EDA

هيئة الدواء المصرية
رئاسة الهيئة

Decree of the Chairman of the Egyptian Drug Authority No. (120) of 2022
Concerning Guideline of conducting risk-based Post Marketing surveillance plan
For Biological products

Chairman of the Egyptian Drug Authority:

Having Considered:

- Law No. (127) of 1955 on Pharmacy Profession Practice and its amendments;
- Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019 and its Executive Regulation;
- Law on Regulating Clinical Medical Researches Promulgated by Law No. (214) of 2020;
- Law on Regulating Blood Operations and Plasma Assembly for Manufacturing its Derivatives and Exporting it Promulgated by Law No. (8) of 2021 and its Executive Regulation;
- Minutes of the Authority's Board of Directors meeting held in its session on 20/07/2020;
- What was presented by Head of the Central Administration of Operations;
- For the sake of public interest;

Has decided

(Article One)

This decree shall be implemented with respect to conducting risk-based Post Marketing surveillance plan for Biological products.

(Article Two)

This decree shall be applied on all stages of supply chain of biological products, alongside applying for exclusion criteria on the basis of risk assessment and in accordance with the applied rules in the Egyptian Drug Authority and the international standards in this regard.

(Article Three)

Head of the Central Administration of Operations shall issue a regulatory guideline on conducting risk-based Post Marketing surveillance plan for Biological products within five days of the issuance of this decree.

(Article Four)

This decree shall come into effect from the date of its issuance, and any other provisions that may contradict this decree shall be null and void.

Chairman

of the Egyptian Drug Authority

Prof./ Tamer Essam

Written on: / /2022