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15 NOV 2021

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Egyptian Drug Authority

Resolution No. 66 of 2020

Chairman of the Egyptian Drug Authority:

After perusal of the following:

- Egyptian Drug Authority Law, promulgated by Law No. 151 of 2019;
- Executive Regulation thereof issued by Prime Minister Decree No. 777 of 2020;
- Authority Chairman Decision No.58 of 2020 on the affiliation of Department of Planning & Monitoring and Departments of Medical Custom Release;
- Ministerial Decrees regulating import and release of registered and non-registered pharmaceuticals, their raw material, opioid materials affecting psychology, precursors, chemicals and their products;
- Until ratifying the organizational structure of the Egyptian Drug Authority and appointing the appropriate competent calibers;
- As per the presentation of the General Supervisor of Pharmaceutical Policies and Market Access Sector;
- For the proper progress and regularity of work.

Decided

Article (1)

The following rules concerning procedures of import and customs release of medical products (human pharmaceutical, biological, veterinary, herbal, and cosmetic products, as well as disinfectants and pesticides); raw materials (active, inactive); packing materials; other materials for analysis requirements and related chemicals are approved:

- For permitting the import of medical products and/or their raw materials; packing materials and/or other materials for analysis requirements and related chemicals, such pharmaceuticals shall be registered or under registration at the Egyptian Drug Authority.
- Human pharmaceuticals and biological products that are not registered at the Egyptian Drug Authority are permitted to be imported as special requests if no similars are registered or circulated in the local market, or if the available quantities are insufficient to cover the needs as per a statement issued by Drug Shortage Department of Egyptian Drug Authority, provided that imported pharmaceutical product shall be from a reference country. In the event that the applicant fails to provide a registered similar and marketed in a reference country, then importation from a non-reference country is permitted subject to satisfying the necessary requirements to ensure their quality, efficacy, and safety.

Article (2)

The guidelines that regulate the mechanism of applying these regulatory procedures and rules shall be issued and announced within five working days in order to ensure the quality and safety of all medical products circulated in the Egyptian market.

Chairman of Egyptian Drug Authority
(signature)
Prof. Dr. Tamer Mohmed Essam

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