Guideline

Central Administration for Pharmaceutical Products
General Administration of Veterinary Pharmaceuticals

Guideline of

Registering Veterinary Pharmaceuticals Imported from Reference Countries According to the Fast Track Registration System

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Guideline Contents

1. Introduction:

This is a regulatory guideline stipulating the procedures and rules used to register veterinary pharmaceuticals imported from reference countries under the Fast Track registration system.

2. Scope of Implementation:

The guideline shall apply to all veterinary pharmaceuticals imported from reference countries and submitted according to the Fast Track registration system.

3. Important Definitions:

- **Veterinary pharmaceutical product:**

- Any substance or mixture of substances that has therapeutic or preventive properties against diseases affecting animals.
- Any substance or group of substances used or given to animals to restore, correct or improve physiological functions through a pharmacological or immunological effect or by affecting the metabolic processes within the animal's body.

- **Imported veterinary pharmaceutical pharmaceuticals:**

- Imported veterinary product [Bulk]

It is a veterinary pharmaceutical product manufactured abroad and packaged and/or packaged in a licensed factory within the Arab Republic of Egypt.

- Imported and finished veterinary product:

It is a veterinary pharmaceutical product fully manufactured abroad, packaged and packaged outside the Arab Republic of Egypt, and imported as a finished product.

4. Procedures:

1. The company shall be committed to submit an inquiry request to check the possibility to register the veterinary pharmaceutical and the availability in the similars box of the imported veterinary pharmaceuticals via EVERS platform during the official working days and hours in accordance with the Annex No. (1)
2. The inquiry request shall be reviewed by the General Administration of Veterinary Pharmaceuticals and the company shall be notified of the acceptance or rejection of the inquiry request (in case of rejection the reasons shall be indicated) via EVERS platform within a maximum period of three working days from the date of the inquiry request submission.

3. In case of the response by accepting the inquiry request, the General Administration of Veterinary Pharmaceuticals shall begin to check whether or not there are available places in the similars box for imported veterinary pharmaceuticals. The company shall be notified whether or not there is an available place in the similars box within five working days via EVERS platform.
4. In case there is an available place in the similars box, an appointment shall be set via EVERS platform to submit the registration file as well as the stability file for imported veterinary pharmaceuticals in accordance with the Annex No. (2). The appointment shall be set at the following week directly.
5. The initial review shall be carried out by a representative of the General Administration of Veterinary Pharmaceuticals and a representative of the General Administration of Stability.
6. In case the company failed to fulfill any of the required documents, the file shall not be received and the applicant shall be obligated to send a request via EVERS platform to set a new appointment within two months to resubmit the registration file as well as the stability file after fulfilling the requirements This period is renewable for once.

First: Pharmaceuticals that have a Certificate of Pharmaceutical Product (CPP) from the US Food and Drug Administration (FDA) or from the European Medicines Agency (EMA)

- A period of two months shall begin on the file receiving date.
- In case of there are required documents after examining the file by any of the relevant departments, the applicant shall be notified of the required documents via EVERS within 15 working days.
- The company shall be granted a grace period of one month as a maximum, renewable for once to submit the required documents. This period shall not be counted within the previously mentioned registration period.
- When fulfilling all the requirements by all concerned authorities, the specified time for evaluating the product shall be resumed.
- In case the preliminary scientific data of the product is not available on the database of the country of origin, or in case of any discrepancy from the data mentioned on the database of the country of origin, the matter shall be presented

to the Specialized Scientific Committee for Veterinary Medicines and Feed Additives to approve the product preliminary scientific data.

- The company shall be committed to apply to the Central Administration of Pharmaceutical Care to approve the scientific leaflet after obtaining the approval of proceeding with the registration procedures from the Central Administration of Veterinary Pharmaceuticals.
- The matter shall be presented to the Technical Committee for Drug Control to adjudicate issuing a registration notification. In case of approval, a final and valid for ten years registration notification shall be issued.

Second: Pharmaceuticals imported from any of the reference countries:

- A period of four months shall begin as from the file receiving date.
- In case of there are required documents after examining the file by any of the relevant departments, the applicant shall be notified via EVERS system within two months.
- The company shall be granted a grace period of one month as a maximum, renewable for once to submit the required documents. This period shall not be counted within the aforementioned registration grace period.
- When fulfilling all the applications from all the relevant authorities, the time specified for evaluating the product shall be resumed.
- In case of the preliminary scientific data of the product is not available on the database of the country of origin, or in case of any discrepancy from the data mentioned on the database of the country of origin, the matter shall be presented to the Specialized Scientific Committee for Veterinary Medicines and Feed Additives to approve the product preliminary scientific data.
- The company shall be committed to apply to the Central Administration of Pharmaceutical Care to approve the scientific leaflet after obtaining the approval of proceeding with the registration procedures from the Central Administration of Pharmaceutical Products.
- The Product shall be presented to the Technical Committee for Drug Control to approve issuing a registration certificate. In case of approval, a final and valid for ten years' registration certificate shall be issued.

Notes:

- The company shall be allowed to carry out the analysis in the Evaluation and Accreditation Department at the Egyptian Drug Authority laboratories after obtaining the final registration certificate from the first incoming imported batch after the issuance of the final registration certificate. The competent administration shall not release this batch until issuance of the analysis indicating the conformity.
- For the pharmaceuticals that are still under registration, fulfill the conditions of applying according to the Fast Track registration system and the company wishes to complete the registration procedures in accordance with this system, the company shall submit an application to the General Administration of Veterinary Pharmaceuticals stating the company's desire to complete the registration procedures in accordance with the Fast Track registration system, the current status of the product regarding registration and the procedures that have been completed, provided that the application shall be approved by the Chairman of the company's Board of Directors.
- The application shall be studied and the product status shall be reviewed to ensure that none of the deadlines specified for fulfilling the registration procedures have been exceeded, which would require canceling the registration application. The service fee shall be paid alongside completing the procedures in accordance with the Fast Track registration system.
- The company has the right to submit five products per month using the Fast Track registration system, as follows:

✓ 2 new products.
✓ 3 products that are still under registration and the company wishes to complete the registration procedures in accordance with this system.

5. Appendixes

Annex No.: 1

Attachments of the Inquiry Request of the Similars Box for Imported Reference Pharmaceuticals According to the Fast Track Registration System

1. A scanned copy of the original inquiry receipt of (1000 EGP) stating the active ingredient, concentration and pharmaceutical form of the submitted product and stating that it is "New Veterinary Inquiry Request".
2. Pharmaceutical Product Certificate (CPP) for the product.
3. In case of veterinary pharmaceuticals (Brand Pharmaceuticals), the applicant shall submit a document stating that the product is the original product (Innovator) from responsible health authority.
4. Agency agreement or authorization letter for registration certified from the commercial chamber and the Egyptian embassy abroad.

Appendix No.: 2

List of Documents Required to Submit a Registration File of an (Imported) Veterinary Product according to the Fast Track Registration System

1. Data certificate of a veterinary product (imported).
2. Receiving and registration receipts.
3. The original payment receipt of the inquiry request stating the active ingredient, concentration and pharmaceutical form.
4. An original receipt of service fee of registering a veterinary product according to the fast track registration system.
5. A stamped and signed composition form on the letterhead of the company owning the product abroad, indicating the properties and specifications of the active and inactive ingredients, according to the most recent edition of the pharmacopeia. The composition form shall indicate the factory name in case of the factory differs from the License Holder.
6. Certificate of product specifications signed and stamped by the factory and on its letterhead.

7. A signed and stamped declaration of the packages sizes to be registered in case of injection. That declaration shall be on the letterhead of the company owning the product.
8. A signed and stamped certificate of the preliminary scientific data on the letterhead of the company owning the product.
9. The original certificate of pharmaceutical product (CPP) fulfilling the conditions issued from the country of origin by the Ministry of Health or the Ministry of Agriculture authenticated by the Chamber of Commerce and the Egyptian Embassy abroad.
10. A copy of the GMP certificate of the factory abroad (if it is not indicated in the product CPP).
11. An agency contract or official authorization for registration. It shall be authenticated by the Chamber of Commerce and the Egyptian Embassy abroad.
12. Declaration to carry out the analysis as of the first incoming imported batch after the issuance of the final registration certificate. This analysis shall be carried out in the Evaluation and Accreditation Department at laboratories of the Egyptian Drug Authority.
13. Register of importers
14. The company's commercial register
15. A copy of a recent authorization for the company's representative authenticated by a valid bank signature.

* The company shall be committed to complete the file and submitting the following documents after fulfilling them at the relevant authorities:

- Report of the General Administration of Stability.
- A scientific leaflet in conformity with the approved leaflet by the Central Administration for Pharmaceutical Care indicating the packages and storage conditions, provided that it shall match the package and storage conditions mentioned in the report of the General Administration of Stability.
- The report of the Central administration of Pharmaceutical Care.