Ministry of Health and Population

Decree No. (645) of 2018

Regarding Regulation of Accepting Registration Applications for Human Pharmaceutical Products in Cases that Exceed the Prescribed Number of Drug Boxes

Minister of Health and Population,

- Having perused Law No. (127) of 1955 on Pharmacy Profession Practice;
- Law No. (15) of 2017 regarding Facilitating the Procedures of Granting the Industrial Licenses;
- President of the Republic's Decree No. (242) of 1996 regarding Organizing the Ministry of Health and Population; and
- The Minister of Health and Population Decree No. (425) of 2015 regarding Reorganization of the Rules and Procedures of Registering Human pharmaceutical Products;

has decided:

Article 1- The application for registering human pharmaceutical products in the cases that exceed the prescribed number of drug boxes according to the Ministerial Decree No. (425) of 2015 shall be accepted referred to in the following cases:

(a) Products incorporated in the drug shortage list that have no similars during the year preceding the effective date of this decree or the drugs that are determined by the Central Administration for Pharmaceutical Affairs in accordance with market needs.

(b) Products manufactured on rare production lines that shall be determined by the Central Administration of Pharmaceutical Affairs every year.

(c) Products submitted by owners of licensed factories during the last ten years.

(d) Products submitted by the owners of under-construction factories.

(e) Products manufactured for the purpose of local marketing and exporting abroad.

Article 2- The controls of implementing this decree, the consideration of the services provided to stakeholders and the enforcement terms shall be determined in accordance with the table attached to this decree for each individual case. The Central Administration of Pharmaceutical Affairs may suggest amending this table whenever necessary, provided that such amendment shall be presented to us to consider its approval.

Article 3- All products registered in accordance with the provisions of this decree shall be subject to the two systems of drug tracking and recalling of the expired drugs.

Article 4- The applicant must undertake that the ownership of the products registered in accordance with this decree shall not be transferred before five years of actual and continuous marketing of the product. In the case of violation, the marketing authorization license shall be cancelled upon a recommendation by the Technical Committee for Drug Control, specifying the reasons for cancellation.

Article 5- The marketing authorization license shall be renewed in the case of compliance with the provisions of this decree and the table attached thereto, otherwise the marketing authorization license shall be canceled in the case of violating any of them.

Article 6- This DECREE shall be published in *Al-Waqa'i' Al-Misriyya* and shall enter into force after three months of its publication date. Any other provisions that may contradict this DECREE shall be null and void.

Written on October, 3rd, 2018

Minister of Health and Population

Prof. Hala Zayed

Table Attached to the Ministerial Decree No. (645) of 2018 Regarding the Implementation Controls, Service Considerations and Enforcement Terms

Cases	Implementation Controls	Service Consideration	Enforcement Terms
The first case	1- The box shall be opened after studying each individual request separately and determining whether or not the product is incorporated in any drug shortage list that have no similar during the year preceding the effective date of this decree or the drugs determined by the Central Administration for Pharmaceutical Affairs in accordance with the market needs, provided that such lists shall be announced once every three months. These lists shall be determined in accordance with the following procedures: (a) The Technical Committee for Drug Control shall set the standards that must be met to incorporate a product in the drug shortage list that have no similar. (b) The Drugs Supply Unit shall conduct the necessary studies to determine the products that meet the aforementioned standards and shall submit reports thereon every three months at most to the Technical Committee for Drug Control. (c) The Technical Committee for Drug Control shall study these lists and determine which products meet the specifications and which do not. Then, it shall prepare a report on the products that meet the specifications. (d) The aforementioned report shall be presented to the Chairperson of the Central Administration for Pharmaceutical Affairs in preparation for submitting it to the Minister of Health and Population to consider its approval. (e) After that, the approved list shall be announced to allow companies to submit applications for registering the products incorporated therein. 2- The product shall be priced at the highest price of any similar and marketed product. 3- The similar case shall be applied to the locally manufactured products. The applicants for	One hundred thousand Egyptian pounds	The registration applicant shall submit the CTD file and shall undertake that production and marketing shall take place within six months from the issuance date of the marketing authorization license.

	registering imported products may submit applications only in the case of products that require high technology, provided that the total number of products presented shall not exceed five similar products imported from reference countries.		
The second case	1- The box shall be opened for all applications submitted for manufacturing on those lines that are determined in accordance with the following procedures: (a) The Inspection Higher Committee shall set the standards required for a production line to be considered as one of the rare lines. (b) The General Administration of Pharmaceutical Inspection shall study the different production lines in accordance with the standards set by the Inspection Higher Committee and it shall submit a report on the lines that meet the standards predetermined by the Inspection Higher Committee once every year. (c) The Inspection Higher Committee shall study those lines and determine which of them meet the specifications and which do not. Then, it shall prepare a report on the lines to which the specifications apply. (d) The aforementioned report shall be presented to the chairperson of the Central Administration for Pharmaceutical Affairs in preparation for submitting it to the Minister of Health and Population to consider its approval. (e) After that, the approved list shall be announced to allow companies to apply for registering the products manufactured on those lines. (f) The product shall be priced at a minimum of at least (65%) of the price of the innovator product. (g) The similar case shall be applied to the locally manufactured products.	Fifty thousand Egyptian pounds	The registration applicant shall submit the CTD file and shall undertake that production and marketing shall take place within one year from the issuance date of the marketing authorization license.

The third case	The registration applicant (who fulfills specified conditions) shall be granted the right to apply for registering only twenty human products - with a maximum of five products every year (three products during the first six months, then two products during the following six months). 2- Fast track registration system shall be applied (for the first year only). 3- The product shall be priced at a reasonable price that matches the best price of a marketed similar product. 4- The similar case shall be applied to the manufacturers licensed recently over the last ten years.	Fifty thousand Egyptian pounds	The registration applicant shall submit the CTD file as of the second year and shall undertake that production and marketing shall take place within one year from the issuance date of the marketing authorization license.
The fourth case	1- The registration applicant shall be granted the right to apply for registering of only twenty human products - with a maximum of five products every year. 2- Fast track registration system shall be applied (for the first year only). 3- The product shall be priced at a fair price that matches the best price of a similar product. 4- The similar case shall be applied to the local factories under construction.	Fifty thousand Egyptian pounds	The registration applicant shall submit the CTD file as of the second year and shall undertake that production shall be performed in the factory and that marketing shall take place within two years from the issuance date of the marketing authorization license.
The fifth case	1- The number of products submitted for registration every year shall not exceed two products (one product every six months). 2- The product shall be priced at a minimum of at least (65%) of the price of the innovator product. 3- The similar case shall be only applied to the locally manufactured products.	Fifty thousand Egyptian pounds	The registration applicant shall submit the CTD file and statement(s) demonstrating the exportation of at least (25%) of total production, provided that the production shall be performed within nine months from the issuance date of marketing authorization license and the exportation shall be performed within thirty months from the issuance date of marketing authorization license.