Regulatory Guideline of

Registration Procedures for Veterinary Pharmaceutical Products Submitted for Export Only or for Export and Tenders

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1. Introduction:

This regulatory guide applies to the rules and procedures of registering new veterinary pharmaceutical products submitted for registration for the purpose of export only or for export and tenders via EVERS Platform.

2. **Scope of Implementation**:

This guide shall apply to all new locally-manufactured veterinary pharmaceutical products submitted for registration for the purpose of export only or for export and tenders.

3. **Important Definitions:**

Veterinary pharmaceutical product:

-Any substance or combination of substances used in animals for treating or preventing disease; or any substance or combination of substances that may be used in animals for restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action

Locally manufactured veterinary pharmaceutical products for export /export & tenders

- [Local] veterinary pharmaceutical product for export/ export and tenders:

It is a veterinary pharmaceutical product that is owned by a factory licensed within the Arab Republic of Egypt; manufactured in the same factory; and registered for the purpose of export only or for export and tenders.

- [Toll] veterinary pharmaceutical product for export/ export and tenders:

It is a veterinary pharmaceutical product that is owned by a company registered in toll manufacturing record in the Central Administration of Operations; that is manufactured in a factory licensed within the Arab Republic of Egypt through a manufacturing contract; and that is registered for the purpose of export only or for export and tenders.

- [F-Toll] veterinary pharmaceutical product for export/ export and tenders:

It is a veterinary pharmaceutical product that is owned by a factory licensed within the Arab Republic of Egypt; manufactured in another licensed factory within the Arab Republic of Egypt that has the required production line through a factory-to-factory manufacturing contract; and registered for the purpose of export only or for export and tenders.

4. Procedures:

First: General rules

*Pharmaceutical products registered for export only are not allowed to be marketed within the Arab Republic of Egypt.

* The registration of pharmaceutical products registered for export only or for export and tenders cannot be changed to local registration. In this case, the pharmaceutical product shall be submitted for registration as a new product, provided that the pharmaceutical product registered for export only or for export and tenders shall be canceled upon the issuance of the registration license of the local product and the database of veterinary medicines at the Egyptian Drug Authority shall be updated.

Second: Mechanism of applying for registration

- The company submits an inquiry request about (the composition reference and the possibility of registering the product) in accordance with Appendix No. (1) via EVERS Platform.

- 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 (alongside an explanation of rejection reasons) within a maximum period of three working days from the date of submitting the inquiry request.

- In the event that some requirements are set out to be fulfilled in the inquiry request, the company shall be committed to fulfill them within 3 working days; otherwise, the inquiry request shall be cancelled.

- In the event that an acceptance response of the inquiry request is provided, the company shall be committed to submit the scientific file via EVERS Platform within one month from the date of accepting the inquiry request; otherwise, the inquiry request shall be considered invalid, provided that the name shall be reviewed when submitting the registration request (scientific file).

*** Presentation to the Specialized Scientific Committee for Veterinary Medicines and Feed Additives**

The scientific file shall be submitted via EVERS Platform within the specified period in accordance with Appendix No. (2), and then it shall be reviewed. In the event that some requirements are set out to be fulfilled, the company shall be notified via the electronic portal within 10 working days from the submission date of the scientific file.

- The company shall be committed to submit the fulfilled required documents in full within a maximum period of two months from the date of notifying the company of the requirements to be fulfilled.

- Fulfilled required documents shall be reviewed within 7 working days from the submission date. In the event of an error, the company shall be notified via the electronic portal. The company shall be committed to submit the fulfilled required documents in full within a maximum period of one month from the date of notifying the company of the required documents to be fulfilled. In the event of repetition of errors in the submitted documents, the prescribed service fee shall be paid and re-submission of the fulfilled required documents shall be accepted.

- Fulfilled scientific file shall be presented immediately to the Specialized Scientific Committee for Veterinary Medicines and Feed Additives to express an opinion on the registration application and approve the preliminary scientific data of the product.

- In the event that the Scientific Committee requests the company to provide some clarifications and fulfill some requirements that contribute to making the final decision, postponement shall be called for and the company shall be notified of the reasons therefor. The company shall be committed to submit the fulfilled documents required by the Committee within a month from the date of notifying

the company of the reasons, and then the matter shall be presented again to the Specialized Scientific Committee for Veterinary Medicines and Feed Additives.

- In the event of rejection, the matter shall be presented to the Technical Committee for Drug Control to take the final decision. If the rejection decision is upheld, a non-approval for proceeding with the registration procedures shall be issued to the company, including the reasons for the rejection.

- In the event of acceptance, an approval for proceeding with the registration procedures shall be issued, the approval shall be valid for a period of three years from the date of the Scientific Committee, noting that this approval shall not be considered a final approval for registration. Rather, it shall be subject to review and amendment, if and where necessary, by the Central Administration of Pharmaceutical Products until obtaining the final registration license.

- The decisions of the Specialized Scientific Committee for Veterinary Medicines and Feed Additives shall be implemented within 3 working days from the date of the Scientific Committee.

- In the event of exceeding any of the grace periods set for fulfilling any of the aforementioned required documents, the company may submit a petition to be granted an additional, similar grace period to complete the fulfilled required documents, which petition shall indicate the reasons for exceeding the specified grace period, provided that the prescribed service fee of granting an additional similar grace period shall be paid.

- As regards veterinary pharmaceutical products whose approval for proceeding with their registration procedures has expired, the company’s request to complete the registration procedures shall be accepted in the event of completing all the required registration procedures in terms of analysis at Central Administration of Drug Control, obtainment of the stability report from the General Administration of Stability, approving the scientific medical leaflet from the Central Administration for Pharmaceutical Care, and submitting the final registration file during the year following the expiration of the approval for proceeding with registration procedures in accordance with the decision of the Technical Committee for Drug Control dated 23/5/2017 regarding this matter, and no other petitions shall be accepted after the expiration of the prescribed grace periods.

<u>* In the case of products submitted for the purpose of export only, the company shall be obligated, during the validity period of the approval for proceeding with the registration procedures, to fulfill the following requirements; otherwise, the registration application shall be considered invalid.</u>

- Producing a development and research (R&D) batch and fulfilling all registration requirements in accordance with the composition form on which this batch is produced.

- Applying for the Central Administration for Drug Control to obtain a conformity report accompanied by the composition form on which the analysis is conducted.

- Submitting the results of the six-month accelerated stability study to be evaluated by the General Administration of Stability in the Central Administration of Pharmaceutical Products; obtaining a stability report of the product, accompanied by the composition form which has been approved.

-Applying for the Central Administration for Pharmaceutical Care after the completion of stability studies and analysis or after the beginning of the last year of the valid approval for proceeding with registration procedures, whichever is earlier, and approving the scientific medical leaflet.

- Submitting the final registration file via the EVERS Platform

<u>* In the case of products submitted for the purpose of export and tenders, the company shall be obligated, during the validity period of the approval for proceeding with the registration procedures, to fulfill the following requirements; otherwise, the registration application shall be considered invalid.</u>

- Producing a pilot batch with no less than the minimum operating capacity of the production line in the presence of an inspector from the Central Administration of Operations; fulfilling all registration requirements in accordance with the composition form on which the pilot batch is produced. The Central Administration of Operations shall withdraw samples from the pilot batch for analysis at the Central Administration for Drug Control.

- Applying for the Central Administration for Drug Control to obtain a conformity report, which states the source of the raw material and includes the composition form that the analysis is based on.

- Submitting the results of the six-month accelerated stability study on the pilot batch to be evaluated by the General Administration of Stability in the Central Administration of Pharmaceutical Products and obtaining a stability report of the product, which states the source of the raw material and includes the composition form which has been approved.

- Applying for the Central Administration for Pharmaceutical Care after the completion of stability studies and analysis or after the beginning of the last year of the valid approval for proceeding with registration procedures, whichever is earlier, and approving the scientific medical leaflet.

- Submitting the final registration file via EVERS Platform.

*** Submission of the final registration file and the issuance of the registration license:**

- The final registration file shall be submitted within the specified period in accordance with Appendix No. (3) via EVERS Platform to be reviewed by the General Administration of Veterinary Pharmaceuticals. The company shall be notified of the required documents within 10 working days from the date of submitting the final registration file, and it shall be obligated to submit the fulfilled required documents within three months from the date of notifying the company of the required documents to be fulfilled.

- Fulfilled required documents shall be reviewed within 7 working days from the submission date. In the event of an error, the company shall be notified via the EVERS Platform. The company shall be committed to submit the fulfilled required documents in full within a maximum period of one month from the date of notifying the company of the required documents to be fulfilled. In the event of repetition of errors in the submitted documents, the prescribed service fee shall be paid and re-submission of the fulfilled required documents shall be accepted.

- In the event of exceeding any of the grace periods set for fulfilling any of the aforementioned required documents, the company may submit a petition to be granted an additional, similar grace period to complete the fulfilled required documents, which petition shall indicate the reasons for exceeding the specified grace period, provided that the prescribed service fee of granting an additional similar grace period shall be paid

- Fulfilled registration file shall be presented immediately to the Technical Committee for Drug Control in order to take the appropriate decision regarding whether or not to register the product. In the event of the approval of the Technical Committee for Drug Control, a final registration license valid for a period of ten years shall be issued.

- In the event of rejection, a letter of non-approval shall be issued to the company including the reasons for the rejection. The company may submit a petition for reconsidering the final decision of the Technical Committee for Drug Control within 60 working days starting from the date of issuing the decision, provided that the petition shall offer all the technical justifications it rests on and it shall be supported by the documents and information that the company is desirous to rely on when its petition is being considered.

5. Appendixes:

Appendix No. (1)

1. A photocopy of the original inquiry receipt of (1,000 pounds) indicating the active ingredient, concentration, and pharmaceutical form of the submitted product and stating that it is "New Veterinary Inquiry Request" with the full name of the company that is identical to the company name mentioned on the Toll Card or the manufacturer's license.

2. A recent scientific reference for the product composition (to be accompanied by the original of a certified translation if necessary).

** Relying on pharmaceutical products registered with the Egyptian Drug Authority as a scientific reference for the submitted composition shall be in the event that similar reference pharmaceutical products are not available.

3. A copy of toll card (for Toll pharmaceutical products).

4. A copy of the factory license of the registration applicant (for Local/F-Toll pharmaceutical products).

5. A copy of the registration license or procedure-proceeding approval (in the case of line extension products).

6. A copy of the commercial record (in the case of products provided by under-construction factories).

Appendix No. (2)

Documents required to submit a new registration application for veterinary pharmaceuticals (scientific file)

- The original fee payment receipt (yellow).
- A certificate of preliminary scientific data of the product printed on the company paper, which is signed, stamped, and supported by the necessary references.
- A declaration of the volumes of containers to be registered in case of injection, which declaration shall be printed on the company paper with valid signature and stamp.

Appendix No. (3)

A list of documents required to submit the final registration file

1- A data certificate of a (Local) veterinary pharmaceutical product, which certificate shall be stamped and signed by the Chairperson of the company's board of directors or his representative who has an official authorization.

2- A copy of the approval for proceeding with the registration procedures.

3- A copy of the report of the Central Administration for Drug Control.

4- A copy of the report of the General Administration of Stability.

5- The scientific leaflet approved by the Central Administration of Pharmaceutical Care.

6- Fee payment receipts.

7- A composition form printed on the paper of the company that owns the product, stating the name of the manufacturer, and the specifications of the active and inactive ingredients in their latest versions, which form shall be stamped and signed by the person in charge.

8- The product specifications certificate, which is printed on factory paper as well as signed and stamped by the person in charge in the factory.

9- An original scientific leaflet printed on the paper of the company that owns the product, which leaflet shall be stamped and signed by the person in charge and identical to the scientific leaflet approved by the Central Administration for Pharmaceutical Care. It shall state the package and the storage conditions that are identical to those mentioned in the stability report.

10- The specifications of non-pharmacopoeia materials (In-House Specifications) shall be printed on the factory paper that is signed and stamped. In the event that the material is pharmacopoeia compliant, the results mentioned in "In House Spec" shall be within the permissible range included in the pharmacopoeia.

11- A declaration by the company stating the name of the factory that manufactures the raw (active) ingredient, which declaration shall be printed on the company paper which is stamped and signed by the chairperson of the board of directors of the product-owning company or his representative who has an official authorization.

12- A certificate of analysis of the raw (active) ingredient from the factory that manufactures the active ingredient, which certificate shall be stamped and signed by the chairperson of the board of directors of the product-owning company or his representative who has an official authorization.

13- A commitment to re-analyze the product (Evaluation and Accreditation Department) in the event that the stability composition form differs from the composition form attached to the laboratory conformity statement on which the analysis was conducted, which commitment shall be stamped and signed by the chairperson of the board of directors of the product-owning company or his representative who has an official authorization.

14- A copy of a recent authorization for the company representative, which authorization shall be authenticated by a valid signature from the bank.

For local pharmaceutical products [Local]

- A copy of the factory license that has the production line that is appropriate for producing the product.

For toll pharmaceutical products [Toll]

- A toll card that includes the name of the factory that manufactures the product and the name of the storage site.

- An addendum to the manufacturing contract in the name of the product, a which is authenticated and approved by Legal Affairs (stating the validity period of the manufacturing contract).

- A copy of the factory license that has the production line that is appropriate for producing the product.

For F -Toll pharmaceutical products [F-Toll]

- A manufacturing contract with an addendum stating the name of the product to be manufactured, which is authenticated and approved by Legal Affairs.

- A copy of the tax card of the factory and company.

- A copy of the commercial record of the factory and company stating the clause of toll manufacturing.

- A copy of the license of the factory that manufactures the product and that has the production line that is appropriate for producing the product.
- A copy of the license of the factory that owns the product.
- A valid storage contract, authenticated and approved by Legal Affairs.