Decree of the Chairman of the Egyptian Drug Authority No. (382) of 2023

Chairman of the Egyptian Drug Authority

Having perused

- 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;
- Minutes of the Authority's Board of Directors meeting held in its session dated on 20/7/2020;
- Ministerial decree No (368) of 2012 regarding Egyptian Pharmacovigilance Center.
- Minister's of Health Assistant Decree No (2) of 2010 concerning the regulations of pharmacovigilance and pharmaceutical products Safety.
- Decree of the Chairman of the Egyptian Drug Authority No. (184) of 2023 for application of the principle of reliance on reference regulatory health authorities approved by the Technical Committee for Drug control regarding pharmacovigilance decisions, reports and information for pharmaceutical and biological products registered or submitted for registration in the Egyptian Drug Authority.
- Material presented by the Head of the Central Administration of Pharmaceutical Care; and
- Having considered the interest of work;

(Article 1)

This decision shall be implemented with respect to the Applying of Good pharmacovigilance practice (GVP) in Egypt.

(Article 2)

The General Administration of Pharmaceutical vigilance (Egyptian Pharmacovigilance Center) detects, receives, reviews, analyzes and assesses case safety reports, evaluation and inspection of the pharmacovigilance system of the Marketing authorization holders of the Pharmaceutical and Biological products, monitoring of safety signals for products, assessment of the benefit risk evaluation reports, risk management plans, and all related pharmacovigilance activities.

(Article 3)

Marketing authorization holders of the Pharmaceutical and Biological products are committed to implement all related pharmacovigilance activities and apply the regulations and rules stipulated in the guideline of this decree.

(Article 4)

The Head of the Central Administration of Pharmaceutical Care shall issue the guideline of Good pharmacovigilance practice (GVP) within five days from the date on which this decree comes into force .and Guideline shall be updated whenever required by work need and in accordance with the updated laws, regulatory rules and the related Scientific updates.

(Article 5)

This decree shall come into effect from the date of its issuance. All competent departments shall implement it in accordance with their respective jurisdictions.

President of Egyptian Drug Authority

Prof. Tamer Mohamed Essam

Issued in: 8/6/2023