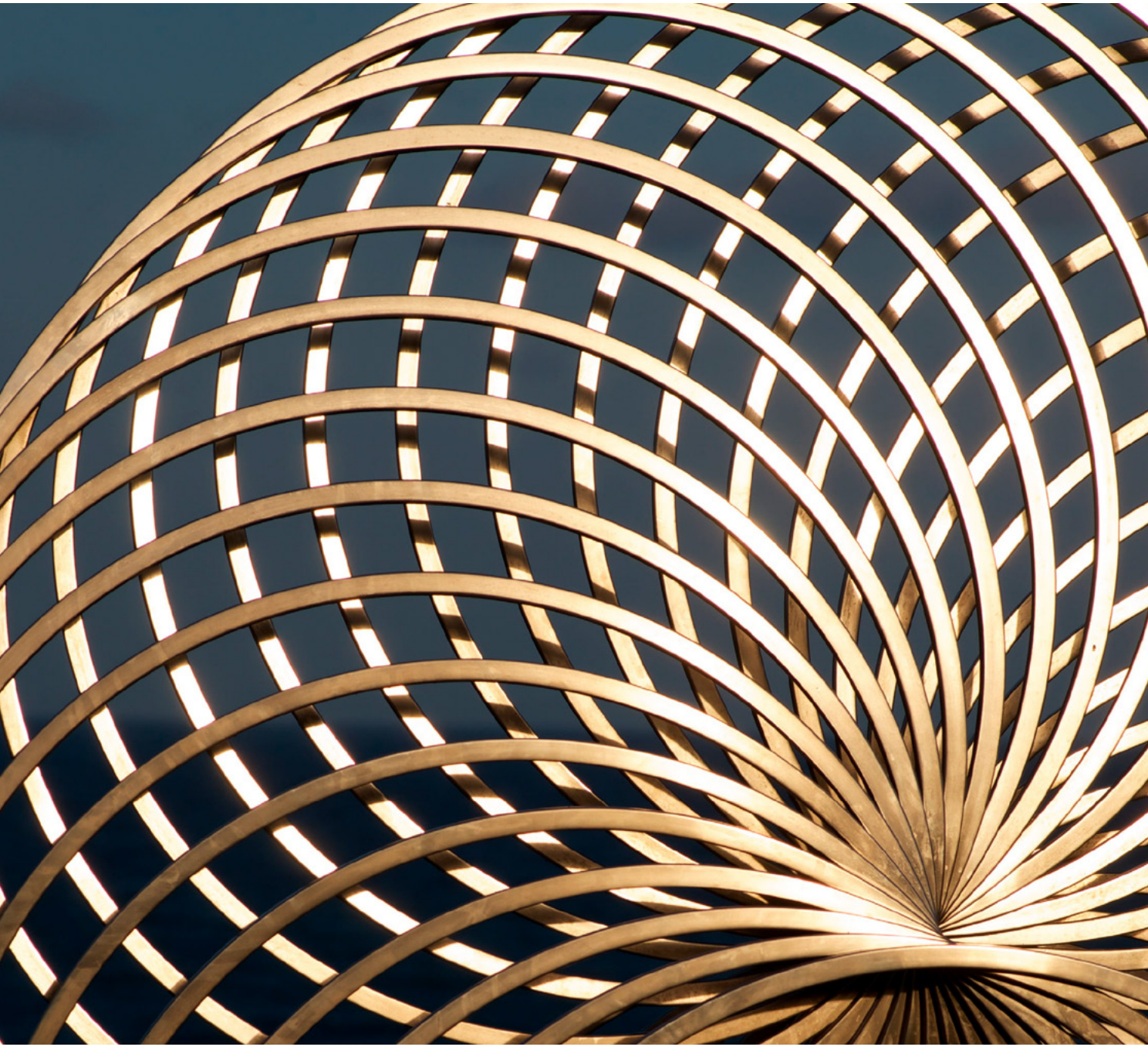

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

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

The UAE Ministry of Health (MOH) is the primary authority responsible for oversight of all the regulatory functions concerning pharmaceuticals in the UAE. The Ministry of Health frames the national medical and healthcare policy for the UAE, in addition to overseeing the healthcare market throughout the Northern Emirates.

To delve into further detail, the healthcare systems in the three largest Emirates are individually regulated by the:

- Health Authority Abu Dhabi (HAAD), responsible for the governance of the healthcare system in Abu Dhabi.
- Dubai Health Authority (DHA), responsible for the governance of the healthcare system in Dubai.
- Emirates Health Authority, responsible for the governance of healthcare in the Emirate of Sharjah.

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

The primary laws governing the authorization, pricing, and reimbursement of pharmaceuticals in the UAE are as follows:

- Federal Law No. 4 of 1983 (Pharmaceutical Law)
  It must be noted that the Federal Law No. 4 of 198 was replaced by the new Law, Law No. 8 of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Establishments on 19 December 2019. However, until the implementing regulations for the same are issued, the implementing regulations under the repealed laws of 1983 and 1995 will remain in effect.
- Federal Law No. 14 of 1995 (Medicine Importation Law)
- Federal Law No. 20 of 1995 (Natural Medicine Law)
- Federal Law No. 5 of 1984 (Medical Licensing Law)
- Federal Law No. 10 of 2008 (Medical Liability Law)
- Federal Law No. 23 of 2005 (Health Insurance Law)
- Federal Law No. 12 of 2002 (Patent Law) and Ministry of Health
- Resolution No. 404 of 2000 (Patent Resolution)

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

The legislation specific to clinical trials in the UAE is the Guidance of the Drug Control Department (DCD Guidance) of the Ministry of Health (MOH).

The regulatory authorities for clinical trials within the UAE are the MOH, HAAD, and DHA.

As per the DCD Guidance, the sponsor of a specific clinical trial or experimental protocol is expected to secure all the necessary agreements between the parties involved.

Designated clinical trial centres must establish independent institutional ethics committees (IECs), which must review the relevant proposals of the sponsors. Then, the IECs shall provide a recommendation on the viability of the clinical trial based upon the information submitted. The findings and recommendations of the IECs will then be forwarded to the concerned governmental authorities for their final approvals and authorizations.

The sponsor must set out the amount of compensation payable for the investigators and the subjects of a clinical trial in its proposal to the IEC.

While all applicable UAE law states that no unregistered drugs can be used in the UAE, the MOH and other government departments have approved the use of unregistered medications in certain circumstances.

The DCD Guidance further states that all clinical trials must follow the principles of the World Medical Association Declaration of Helsinki (Helsinki Declaration).

Consent- All clinical and research trials in the UAE require human subject consent, as well as the written approval of the MOH or other concerned governmental authorities.

Trial pre-conditions- The IEC must ratify the proposal of the sponsor concerning insurance coverage, indemnities, or other forms of compensation in case of injury or harm to the subject.

Procedural requirements - The clinical trial must follow the protocols and procedures delineated in the ratified proposal.

Concerning manufacturing, under the Pharmaceutical Law, applications must be made to the Licensing Committee of the Ministry of Health (MOH).

The application must include, (i) the corporate documents for the company (including the names of the shareholders), (ii) the license number and date of issue of the managing pharmacist of the factory, and additional licenses of the pharmacists who will be employed there, and (iii) other documents as determined by the Minister of Health.

Concerning marketing, under the Pharmaceutical Law, all applications for marketing authorization must be made through the conduit of the Ministry of Health (MOH).

The key stages are submission of the application process; inspection of the compounds contained in the drugs to be marketed; and compliance review. The MOH shall conduct inspections of applicant pharmacies.

4. What are the approximate fees for each authorization?

With regard to marketing, the licensing fee is AED7,500, and the initial inspection fee is AED100. Other fees are contingent on the type of medication to be marketed, advertising guidelines, and media type.

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

The license is valid for one year, and must be submitted for renewal 90 days before its expiry.

The trade license for the factory is usually renewed on a yearly basis.

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

Market authorizations from foreign jurisdictions are not recognized, and cannot be used, in the UAE. All entities which intend to sell or market their products must obtain the applicable licenses and authorizations from the Ministry of Health (MOH). However, it must be noted that a foreign company can hire a local distributor or agent already licensed by the MOH.

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

The Ministry of Health (MOH) (through its Registration and Control Department (RCD) is responsible for the overall regulation of biologicals and combination products in the UAE. Under the Pharmaceutical Law, all pharmaceuticals must be registered by the MOH before they can be imported into the UAE for sale and distribution.

A pharmaceutical manufacturer must have registered successfully with the MOH before its pharmaceuticals can be registered in the UAE. The application process for the registration of pharmaceuticals in the UAE involves submitting an application through the MOH which must include a Certificate of Pharmaceutical Product (CPP) per the World Health Organization (WHO) Certification Scheme or Free Sale Certificate (FSC) of the product.

Additionally, a statement must be submitted from the parent company that the product is free from, among other things, hormones, heavy metals, and pork products. The medication must further be accompanied by a halal certification (that is, that it contains no pork products, alcohol or other intoxicants).

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

Article 77 of the Pharmaceutical Law, detailed in Chapter 12 on the Persons with Judicial Authority states that the Minister of Justice, Islamic Affairs and Awqaf shall, upon consultation with the Minister of Health, issue a decision determining the persons who have judicial authority to inspect pharmaceutical establishments with the single-minded goal of verification of their compliance with the provisions of the Pharmaceutical Law, and its implementing rules and regulations.

These inspectors appointed by the Ministry of Health form the compliance regime – they have broad powers to inspect pharmacies, marketing materials, and prescriptions to patients. Where the inspectors find any violations, they can conduct full reviews, prepare reports, issue fines, and recommend criminal actions for public prosecution.

The investigators take into account all available Ministry of Health, federal and international guidelines and best-practices such as those published by the U.S. Food and Drug Administration, the European Medicines Agency, World