

**Decree of the President of Egyptian Drug Authority No. (213) of 2023
Concerning Regulating the Rules and Procedures of Listing the Active
Pharmaceutical Ingredients of the Medicinal Products**

President of Egyptian Drug Authority,

Having perused:

- Law on Pharmacy Profession Practice and its amendments Promulgated by Law No. (127) of 1955;
- 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 on 20/07/2020;
- Ministerial decrees Nos.: (113 of 2004), (191 of 2005), (296 of 2009), (575 of 2012), (645 of 2012), (342 of 2014), (425 of 2015), (820 of 2016), (600 of 2018) and (645 of 2018) regarding the rules and procedures of granting marketing approval to the pharmaceutical products, reorganizing and amending some provisions of the rules and procedures of the registration of human pharmaceutical products;
- Ministerial decree No. (499) of 2012 on pricing human pharmaceutical products;
- The decree of the president of the Authority No. (150) of 2022 regarding reorganizing the rules and procedures of re-registration of human pharmaceutical products;
- The decree of the president of the Authority No. (780) of 2022 on the system of reliance on referenced health authorities in registering and analyzing imported products that have obtained a registration and marketing certificate from one of the reference countries approved by the Technical Committee for Drug Control;
- Material presented by the Head of the Central Administration of Pharmaceutical Products;
- Having considered the interest of work;

**has decided
(Article One)**

The provisions of this decree shall be implemented with regard to regulating the rules and procedures of the voluntary listing of active pharmaceutical ingredients of medicinal products submitted by active pharmaceutical ingredients' factories inside or outside the Arab Republic of Egypt, their agents, their legal representatives, licensed human pharmaceutical products' factories or companies recorded in toll manufacturing register.

(Article Two)

For the purposes of the provisions of this decree, the following terms shall have the meanings set out for each term hereunder:

- **The law:** Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019

- **The executive regulation:** The executive regulation of the Law on Establishing the Egyptian Drug Authority promulgated by the Prime Minister's Decree No. (777) of 2020.
- **The Authority:** The Egyptian Drug Authority.
- **The active pharmaceutical ingredients:** The active ingredients used in manufacturing the medicinal products.
- **Voluntary listing:** A process conducted by active pharmaceutical ingredients' factories inside or outside the Arab Republic of Egypt, their agents, their legal representatives, licensed human pharmaceutical products' factories or companies recorded in toll manufacturing register where they submit an application for listing in the list of the published active pharmaceutical ingredients at Egyptian Drug Authority to enjoy the benefits of the listing.
- **The quality file of the active pharmaceutical ingredients (Drug Master File/ Quality Module 3 "S-part"):** A file that contains the chemical description of an active pharmaceutical ingredient, the site and method of its manufacturing, its specifications, limits of impurities therein, methods of analysis and validation thereof, storage data and validity period of use.
- **List of active pharmaceutical ingredients:** The Egyptian Drug Authority database published on the Authority website, which database includes the data of the active pharmaceutical ingredients accepted by the Authority.
- **Benefits of listing the active pharmaceutical ingredients:** A package of benefits provided for listing active pharmaceutical ingredients or for making use of an active pharmaceutical ingredient from the list of the listed active pharmaceutical ingredients

(Article Three)

An active pharmaceutical ingredient shall be granted a five-year listing approval, which shall allow such ingredient to be used in manufacturing medicinal products without the need for re-assessment of such ingredient within the application for registration, re-registration or performing variations of the product, provided that it shall conform to the specifications of the approved active pharmaceutical ingredient and as long as there is no change in or amendment to the approved quality file of the active pharmaceutical ingredient.

(Article Four)

The submitted listing applications shall be arranged in accordance with the mechanisms specified in the Regulatory Guide. When applying for the same active ingredient that belongs to the same source, completed applications shall take priority over other applications. When applications are equally complete, priority shall be given on a first-come, first-served basis, and the order of precedence shall be in accordance the date of submission of the application.

(Article Five)

The active pharmaceutical ingredient, its data and the version number of its approved file shall be listed in the list of active pharmaceutical ingredients approved by Egyptian Drug Authority. Such active pharmaceutical ingredients shall be published on the authority's website to allow their use in the registration of medicinal products.

(Article Six)

The applicant for listing an active pharmaceutical ingredient shall be committed to notify the Authority in the event of any change in or addition to the content of the active pharmaceutical ingredient file within a maximum period of thirty days from the date of the change or addition throughout the validity period of listing. The entities which make use of the listed active pharmaceutical ingredient shall notify the Authority once they become aware of any change in or addition to the content of the listed active pharmaceutical ingredient file.

(Article Seven)

The applicant for the first listing application or other applicants may re-list the active pharmaceutical ingredient after expiry of the approval period granted thereto, provided that the re-listing application shall be submitted within the last six months of the validity of the granted approval. The applications shall be arranged in accordance with the text of Article Four of this decree.

(Article Eight)

The entity in charge of listing enjoys a set of benefits in accordance with the Regulatory Guide issued in implementation of the provisions of this decree.

(Article Nine)

The Head of the Central Administration of Pharmaceutical Products shall issue the regulatory guide for the rules and procedures of listing active pharmaceutical ingredients for medicinal products within five days from the effective date of this decree, provided that this regulatory guide shall include all the requirements, approvals and studies required for listing as well as all the mechanisms of implementing this decree. The mechanisms of implementation shall be updated whenever necessary in accordance with the relevant scientific developments.

(Article Ten)

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**

Written on: 3/4/2023