The Pharma Legal Handbook

Egypt

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

PHARMA BOARDROOM

Egypt

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

Prepared in association with Youssry Saleh, a full service law firm in Egypt, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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YOUSSRY SALEH &PARTNERS

Youssry Saleh Law Firm, established in 1985 is a full-service law firm in Egypt, which has gained a strong reputation for supporting businesses in a wide range of industries as well as helping individual clients.

Today, the law Firm provides integrated service to the clients throughout the Middle East, helping them cover their current business needs and requirements. The Firm also represents its clients in locations that their businesses take them to as well as SMEs (small/medium enterprises) in emerging industries and markets.

Youssry Saleh Law Firm, founded and led by Mr. Youssry Saleh, an experienced Supreme Court attorney-at-law, offers a well-structured, cross-disciplinary team of experienced attorneys who create synergy and provide our clients with needed depth of knowledge, breadth of experience and responsive service, so critical for the resolution of clients' issues and meeting key business objectives.

Youssry Saleh Law Firm in Egypt represents large manufacturers, distributors and dealers in pharmaceuticals and medical technology. Throughout years of service the Firm has established a solid reputation with these companies, and it now serves and supports them on constant basis.

By way of synergizing expertise of field professionals with medical degrees, insurance specialists and other specialized in the field counselors, our team becomes able to provide comprehensive, integrated support to our clients. Our work starts from square one, with consulting in the initial phase of a company's life on set-up, financing, and establishment and continues along the lifecycle through licensing, trademark registration, intellectual property related issues, financing, and various regulatory and litigation matters arising in the way.

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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 pharmaceutical regulatory body in Egypt is the Egyptian Drug Authority (EDA) operating and working under supervision of the Ministry of Health (MOH) in Egypt.

The EDA comprises three independent organizations consisting of the following:

a) Central Administration for Pharmaceutical Affairs (CAPA): which is mainly responsible for the registration and pricing of medicines, and inspection of pharmacies and manufacturing facilities.

The CAPA hosts four departments for registration: Licensing and Pharmacists services, Inspection and Control, and Importation and Exportation department.

b) The CAPA includes a department (Egyptian Pharmacovigilance Center "EPVC") that monitors the use of the drugs and medical devices after their registration.

c) The National Organization for Drug Control and Research (NODCR): which is responsible for quality control of pharmaceutical products, medicines, medical plants, cosmetics, raw materials, insecticides, and products from natural origin. The organization entails many laboratories for testing all the pharmaceutical products under registrations, which will be marketed in Egypt.

d) National Organization for Research & Control of Biologicals (NORCB): which is responsible for the marketing authorizations and licensing activities.

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

The authorization process is regulated by Decree 425 of the year 2015.

Pricing of drugs is regulated through a pricing committee. Any price increases of medicines and drug products are determined according to issued Ministerial Decrees.

The drug manufacturers recommend the prices of the new medicines, the pricing committee reviews the recommended prices, and the pricing committee then determines whether to approve or reduce the prices to the lowest price of the referenced countries.

The Ministry of Health is responsible for the registrations and approvals regarding medicines and medical devices in Egypt through the Drug Policy and Planning Center and the Central Administration for Pharmaceutical Affairs in Egypt.

Reimbursement of drugs, biologicals, and medical devices:

MOHP's facilities and Health Insurance Organizations follow the reimbursement process provided by MOHP. There are other institutions or

ministry-affiliated public facilities follow MOHP regulations but have their own budget and autonomy.

Regarding the private sector entities, they have to abide by the MOHP healthcare standards and regulations, as they do not have to follow the same reimbursement regulations at the MOHP. The procurement department is responsible for setting the tender drug list and reimbursement price, which is published and distributed to all MOHP facilities. Each hospital or primary care facility with a plausible budget can purchase their drugs directly from the drug manufacturers or wholesalers according to the price specified in the tender drug list (No negotiations).

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

A variation application details a proposed change to approved documentation, providing a formal means by which the approved license details held by the Competent Authorities for a given medicinal product can be updated.

Types of variation such as follows: Variation department approval (VDA): They need prior approval by the variation department (VDA) before implementation;

Variation committee approval (VCA): They need prior approval by the variation committee (VCA) before implementation;

Technical committee approval (TCA): They need to be approved by the technical committee (TCA) before implementation;

Requirements to be fulfilled according to the type of change in the guidelines:

A) NODCAR:

1. Notification (N);
2. Analysis inspection Department (AI);
3. Analysis registration Department (AR).

B) Stability:

1. None;
2. Ongoing;
3. Accelerated (6M);
4. 6M + long-term stability.

C) Dissolution:

1. None (DN);
2. Comparative In-Vitro dissolution in most suitable medium (D1);
3. Comparative In-Vitro Dissolution at three different PH media (1.2/4.5/6.8) and most suitable medium (D3/4);
4. Bioequivalence study (BE).

D) Pricing (P)

N.B: In some cases, request within reporting category VDA can be issued to VCA if needed according to file case.

4. What are the approximate fees for each authorization?

The approximate fees for marketing application form is EGP 10,000.

The registration fee is EGP 1000 for each "Application Form"; the fee is non-refundable.

The registration is valid for 10 years starting from the day of obtaining the approval of the Technical Committee for Pharmaceutical Control, and the renewal procedures shall be renewed at the CAPA during the last year of its validity shall be applied at the beginning of the last year from the tens the applicant shall apply for renewing the registration to the General Authority for Registration. While the registration of the biological products, serums and vaccines are re-registered every 5 years according to a request submitted by the product owner to the CAPA as per Decree 297 of the year 2009.

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

According to Decree No. 425 of the year 2015, in order for a pharmaceutical company to market and sell drug products under a brand-name the company shall firstly obtain approval from the Food and Drug Administration (FDA) by submitting a new drug application and a documentation shall include all data to establish drug's clinical safety and efficiency. Moreover, studies will be performed to determine the characteristics of the drug dosage form, including the manufacturing process, drug stability, purity, strength, and how it dissolves. Once the drug receives FDA approval, the innovator company can then exclusively market and sell this 'brand-name' product for as long as the company has patent protection.

The "Box" system in the authorization of Pharmaceuticals in Egypt must include 12 products, in which one of them must be a brand-name product and the rest (eleven) are generic products.

Yes, there are differences. The authorization process of the local manufacturers differs from the foreign owned manufacturers.

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

The locally manufacturers' authorization procedures will be as follows:

In accordance with the standards of the World Health Organization, a minimum of 10% of the production of Pilot Batch volume shall be complied with in the presence of an inspector from the General Directorate of Inspection. This operation shall not be carried out in the local market at all. The registration procedures shall be completed according to the installation statement on which the production was based. For the next steps:

1) Take off samples through Pharmaceutical Inspection from the "Pilot Batch" for analysis at the National Organization for Drug Control and Research. The applicant shall submit the file of the analysis to the above-mentioned authority containing the required documents and attachments for the analysis file specified in Annex No.8, the committee is obliged to issue the analysis results within 60 working days form the date of the submitting of the file.

2) Provide the accelerated stability study for a period of six months on the Pilot batch for evaluation by the scientific committee to evaluate the stability studies. The evaluation shall be within 60 working days from the date of presenting the stability study file.