Decree of the Chairman of the Egyptian Drug Authority No. (434) of 2022

on Reorganizing the Rules and Procedures of Re-registration of Veterinary Pharmaceutical Products

Chairman of Egyptian Drug Authority,

Having perused

- Law No. (127) of 1955 on Pharmacy Profession Practice and its amendments;
- Law on Establishing the 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 dated 20/07/2020;
- Ministerial Decrees Nos. (94) and (113) of 2004, and (191) of 2005;
- Material presented by the Head of the Central Administration of Pharmaceutical Products;
- Having considered the interest of work;
- has decided;

(Article One)

This decree shall be implemented with respect to reorganizing the rules and procedures for re-registration of veterinary pharmaceutical products, whether locally manufactured or imported, for the purpose of local marketing. 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 the 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.
- **Locally manufactured veterinary pharmaceutical products**: Veterinary pharmaceutical products that are manufactured in licensed factories within the Arab Republic of Egypt.
- **Imported veterinary pharmaceutical products**: Veterinary pharmaceutical products that are imported from abroad as finished products or manufactured abroad and packed in licensed factories within the Arab Republic of Egypt.
- **The company**: The company holding the registration of the product in the Arab Republic of Egypt.

(Article Two)

Veterinary pharmaceutical products, whether locally manufactured or imported, shall be re-registered every ten (10) years, based on an application submitted by the company to the General Administration of Veterinary Pharmaceuticals at the Central Administration of Pharmaceutical Products, during the last year of validity of the registration certificate; otherwise, the product shall be cancelled. In case of exceeding the prescribed period, the company may submit a request for re-registration including the reasons for exceeding such period and upon payment of the prescribed service fee in accordance with the number of months of delay, as outlined in the regulatory guideline issued for this decree.

(Article Three)

The product shall be granted approval to proceed with re-registration procedures for a period not exceeding four (4) years, in order to fulfill requirements for obtaining the final re-registration certificate, starting from the date of expiry of the registration certificate or from the date of approval to proceed with re-registration procedures, whichever is later. During such period, importation, production, and marketing shall be permitted in accordance with the governing rules, unless otherwise regulated.

In case of exceeding such period, the company may submit a request for extension for a period not exceeding one year, including the reasons for exceeding the prescribed period and upon payment of the prescribed service fee in accordance with the requested extension period, in accordance with the provisions outlined in the regulatory guideline issued for this decree. If all deadlines related to the validity of approval to proceed with re-registration procedures are exceeded without submission of the final re-registration dossier, the product file shall be presented, on a case-by-case basis, to the Chairman of the Authority, based on a comprehensive report, to consider suspending production or importation of the product, as applicable, in accordance with the procedures outlined in the regulatory guideline issued for this decree to take such action as deemed necessary to achieve the public interest.

(Article Four)

The company shall be obligated to submit the final re-registration dossier within the prescribed time limits, complete with all requirements, approvals, and all supporting documents, as well as to complete the technical studies required for re-registration in all cases, all in accordance with the procedures and rules outlined in the regulatory guideline issued for this decree .

(Article Five)

Upon completion of the final re-registration dossier, it shall be presented to the Technical Committee for Drug Control within ninety (90) days. In case of approval, the product shall be re-registered for a further period of ten (10) years under the same registration number, as outlined in detail in the regulatory guideline issued for this decree. In case of rejection, the company may submit a petition for reconsideration of the final decision of the Technical Committee for Drug Control within sixty (60) working days from the date of issuance of the decision, provided that the petition is complete with all technical justifications and supported by the documents and information relied upon, and a decision shall be issued within sixty (60) working days from the date of submission.

(Article Six)

The Head of the Central Administration of Pharmaceutical Products shall issue the regulatory guideline within ten (10) working days from the date of publication of this decree, provided that such guideline shall include the consolidated executive mechanisms for all rules and procedures for the implementation and application of this decree, and shall set out all requirements, approvals, technical studies, and supporting documents necessary for re-registration, as well as the cases of exemption of products from re-submission and evaluation, following their approval by the relevant central administrations, each within its respective competence, in accordance with the approved and updated technical rules in force at the time of such approval. The issuer of the regulatory guideline shall also ensure that it is updated whenever required by the needs of work and in accordance with any newly issued laws and regulatory rules.

(Article Seven)

The time limits necessary for fulfilling the requirements, approvals, technical studies, and supporting documents required for re-registration of products submitted for re-registration prior to the entry into force of this decree shall be determined, provided that, during such periods, importation, production, and marketing shall be permitted in accordance with the applicable rules and decisions, all as follows:

- Products that have submitted a scientific dossier to the reception unit shall be granted a period of six (6) months from the date of entry into force of this decree to obtain approval to proceed with re-registration procedures and to complete the registration procedures in accordance with this decree.
- Products that have obtained approval to proceed with re-registration procedures shall be granted a period of four (4) years from the date of entry into force of this decree to complete the technical studies, requirements, approvals, and supporting documents necessary to finalize the re-registration procedures and to submit the final re-registration dossier.
- Products that have submitted the final re-registration dossier to the examination unit shall be granted a period of one (1) year from the date of entry into force of this decree to obtain the final re-registration certificate.

In the event of exceeding such period, the matter shall be presented, by means of a detailed report, to the Chairman of the Authority to consider suspending the production of the product or suspending its importation, as the case may be, until obtaining the final registration certificate; provided that production and importation may be permitted for the purpose of completing the re-registration procedures.

In the event of any change in the active substances, whether in quantity or quality, in a manner consistent with the reference products, or in accordance with scientific references, or in implementation of the recommendations of the scientific committees, all procedures prescribed for registration as a new product shall be followed; and the product may be permitted to be marketed, after presentation to the Technical Committee for Drug Control, until completion of the registration procedures with the new formulation, in accordance with the governing rules.

(Article Eight)

The Chairman of the Authority may, based on a technical memorandum supported by scientific evidence, and on a case-by-case basis, suspend or cancel the continuation of re-registration procedures of any veterinary pharmaceutical product whose marketing may cause harm to public health.

(Article Nine)

In cases of emergency circumstances, any veterinary pharmaceutical product may be permitted to be marketed with exemption from certain re-registration requirements outlined in this decree, based on a technical memorandum supported by scientific evidence prepared by the Central Administration of Pharmaceutical Products and approved by the Chairman of the Authority.

(Article Ten)

This decree shall be published in Al-Waqa'i' Al-Masrya and shall enter into force as of the day following the issuance of its regulatory guideline. Any provisions that contradict this decree shall be null and void.

Chairman of
Egyptian Drug Authority
Prof /Tamer Mohamed Essam

Written on: 25/7/2022