THE PHARMACEUTICAL INDUSTRY

RESPONSIBLE ENTITIES:

- The House of Representatives
- The Cabinet
- The Ministry of Health and Population

CHALLENGE	RECOMMENDATION	STATUS/NOTES
Pharmaceutical pricing policies are out of sync with changing market conditions, including exchange rate movements, rising inflation, and increases in energy prices; operating costs; and interest rates. The current pricing scheme— a cross-reference pricing scheme that takes into account the prices of pharmaceuticals in 36 countries— is unfavorable to the industry. Under this scheme, the lowest price in any of the reference countries is used to guide the pricing of pharmaceuticals in the Egyptian market, with no consideration for the difference in distribution margins, which should be a key factor in pricing. Thus, the current system needs to be seriously and comprehensively reviewed in order to make it more responsive to market changes, and render investment in the industry attractive.	Revisit the current pricing policy to bring it in line with the requirements of the global market and the practiced pricing methods. This should increase the volume of pharmaceutical exports, and make it commensurate with the size and capacity of the industry in Egypt. For new Common Technical Document (CTD) submissions for generics, price them at 65% of the price of the innovator or branded counterpart (the patented). Approve the pricing of registered pharmaceutical products, giving priority to alternative products that are in short supply or missing in the market. Expedite the re-pricing of registered pharmaceuticals, which are not yet marketed, even if their notifications have lapsed (these pharmaceuticals were priced prior to the floating of the Egyptian pound). Abolish the VAT on imported pharmaceutical raw materials, which are pre-blended and processed using two or more ingredients. At the same time, impose on them the 2% tariff rate prescribed for customs category No. 3003, rather than the 5%, tariff rate prescribed for customs category No. 3824, in addition to the 14%VAT.	
The policy named the 'Box'* , which regulates the registration of pharmaceuticals in Egypt, is abused by international pharmaceutical companies that hold the patents. These companies fill up a particular 'Box' with phantom products, thereby locking up the 'Box', and thus hinder effective competition of local companies, and limit the availability of affordable pharmaceuticals in the local market.	Abolish the 'Box' system, and allow Egyptian companies to produce and register generic pharmaceutical products. Over the coming two years, complete the registration of all pharmaceutical products that are currently in the registration queue.	In November 2018, Ministerial Decree No. 654 of 2018, concerning the registration of human pharmaceuticals, was issued. It stipulated that under certain conditions, biosimilars registration applications, which exceed the number of pharmaceuticals allotted to a biosimilar 'box' (referenced in Ministerial Decree No. 425 of 2015) will be accepted. Specifically, applications will be accepted for pharmaceuticals listed as in short supply and with no substitute, during the year preceding the issuance of the Decree, or in other cases determined by the Central Administration for Pharmaceuticals Affairs, according to market needs.

**The 'Box' policy, which regulates the registration of pharmaceuticals in Egypt, limits the number of generic drugs of any brand that could be registered in the local market to a maximum of ten products. Each 'Box' is composed of one brand product, and 11 generic products (10 locally manufactured generic products and 1 imported generic product).*

Registration of new pharmaceutical products is a very lengthy process even though these products have already been approved and licensed in developed countries, which should serve as a solid reference for pharmaceuticals quality control testing.	Grant instant approval of pharmaceutical registration applications if the product concerned is registered in any two countries that are considered advanced in the pharmaceutical industry. Reform the registration process of pharmaceutical factories. The process should entail submitting a Common Technical Document (CTD) dossier and payment of LE 120,000 registration fee; the 'Box' system should be discarded in the process. The registration process should be completed in less than six months, and there should be a no set limit on the number of dossiers that can be submitted each month. Pharmaceutical factories should obtain international accreditation from the World Health Organization (WHO), the U.S. Food and Drug Administration (FDA), GTA, and the European Medicines Agency (EMEA).	
A national body to oversee the safety of pharmaceuticals, the Egyptian Drug Authority (EDA), was created in 2019. However, the following requirements pose obstacles for manufactures: - The requirement that manufacturers obtain an import approval for each consignment of imported raw materials; the additional fees associated with this requirement result in raising the price of the final. - The extreme processing delays in obtaining certificates of Free Sale and certificates of GMP negatively affects the exportation of products. - The Central Administration for Pharmaceutical Affairs refuses to accept the trading certificates for non-sterile products, which are issued by the IDA and sent by express mail. - Exporters must fulfill additional requirements to be able to export their products, including a commitment to provide production materials for a period of 6 months; receiving visits for verification; and obtaining the approval of the Public Authority for Unified Procurement.	Abolish the requirement that manufactures obtain an import approval for each consignment of imported raw materials. Expedite the issuance of the certificates of Free Sale and the certificates of GMP. Refrain from issuing any new export requirements without consulting with exporters.	On August 25, 2019, the President ratified Law No. 151 of 2019; Article 14 established the Egyptian Drug Authority (EDA), and Article 16 specified its mandate. According to Article 14, "A public service authority, called the Egyptian Drug Authority, is created; it has a juridical personality and is affiliated with the Prime Minister; the location of its headquarters is to be determined by the Prime Minister, and the board of directors may decide to open additional locations." Article 16 stipulates that "The new Authority aims to organize, implement, and control the quality, effectiveness, and safety of the medical preparations and devices provided for in the provisions of this Law. It is also tasked with enforcing the provisions of the current law governing the practice of pharmacy, provided that they do not contravene any of the provisions of this law. To accomplish this, it shall also assume all the necessary powers, functions and legal actions."
The absence of a clear legal framework governing the pharmaceuticals and medical devices sector.	Develop a new legal and institutional framework to govern the pharmaceuticals and medical devices sector.	On August 25, 2019, the President ratified Law No. 151 of 2019, the "Egyptian Authority for the consolidated procurement, supply, medical provisions, management of medical technology and the Egyptian Pharmaceutical Authority Law". The new law provides a clear legal and institutional framework to govern the sector.