Decree of the Chairman of the Egyptian Drug Authority No. (625) of 2024 on Regulating the Rules and Procedures of 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;
- Presidential Decree No. (7) of 2024 regarding the formation of the Board of Directors of the Egyptian Drug Authority;
- Minutes of the Authority's Board of Directors meeting held in its session No. (1) dated 20/07/2020;
- Ministerial Decrees Nos. (94) and (113) of 2004, and (191) of 2005;
- The decree of the Chairman of the Authority No. (434) of 2022 regarding reorganization of the rules and procedures of the re-registration of veterinary pharmaceutical products;
- The decree of the Chairman of the Authority No. (780) of 2022 regarding the application of the principle of reliance on reference health authorities in the registration and laboratory testing of imported pharmaceutical products that have been granted a Certificate of Pharmaceutical Product from one of the reference countries approved by the Technical Committee for Drug Control;
- The decree of the Chairman of the Authority No. (783) of 2022 regarding the sample collection and analysis of human, veterinary pharmaceutical products, herbal, disinfectants, cosmetic products, pesticides, raw materials, and extracts of medicinal plants and the like, in accordance with the applicable references and scientific updates.
- Material presented by the Head of the Central Administration of Pharmaceutical Products;
- Having considered the interest of work;

(Article One)

This decree shall be implemented with respect to regulating the rules and procedures of registration of veterinary pharmaceutical products, whether locally manufactured or imported.

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 applicant for registration – the marketing authorization holder in Egypt**: A legal entity established in accordance with the relevant laws of the Arab Republic of Egypt; provided that it is registered in the electronic register for listing companies established at the Egyptian Drug Authority, and is authorized, in accordance with the law and the applicable regulatory decisions governing this matter, to submit applications for the registration of veterinary pharmaceutical products and to undertake all procedures necessary for the registration of the product, starting from submission of the registration application up to obtaining the registration certificate thereof.
• **The marketing authorization holder of the product in the country of origin / the marketing authorization holder of the product outside the country of origin:** The foreign legal entity that owns the product and in whose name the certificate of pharmaceutical product (CPP) is issued in the country of origin, or the entity that owns the rights to market the product abroad.
• **Imported veterinary pharmaceutical products box**: A box comprising a set of pharmaceutical forms for each imported veterinary pharmaceutical product, wherein the number of products contained therein and the distribution of the pharmaceutical forms are determined in accordance with the governing rules; and it shall be referred to in this decree as the "products box"
• **Reliance**: Relying on decisions, reports and information of reference health authorities regarding registration, analysis, and pharmacovigilance procedures.
• **Reference countries**: The group of countries for which a decision has been issued by the Technical Committee for Drug Control designating them as such, and whose regulatory authorities' decisions are relied upon.
• **Reference product**: A veterinary pharmaceutical product registered and marketed in one of the reference countries approved by the Technical Committee for Drug Control.

(Article Two)

Veterinary pharmaceutical products shall be submitted for registration based on a reference product registered and marketed in any of the reference countries approved by the Technical Committee for Drug Control.

(Article Three)

Preliminary acceptance of applications for registration of locally manufactured veterinary pharmaceutical products submitted without a reference product may be permitted, provided that such applications are presented to the competent scientific committee for veterinary medicines and feed additives to decide on whether to accept the registration application, in accordance with the regulatory guideline issued in implementation of this decree.

(Article Four)

Imported veterinary pharmaceutical products shall be submitted according to the permitted number within the imported veterinary pharmaceutical products box, provided that the number of products within the box shall be determined starting from the originator product of the active substance, in accordance with the rules outlined in the regulatory guideline issued in implementation of this decree. Pharmaceutical forms shall be updated within the box upon the emergence of a new pharmaceutical form, after presentation to the Technical Committee for Drug Control.

(Article Five)

For the issuance of a registration license for imported veterinary pharmaceutical products, the product shall be registered and marketed in the country of origin or in any of the reference countries approved by the Technical Committee for Drug Control.

Subject to the approval of the competent scientific committee, applications for the registration of imported veterinary pharmaceutical products from non-reference countries and not marketed in any of the reference countries may be accepted, with exemption of the veterinary pharmaceutical product from the requirement of being marketed in one of the reference countries, provided that the matter is presented to the Technical Committee for Drug Control to decide on whether to register the product, all in accordance with the conditions outlined in detail in the regulatory guideline issued in implementation of the provisions of this decree.

(Article Six)

The principle of reliance on reference health authorities may be applied to imported veterinary pharmaceutical products that have been granted a Certificate of Pharmaceutical Product (CPP) from one of the reference countries approved by the Technical Committee for Drug Control.

(Article Seven)

The veterinary pharmaceutical product shall be granted approval to proceed with registration procedures for a period of three years from the date of such approval, in order to fulfill requirements, complete technical studies, obtain necessary approvals, and submit the final registration dossier, to obtain the final registration certificate. In case of exceeding such period, the company may submit a request for extension for a period of one year, including the reasons for exceeding the prescribed period and upon payment of the applicable service fee, in accordance with the provisions outlined in the regulatory guideline issued for this decree. The application for registration of the veterinary pharmaceutical product shall be cancelled in the event of exceeding any of the deadlines and time limits specified in this decree and its regulatory guideline.

(Article Eight)

Upon completion of the final registration dossier, it shall be presented to the Technical Committee for Drug Control within (90) days. In case of approval, a final registration certificate valid for (10 years) shall be issued from the date of approval.

In the event of rejection of the registration of the product, the company may submit a petition for reconsideration of the final decision of the Technical Committee for Drug Control within (60) working days from the date of notifying the applicant of such decision, provided that the petition is complete with all technical justifications on which it is based and supported by the documents and information that the company seeks to rely upon in considering its petition; provided that a decision on the petition shall be issued within (60) working days from the date of its submission.

(Article Nine)

Products registered in accordance with the provisions of this decree shall be granted a registration certificate valid for ten (10) years. The company shall be obligated to commence production of locally manufactured products or importation of imported products within three (3) years from the date of issuance of the registration certificate; otherwise, the registration of the product shall be cancelled based on a report submitted by the Central Administration of inspection on pharmaceutical institutions

The company may submit a request within three (3) months from the date of expiry of the period specified for production or importation, supported by justifications, for the extension of such period, provided that the prescribed service fee is paid in accordance with the requested extension period; and such extension shall not be granted except upon the approval of the competent administration, in accordance with the provisions outlined in the regulatory guideline issued for this decree.

Products registered for export only or for export and tenders shall not be subject to the production and import timelines.

(Article Ten)

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 documents necessary for the registration of veterinary pharmaceutical products, 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 Eleven)

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

(Article Twelve)

In cases of emergency circumstances, any veterinary pharmaceutical product may be permitted to be marketed with exemption from certain 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 Thirteen)

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

Dr.Ali El-Ghamrawy

Chairman of the Egyptian Drug Authority

Written on: 29/10/2024