THE COSMETICS INDUSTRY

RESPONSIBLE ENTITIES:

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

CHALLENGE	RECOMMENDATION	STATUS/NOTES
The cosmetics registration process is unnecessarily long and costly and hinders the expansion and competitiveness of the local industry.	Registration of cosmetics should be based on the product formula rather than the product Stock keeping Unit (SKU); instant approval of registration applications should be granted if the product is registered in any two developed countries.	
The inclusion of cosmetics in the definition of pharmaceuticals is problematic as they will be subject to the same registration, pricing, and testing rules and procedures applicable to pharmaceuticals. This is contrary to the nature of the industry and how cosmetics are regulated across most countries globally. Cosmetics are non-medical products, and are treated as such; they are governed by separate laws and regulations in many countries (e.g., European Union countries, the US, Saudi Arabia, the Arab Gulf States, and all African countries). Categorizing cosmetics under the rubric of pharmaceuticals is likely to have a significant adverse impact on the industry, and its ability to attract future investments, which was estimated at approximately LE 18 billion in 2018. The definition of cosmetics is inconsistent with the definition currently adopted in Egypt, which agrees with the internationally recognized definition of cosmetics. The draft law includes mandatory standard specifications for cosmetics. The controls and procedures regulating the importing, exporting, registration, and pricing of cosmetics go against the nature of the product itself. The absence of a clear definition of the term "pharmaceutical entity", which is to be licensed under this law. The release of imported medical products and other materials that fall under the jurisdiction of the Egyptian Drug Authority "EDA" is not allowed before all required tests and analyses are completed.	Develop effective implementation mechanisms to facilitates the enforcement of the law. The mechanisms should be appropriate to the nature of the cosmetics market, which differs drastically from that of pharmaceuticals. FEI's recommendations should be taken into consideration when developing the executive regulations of the law. Issue separate executive regulations to govern the cosmetics industry; the regulations should be appropriate to the nature of cosmetic products that are not used for medicinal purposes. Adopt the internationally recognized definition for cosmetics— "Any product containing one or more substances intended for use on the external parts of the human body, including skin, hair, nails, and lips, or on the external parts of the genitals, teeth, or mucous membrane of the oral cavity for the purpose of cleaning them, or perfuming them, or protecting them, or keeping them in good condition, or changing and improving their appearance, or correcting body odors and improving it". Delete the reference to "mandatory standard specifications" and replace it with "mandatory technical regulations based systems adapted from globally recognized systems, such as those adopted in EU countries. Cosmetics should not be subject to product registration requirements but to a notification system. This aligns with practices in EU countries, Saudi Arabia, as well as all East Asian countries, and is in line with the discussions that took place between the Cosmetics Sub-Chamber at FEI, and the Central Administration for Pharmaceutical Affairs as directed by the Minister of Health and Population.	According to Law No. 151 of 2019, cosmetics are defined as "any preparations developed for use on the external parts of the body, teeth, or the mucous membrane of the oral cavity for the purpose of cleaning them, or perfuming them, or protecting them, or keeping them in good condition, or changing and improving their appearance, or any other existing preparations, or yet to be developed and will be categorized as cosmetics according to international standards". Article 17, Section 2, Item 3 of the law vested EDA with the responsibility, among several other executive responsibilities, of inspecting and analyzing cosmetic products. It stipulates that EDA will have the responsibility to inspect and analyze "pharmaceuticals, and biological preparations, medicinal plants and herbs, cosmetics and all other similar or related products, according to international standards and references to verify their quality, validity, efficacy, and safety, as well as ensure the compliance of pharmaceuticals with pharmacopoeia requirements and the mandatory standard specifications approved by EDA". FEI will continue to engage and advocate for improving the Executive Regulations to better serve the needs of the industry.

The trading of domestic pharmaceuticals and other related products that fall under the jurisdiction of EDA is not allowed before all required tests and analyses are completed. Absence of a clear grievance processing procedures, including the specific time frame for filing a grievance and receiving a determination on it. The fees associated with the record-filing and inspection of cosmetics are excessively high. The cosmetics industry is a fast- moving and changing industry, where products develop periodically and 25% of the used formulas change annually. Thus, applying the rules and regulations pertaining to medical and pharmaceutical products on cosmetic products will hinder the development and prosperity of the industry. Requiring that each shipment of cosmetic products be analyzed will cost the government and the industry large sums of money for intangible benefits, and does not provide any assurance that the products are safe for consumers. This requirement is largely applied to companies and products that conform and comply with required standards, while many cosmetic products illegally reach the Egyptian market. Requiring that cosmetics be subject to testing prior to their release from customs release and their placing on the market is inconsistent with the global trend in cosmetic product control and analysis, which rely heavily on in-market control; this is more appropriate to the nature of the products, their volume of circulation, and the degree of potential health risks associated with using cosmetics, compared to other medicinal and pharmacological products.	Cosmetic products should not be subject to an enforced pricing system due to their nature, the manner in which they are traded, and being consumer products that are used regularly and daily (shampoo, skin and shaving creams, and toothpaste). Include a definition for pharmaceutical entities. Institute an in-market control system for cosmetic products to protect consumers. The time frame for filing a grievance must be within 15 days from the receipt of the notice of the decision. Inspection should be limited to accessing and reviewing records, books, and other documents related to the products and manufacturing processes; manufacturers should be given sufficient time to provide the required documents. Include an article in Law No. 151 of 2019 to mandate the issuance of separate executive regulations to govern the cosmetics industry; the regulations should be informed by the draft paper under discussion between and the Central Administration for Pharmaceutical Affairs, and the Cosmetics Sub-Chamber at FEI. Develop a separate fee schedule, including reasonable fees for the administration and testing of inspecting cosmetics. Similar to special food* products, registration of cosmetic products should be based on the product category and not the retail package.	

** Any food prepared or formulated to meet special nutritional or medical requirements.*

The executive regulations of Law No. 151 of 2019.	***The following elements should be taken into consideration when developing the executive regulations of Law No. 151 of 2019.*** - Amend Article 1 of Chapter 1, Definitions, by including the following: "Medical products and devices are the medical products and medical devices as defined in Clauses 2 and 3 of Article 1 of the law". - The fee schedule included in Law 151 of 2019 should make reference to medical devices. - Ensure making reference to the European standards that are adopted by medical equipment and laboratory reagents manufacturers, who have ben l under the supervision of the Ministry of Health for the past 20 years. - Licensing local factories and warehouses: Factories should obtain their licenses from IDA and EDA to ensure that they adhere to GMPs, which are included in ISO 22716 or its equivalent. - Oversight, inspection and market surveys: EDA must assume the responsibility to overseeing, and periodically inspecting cosmetics establishments, including factories, warehouses and places of sale. In carrying out their responsibilities, inspectors should be vested with law enforcement authority and powers. To ensure product compliance, EDA's inspector may enter cosmetics factories, warehouses and places of sale for the purpose of inspection; they have the right to review the relevant records and documents, as well as collect samples of cosmetics products for inspection and analysis in the EDA's laboratories or other accredited laboratories. -Adopt an Egyptian system for cosmetic products that aligns with international practices adopted in EU countries, Saudi Arabia, as well as all East Asian countries; adopting such a system promises to expand Egypt's cosmetics exports. - Cosmetic products should not be subject to registration requirements; a notification system, which is adopted worldwide, should be used instead.	On March 29, 2020, the Prime Minister issued Decree No. 777 of 2020 promulgating the Executive Regulations of Law No. 151 of 2019; they reflected several of the recommendations that were put forward by FEI. However, to avoid an implementation gap, FEI calls on the government to consider the other proposed recommendations.

	- Use international standards as a reference for setting the mandatory standard specifications for cosmetics. - Institute an in-market control system for cosmetic products instead of requiring that products be tested prior to being placed on the market. In-market control system, which relies heavily on carrying out the needed testing while the product is on the market, is more appropriate to the nature of the cosmetic products, their volume of circulation, and the degree of potential health risks associated with using cosmetics, which is drastically lower than that of other medicinal and pharmacological products. This system will ensure the safety of customers, especially that many cosmetic products reach the Egyptian market in an illegal manner. - Include representatives from the Cosmetics Sub-Chamber of FEI's Pharmaceutical Chamber in the technical committee that will be set up for developing the executive regulations of the law.	
Covid-19-related problem: the lack of some production inputs required for dealing with the current crisis.	***Exceptional Measure:*** Take advantage of the existing production capacity in the cosmetics sector to meet urgent needs; allow cosmetics manufacturers to obtain alcohol in order produce disinfectants for hospitals and other facilities.	