Decree of the Chairman of the Egyptian Drug Authority No. (354) of 2026

Chairman of the Egyptian Drug Authority,

Having considered:

- Law No. (127) of 1955 on Pharmacy Profession Practice;

- Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019;

- Pursuant to Presidential Decree No. 28 of 2026 concerning the formation of the Board of Directors of the Egyptian Drug Authority;

- Minutes of the Authority's Board of Directors meeting held in its session number (1) 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 monitoring regarding pharmacovigilance decisions, reports and information for pharmaceutical and biological products registered or submitted for registration in the Egyptian Drug Authority;

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

-Material presented by the Head of the Central Administration of Pharmaceutical Care;

- Having considered the interest of work;

(Article 1)

This decision shall be implemented with respect to theApplying 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 companies and 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)

Pharmaceutical and biological product companies and Marketing authorization holders shall establish a pharmacovigilance system and implement its concerned activities to monitor the safety of their products and report safety information to the General Administration of Pharmacovigilance. They shall also appoint a qualified person responsible for the pharmacovigilance system within the company, in accordance with the regulatory guidelines of that decree and other related regulatory guideline issued by the General Administration of Pharmacovigilance.

Pharmaceutical and biological product companies and Marketing authorization holders shall, upon request of the General Administration of Pharmacovigilance, conduct post-marketing

(efficacy /safety) studies within the specified timelines and in accordance withthe methodologies and standards approved by the Administration, ensuring the continuous evaluation of the safety and efficacy of their products.

(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.

The currently applicable Egyptian regulatory guideline for Good Pharmacovigilance Practices shall remain in force until the issuance of the regulatory guideline referred to in the preceding paragraph.

(Article 5)

This decree shall come into effect from the date of its issuance, and be published on EDA website, All competent departments shall implement it in accordance with their respective jurisdictions.

President of the Egyptian Drug Authority

Dr. Ali El Ghamrawy

Written in: 24/6/2026