Decree of the President of the Egyptian Drug Authority No. (146) of 2022

Concerning the Roles of Rapid Alert System and Recall the

Medical and Biological Products

President of the Egyptian Drug Authority:

Having Considered:

- Law on Preventing Fraud Promulgated by Law No. (48) of 1941 and its Executive Regulation;
- Law No. (127) of 1955 on Pharmacy Profession Practice and its amendments;
- Law on Reorganizing Importation, Manufacturing, and Trading of Drugs, Medical and Chemical Devices No. (113) of 1962 and its amendments;
- Law on Intellectual Property Rights Promulgated by Law No. (82) of 2002 and its Executive Regulation;
- Law on Establishing the Egyptian Drug Authority Promulgated by Law No. (151) of 2019 and its Executive Regulation;
- Law on Organizing Clinical Medical Researches Promulgated by Law No. (214) of 2020;
- Law on Organizing Blood Operations and Plasma Assembly for Manufacturing its Derivatives and Exporting it Promulgated by Law No. (8) of 2021 and its Executive Regulation;
- Ministerial Decree No. (540) of 2007 regarding Recall the Non-conforming to Specifications Products;
- Minutes of the Authority's Board of Directors meeting held in its session on 20/07/2020;
- What was presented by the Chairman of the Central Administration of Operations;
- Having considered the interest of work;

Has decided

(Article One)

This decree shall come into effect with respect to **implementing the Rapid Alert System and Recall of the Medical and Biological Products**. For the purposes of its provisions, the following terms shall have the meanings set out for each term hereunder:

1) **Law**: Is the Law on Establishing the Egyptian Drug Authority Promulgated by Law No. (151) of 2019.
2) **Executive Regulation**: Is the Executive Regulation Promulgated by the Prime Minister Decree No. (777) of 2020 of Law on Establishing the Egyptian Drug Authority Promulgated by Law No. (151) of 2019.

3) **Medical Products circulating**: Is one or more process subjected to the provisions of law such as manufacturing, distributing, possessing, presenting for sale, storing, use, keeping, packaging, transporting, delivering, importing or exporting the medical and biological products.
4) **Recall for Medical Product**: It is the process of the product withdrawal from the supply chain, and the consumer or user shall be advised to take the appropriate action.
5) **Rapid Alert System**: They are the reporting mechanisms used in publishing the most important, urgent and unpostponable recall decisions. Assessing the defects shall be in accordance with their severity and the potential harm to public health.

(Article Two)

This decree shall apply on all **Medical and Biological Products** subjected to the provisions of law in any of circulating stages which the product is subjecting to the recall decision according to the applicable provisions and conditions.

(Article Three)

The Head of the Central Administration of Operations has the right to take a decision of recall and prohibit of circulating of any product subjected to the law provisions in case of non-conformity to specifications is proven, recommendations issued by (WHO) or any of the international entities of recalling the product or if it is found that the use of the product results in harm or side effects not specified in its leaflet.

The recall decisions are divided into three classes according to the severity of the defect as indicated in the Regulatory Guideline of Rapid Alert System and Recall of the Medical and Biological Products in detail.

The procedures of Rapid Alert System shall be implemented in accordance with the procedures, conditions and dates stipulated in the Regulatory Guideline of Rapid Alert System and Recall of the Medical and Biological Products.

(Article Four)

The manufacturing or importing companies are obligated, as needed, to recall the defective product from the markets on their own expense within the specified periods in the aforementioned Regulatory Guideline under the supervision of the pharmaceutical inspection. To ensure the implementation, all EDA branches in the governorates, distribution points and pharmacies shall be informed of the recall decision.

Just after the grace period for the company to recall the product ends, the Head of the Central Administration of Operations shall send a report of the achieved procedures to the Chairman of the Authority (EDA). In case of failure of the company in recall the entire amount of the non-conforming product within the specified period, a decision of suspending the product manufacturing or prohibiting the product importing for three months shall be issued. In case of repetition of the violation, the competent central administration shall send a technical, reasoned and integrated report to the Chairman of the Authority (EDA) to take the decision that consider the public benefit according to the reasons described in the report.

(Article Five)

Non-conforming products shall be sealed by the pharmaceutical inspection and shall be destructed by the competent committee in the presence of a representative of the company owning the product. The company has no right to claim any compensation from the authority.

The company may submit appeal to the Chairman of the Egyptian Drug Authority, after charge of the service is paid, to consider suspending the procedures of recall and destructing the product. The competent central administration shall study the request to see the necessary corrective procedures taken by the company to correct the defect then the administration shall send a technical, reasoned and integrated report of all abovementioned to the Chairman of the Authority (EDA) to take the decision that consider the public benefit according to the reasons specified in the report.

(Article Six)

The concerned persons have the right to submit appeal of the issued decisions by the competent administration in the Egyptian Drug Authority regarding of recall or destruction a product in accordance with the provisions and procedures stipulated in the executive regulation.

(Article Seven)

the Head of the Central Administration of Operations shall issue the Regulatory Guideline of Rapid Alert System and Recall the Medical and Biological Products, within five days of the date of approving this decree

(Article Eight)

This DECREE shall be published in Al-Waqa'i' Al-Misriyya, and shall come into effect from the date of its publication therein. Any other provisions that may contradict this DECREE shall be null and void

President

of the Egyptian Drug Authority

Written on: / /2022

Prof./ Tamer Essam