

## Ministry of Health and Population

### Decree No. (600) of 2018

#### Regarding Amending Some Provisions of the Ministerial Decree No. (425) of 2015

#### On Reorganizing the Rules and Procedures of the Registration of Human Pharmaceutical Products

#### Minister of Health and Population:

- After perusing Law No. (127) of 1955 on Pharmacy Profession Practice;
- President of the Republic's Decree No. (242) of 1996 on Organizing the Ministry of Health and Population;
- Ministerial Decree No. (425) of 2015 Regarding Reorganizing the Rules and Procedures of the Registration of Human Pharmaceutical Products; and
- Materials presented by the Head of the Central Administration for Pharmaceutical Affairs;

**has decided:**

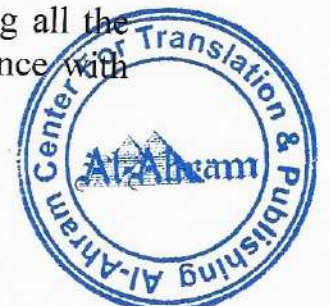
#### (Article One)

The text of the Articles 8/first paragraph and article 11 of the aforementioned Ministerial Decree No. (425) of 2015 shall be replaced by the following two texts:

«**Article 8/ first paragraph**– Human pharmaceutical products shall be re-registered every ten years upon a request submitted by the license holder to the General Administration of Registration, in the last year of the marketing authorization license validity, provided that the applicant for re-registration shall adhere to the following:

Submitting an initial file for re-registration containing the documents approved by the General Administration of Registration in the light of Appendix No. (12).

Fulfilling the requirements of the Egyptian Pharmacovigilance Center in accordance with Appendix No. (13) and fulfilling all the requirements of the final file for re-registration in accordance with



Appendix No. (12). All the aforementioned requirements shall be fulfilled within a period not exceeding three and a half years as of the following dates:

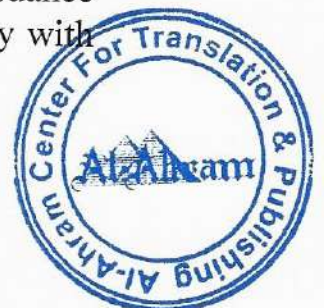
- 1- The expiry date of the marketing authorization license, the issuance date of the Preliminary Re-registration approval procedures or the date of issuing the approval of the Technical Committee for Drug Control, whichever is later, in the case of products that have a scientific reference.
- 2- The issuance date of the product approval by the scientific committees or the Technical Committee for Drug Control, whichever is later, in the case of products that do not have a scientific reference.

A product may be permitted to be produced, imported and marketed with a temporary license from the General Administration of Registration until the expiry of the period of three and a half years. In the case that this period expires and fulfilling the requirements of the final re-registration file fail to be met, the product shall be granted an additional period of 6 months to complete the re-registration procedures and submit the re-registration final file, while the product manufacturing or importation shall be suspended. In the event that fulfilling the requirement of the final re-registration file are not met during the additional 6 months, the product marketing authorization license shall be canceled.

The provisions of the previous paragraph shall be applied to the products that have been already submitted or that will be submitted for re-registration. »

**Article 11**– The marketing authorization license shall be canceled by a decision from the Head of the Central Administration for Pharmaceutical Affairs upon a recommendation of the Technical Committee for Drug Control, specifying the reasons for cancellation, in the following cases:

- 1- If the locally manufactured products for local marketing are not produced within eighteen months from the issuance date of the final marketing authorization license as well as if the imported products that obtained a final marketing authorization license in the Egyptian markets are not imported within eighteen months from the issuance date of the final marketing authorization license, in conformity with



the report submitted by the General Administration of Pharmaceutical Inspection.

- 2- If the locally manufactured products are not produced for local marketing before the expiry date of the last production batch as well as if the imported products that obtained a final marketing authorization license are not imported before the expiry date of the last importation batch, in conformity with the report submitted by the General Administration of Pharmaceutical Inspection.

The provision of the previous two clauses shall be applied to all products that have obtained or will obtain a final marketing authorization license in accordance with the different registration systems.

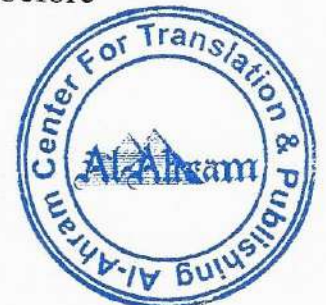
- 3- If the company fails to submit accelerated and long-term stability studies for the first three production batches together, for locally manufactured products that are locally marketed or for the products allocated for export or tenders within five years from the issuance date of the final marketing authorization license.
- 4- An exception to the periods mentioned in the previous clauses shall be made for generic drugs, whose innovator product was granted an Egyptian patent, until the expiry of the patency protection period, without prejudice to the provisions of the Intellectual Property Rights Protection Law promulgated by Act No. (82) of 2002.

**(Article two)**

Three new articles shall be added to the Ministerial Decree No. (425) of 2015 under numbers (15,16 & 17), stating the following:

«**Article 15**– The validity period of the final marketing authorization license for a human pharmaceutical product, which has obtained a tentative marketing authorization license in accordance with the previous ministerial decrees and for which a registration application has been submitted, shall be ten years from the date of approval of its issuance by the Technical Committee for Drug Control.

A product, which has no scientific reference and for which an application is submitted to convert its tentative marketing authorization license into a final marketing authorization license, shall be presented to the specialized scientific committees before being presented to the Technical Committee for Drug Control.



The applicant companies requesting to convert the tentative marketing authorization license into a final marketing authorization license shall comply with the following:

- 1- Submitting all necessary studies and applications required for converting in accordance with the relevant ministerial decrees.
- 2- Applying for the pharmacovigilance center within a maximum of 3 months from the issuance date of the final marketing authorization license, provided that the pharmacovigilance requirements shall be completed within 3 years from the issuance date of the final marketing authorization license. In the case of failure to apply to the pharmacovigilance center, application rejection or failure to fulfill the requirements, this issue shall be presented to the technical committee to take whatever action it deems appropriate in this regard.
- 3- Payment of this service consideration estimated at 10,000 LE for each application.

And for the human pharmaceutical products that have previously obtained a final marketing authorization license two years or less before the expiry of the ten-year period of the marketing authorization license, an application may be submitted for them to extend the validity of the final marketing authorization license in accordance with the previous provisions. »

«**Article 16**– The validity period of the re-registration license of human pharmaceutical products applying for re-registration in accordance with the various registration decisions shall be ten years starting from the date of re-registration approval of the Technical Committee for Drug Control, provided that this service consideration estimated at 10,000 LE shall be paid. »

«**Article 17**– A product for which a re-registration application has been submitted -or will be submitted- in accordance with the different registration systems shall be exempted from submitting the stability study required for re-registration, whenever such product fulfills following requirements:

- 1- The product was previously re-registered at least for one time.
- 2- The stability study, which was carried out on the production batches of this product, was previously evaluated by the Specialized Scientific Committee for Assessing Stability Studies.



- 3- The stability approval previously issued must fulfill all the required data necessary for completing the product re-registration file, provided that the applicable rules in the event of any variation in the product, shall be adhered to. »

**(Article Three)**

Companies that had previously submitted an application for registering a new human product in accordance with the Ministerial Decree No. (425) of 2015, but they exceeded any of the periods stipulated therein, shall be granted a grace period of forty-five working days - for one time only - to complete the registration procedures. This grace period shall start from the effective date of this decree, provided that these companies shall pay the service consideration estimated at 10,000 LE.

**(Article Four)**

A grace period of not more than 30 days may be granted to the companies that exceeded the periods stipulated in the Ministerial Decree No. (425) of 2015 by a decision of the Technical Committee for Drug Control, provided that these companies shall submit a request in that regard within thirty working days of the expiry date of these periods specifying the reasons for asking for this grace period. The supported documents for this request shall be submitted and amount of 10,000 LE shall be paid in return for this service.

**(Article Five)**

This DECREE shall be published in *Al-Waqa'i' Al-Misriyya* and shall enter into force as of the day following its publication therein.

Written on October 4<sup>th</sup>, 2018

**Minister of Health and Population**

**Prof. Hala Zayed**

