EDA Chairman decree no. (99) for the year 2021

EDA Chairman:

Having considered:

- Egyptian Drug Authority Law No. (151) for Year 2019, and its Executive regulations issued by the Prime Minister Decree No. (777) for Year 2020;

- Law No. (95) for Year 2018 establishing the Industrial Development Authority;

- Laws and ministerial decrees regulating in this regard;

- According to what was presented by each of EDA Legal Counsellor, and the Head of the Central Administration of pharmaceutical Policies and Market Access;

- For Work interest;

(Article One)

According to the terms and Conditions stipulated within Law No. (151) of 2019 and its executive regulation, it is impermissible to establish medical products or devices factories, or adding new production lines to existing factories, except after being formally licensed by EDA.

(Article Two)

It's prohibited to undergo any legally binding actions over any medical products or devices factories, unless after formally notifying EDA with such legal action, according to the form prepared for such purpose, and attached thereto all required warrants determined by the authority per each case circumstances. All of which, to evade any negative impact on the availability of the medicine necessary fortreatment of the patient, as well as to ensure eluding the technical aspects required from the parties tothe legal action to maintain the Egyptian drug market stability.

EDA shall issue an official statemeaent regarding each legal action, for both parties thereto indicating all the technical and legal details in order to achieve the legal effect of such action. Any legal action contrary to such procedures shall be considered null and void.

(Article Three)

The current owner (seller) shall submit to the authority, a detailed report about the factory's status, including compliance with technical requirements, and the status of all registered medical product and devices regarding its market avaliability, production, inventory, and importation, and production lines.

(Article Four)

The new owner (the buyer) shall undertakes to guarantee the availability of medical products and devices in the market, and shall not undergo any amends that may impact such availability within six months commencing from the date of ownership, tranfer,except for EDA prior approval.

(Article Five)

In any case, the legal action conducted over any medical products or devices factories, shall not after the factory status, regarding its commitment to apply all technical provisions required in the factory, according to EDA for the continulty of manufacturing and production. The new owner shall implement all technical and administrative decrees issued by the competent EDA'S central administrations related to the factory in question. The new owner shall also preserve the rights of the employees in the facility in accordance with the related laws.

(Article Six)

EDA'S competent central administrations shall ensure the implementation of the provisions of this decree. In the event of violating the aforementioned provisions, EDA shall suspend the factory's license and take all necessary measures towards implementing the suspension decision until rectifying the reasons thereof.

(Article Seven)

This decree shall be published in the Egyptian Gazette and shall become enforceable as of the next day after its publication therein. All decrees in contradiction with any of the provisions of this decree shall be considered null and void.

Egyptian Drug Authority Chairman
Prof /Tamer Mohamed Essam

25/2/2021