



**Central Administration for Pharmaceutical Products
General Administration For Veterinary Pharmaceuticals**

**Guidelines on Registration Procedures of Veterinary Pharmaceuticals
According to the Chairman of Egyptian Drug Authority's
Decision No. 625 Year 2024**

Code: EDREX: GL.CAPP.038

Version No: 2

Issue Date: 25/8/2025

Effective date: 25/8/2025

Table of Contents

Content	Page
Introduction	3
Scope	3
Definitions	3
General Rules	4
Procedures	6
Appendices	21
Versions	26

1. Introduction

The guidelines to clarify the rules and procedures required for registering veterinary pharmaceutical products according to the decision of the Chairman of the Egyptian Drug Authority (EDA) No. 625 of 2024.

2. Scope

The guidelines apply to all of the new veterinary pharmaceutical products submitted for registration to be locally marketed, or locally manufactured submitted for registration for the purpose of export only or for export and tenders.

3. Definitions

-Veterinary Pharmaceutical:

Any substance or combination of substances used in animals for treating or preventing disease. 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:**

They include the following:

-[Local] Veterinary Pharmaceutical Product:

It is a veterinary pharmaceutical product that is owned by a licensed factory within the Arab Republic of Egypt & manufactured in the same factory.

-[Toll] Veterinary Pharmaceutical Product:

It is a veterinary pharmaceutical product that is owned by a company registered in toll manufacturing record in the Central Administration of Inspection on Pharmaceutical Institutions and it is manufactured in a licensed factory within the Arab Republic of Egypt through a manufacturing contract.

-[F-Toll] Veterinary Pharmaceutical Product:

It is a veterinary pharmaceutical product owned by a licensed factory within the Arab Republic of Egypt and it is manufactured in another licensed factory within the Arab Republic of Egypt that has the required production line through a factory-to-factory manufacturing contract.

- Veterinary Pharmaceutical Product locally manufactured [Under License]:

It is a veterinary pharmaceutical product that is produced and manufactured in a licensed factory inside the Arab Republic of Egypt under license from a foreign company outside the Arab Republic of Egypt that owning the product name and composition through a contract between the two companies.

▪ The Imported Veterinary Pharmaceutical Products:

-[Bulk] Imported Veterinary Product:

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

-Finished Imported Veterinary Product:

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

4. General rules:

- All veterinary products submitted for registration, its composition shall be referential, i.e. the veterinary product shall match the active ingredient, concentration and dosage form of the veterinary product registered and marketed in one of the reference countries.

- In case of the company was desirous to register a local product has a non-reference composition based on the presence of a similar product in Egypt valid and registered or approved to proceed with the re-registration procedures, the company shall submit a registration application and that registration application shall be initially accepted and presented to the Scientific Committee to decide whether or not to accept this application. In case of rejecting the composition by the Scientific Committee, the product shall be presented to the Technical Committee for Drug Control to take the final decision. In case of affirmation of the Scientific Committee decision, the General Administration of Veterinary Products shall issue a letter of the final decision to the company stating a reason of non-approval to proceed with the registration procedures. That decision shall be applied to all of the similar products under registration and the registration certificates for the similar registered products shall be cancelled.

- In the case of reference composition submitted for registration that are imported from a non-reference country and are not marketed in any of the reference countries; If the inquiry request is accepted and there is available place in the similars box, the matter shall be referred to the Scientific Committee to consider exempting the product from the requirement/condition of being marketed in one of the reference countries and to evaluate the product; the Scientific Committee's decision shall then be presented to the Technical Committee for Drug Control to make the appropriate decision.

*If the Technical Committee for Drug Control requests certain documents from the company, the company must submit the requested documents within 30 working days maximum from the date of notifying the company; otherwise, the registration request will be cancelled.

*If the Technical Committee approves the request, the company must submit a Site Master File to the Central Administration of Inspection on Pharmaceutical Institutions and inspection on abroad factory; then resubmitted to the Technical Committee to decide whether or not to register the product.

*If the Technical Committee refuses to exempt the product from the marketing requirement in one of the reference countries, the company may submit an appeal on the decision of the Technical Committee for Drug Control in accordance with the regulations, provided that a new registration request is submitted to the General Administration of Veterinary Pharmaceuticals with payment of the service fees.

- For locally manufactured veterinary products that will be locally marketed, the number of products received monthly shall be as follow:

* Two products for each company owning a licensed factory or a factory under construction.

* One product for each (Toll) manufacturing company.

-For imported veterinary products that will be locally marketed, the number of products received monthly from each company shall be only one product.

-It is allowable to submit different concentrations of the same dosage form in one inquiry request, provided that the registration fees prescribed for each concentration separately shall be paid and the registration file for each concentration shall be submitted.

-The number of imported similar products allowed to be registered for each concentration of the active ingredient shall not exceed three products. They shall be divided as follows: The innovator product (Brand product) as well two generic products, in accordance with the dosage forms presented in each similar box of the imported veterinary products and approved by the Technical Committee for Drug Control.

-Imported veterinary products containing only vitamins, minerals, and amino acids, without any other active ingredients, are exempt from the similar box system.

-The company is required to manufacture products using the same source of raw materials as that used in the pilot batch, for which all required studies have been conducted. This applies to locally manufactured products intended for local marketing, export, or tenders, and a registration license is issued accordingly.

-The pilot batch must be manufactured using the same composition, specifications, primary packaging, and manufacturing process that will be used in the production of the final product intended for marketing.

-The company is committed full responsibility for the storage of raw materials, all stages of the product's manufacturing, the product's compliance with technical specifications, and the storage of the product until distribution is complete. In the case of products manufactured locally for local marketing, export, or tenders, the factory must be licensed by the Egyptian Drug Authority and must comply with all set obligations/requirements in this guideline and the Good Manufacturing Practice (GMP) guidelines.

-The company is committed to write the following data on the outer package: The factory name and address based on the data indicated in the factory license and the product owner name. In the case of the imported products, the applicant is committed to write the factory name and address and it is allowed to write the name of the market authorization holder instead of the product owner/license holder, based on the submitted CPP certificate.

-The company is committed to write the production date, expiration date, batch number and registration number on the outer packaging of all products and not to make any change in the product except after obtaining the CAPP approval.

-The company shall undertake its commitment to the provisions of the Intellectual Property Rights Law No. (82) of year 2002 and its executive regulations without any responsibility on the part of the Egyptian Drug Authority.

-The company undertake that all the product data submitted in the analysis file at the Central Administration for Drug Control shall match the data submitted in the registration file at the Central Administration of Pharmaceutical Products and that all documents and data are correct and on its own responsibility.

-The applicant must commit to production or import within 3 (three) years from the issue date of the registration license otherwise the registration license shall be cancelled based on a report from the Central Administration of Inspection on Pharmaceutical Institutions, the company may submit a request within three months from the end of the specified timeframe for production or import, supported by reasons for extending that timeframe, provided that the service fees are paid in accordance with the requested extension, for a period not exceeding three years. The extension shall be granted only upon approval by the General Administration of Veterinary Pharmaceuticals. An exception to the three-month deadline for submitting an extension request shall apply to veterinary products that obtained a registration license prior to the entry into force of this regulatory guide.

- The company is committed not to make any change except after the Central Administration of Pharmaceutical Products approval, otherwise the registration license will be cancelled based on a report from the Central Administration of Inspection on Pharmaceutical Institutions.
- For locally manufactured products, the company is committed to submit accelerated and long-term stability studies for evaluation by the General Administration of Stability. These studies must be conducted on the first three production batches within five years of the production date of each batch, and is monitored by the Central Administration of Inspection on Pharmaceutical Institutions.
- 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.

5.Procedures:

First: Procedures for registering veterinary pharmaceuticals submitted for local market registration:

***Registration Application Mechanism:**

***Steps to begin submitting a registration request for new veterinary pharmaceuticals:**

A- Regarding locally manufactured veterinary products intended for local distribution:

- The company is committed to submitting an inquiry request regarding (formula reference and the possibility of registering the product) according to Annex No. (1) via the Electronic Veterinary Registration System) EVERS.
- The company may submit an additional inquiry request after paying the service fee, with a maximum of two additional requests beyond the allowed number.
- The inquiry request is reviewed by the General Administration of Veterinary Products, and the company is notified of the acceptance or rejection of the inquiry (with clarification of the reasons for rejection) via the electronic platform (EVERS) within a maximum of five working days from the date of submission.
- In the event of a request to complete certain requirements in the inquiry, the company must fulfill them within three working days ;otherwise, the inquiry request will be considered void.
- In case the inquiry request is accepted, the company must submit a list of proposed names for the product (minimum 5 names and maximum 20 names) within 25 working days from the date of acceptance via the EVERS platform.
- The list of proposed names is reviewed and a name is selected within 9 working days from the date of submission.
- If the first list of names is rejected, the company is notified; the company must then upload another list within 15 working days from the notification date, otherwise the inquiry request will be canceled.
- The company is permitted to submit a maximum of four lists of proposed names (including the first list). If all of the four lists are rejected, the product must use the scientific name coupled with the company name as stated in the commercial register.

- The company is committed to submitting the scientific file via the EVERS platform within one month from the date of being notified of the selected product name; otherwise, the inquiry request will be considered void.

B- Regarding imported veterinary products intended for local distribution:

- The company is committed to submitting an inquiry request regarding the formula reference and the possibility of registering the product according to Annex No. (2) via the Electronic Veterinary Registration System (EVERS)
- The company may submit an additional inquiry request after paying the service fee, with a maximum of two additional requests beyond the allowed number.
- The inquiry request is reviewed by the General Administration of Veterinary Products, and the company is notified of the acceptance or rejection (with clarification of the reasons for rejection) within a maximum of five working days from the date of submission.
- In the event of a request to complete certain requirements in the inquiry, the company must fulfill them within 3 working days ;otherwise, the inquiry request will be considered void.
- If the inquiry request is accepted, the General Administration of Veterinary Products begins reviewing the availability of a slot in the Similar Products Box for imported veterinary products. The company is notified of slot availability or unavailability within 15 working days starting from the date the inquiry acceptance was issued.
- The company is committed to submitting the scientific file via the EVERS platform within one month from the date of being notified of slot availability in the Similar Products Box; otherwise, the inquiry request will be considered void.

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

- The scientific file shall be submitted via the electronic platform for registering of veterinary products (EVERS) within the specified period in accordance with Appendix in order to be reviewed. In case of there are documents required to be fulfilled, the company shall be notified via the electronic platform for registering of veterinary products (EVERS) within one month from the date of submitting the scientific file.
- The company shall be committed to submit all the required documents within a period of two months as a maximum from the date of notifying it of such documents. This period is renewable for once, provided that the prescribed service fee shall be paid, otherwise the registration application shall be cancelled.
- The required documents shall be revised within one month from its submission date. In case of there are failure, the company shall be notified via the electronic platform. The company shall be committed to submit all of the required documents within a maximum period of one month from the date of notifying the company of such documents, otherwise the registration application shall be cancelled.
- In case of failure to submit the required documents again, the documents shall be resubmitted within a maximum period of one month from the date of notifying the company of these documents "twice as a maximum", provided that the prescribed service fee shall be paid, otherwise the registration application shall be cancelled.
- After fulfilling the scientific file, the product shall be presented to the Specialized Scientific Committee for Veterinary Pharmaceuticals and Feed Additives to express an opinion on the registration application and approve the preliminary scientific data of the product.
- In case of there are clarifications and documents contributing to make the final decision required by the Scientific Committee from the company, the registration application shall be postponed and the company shall be notified of the postponement reasons. The company must submit the clarifications and documents required by the committee within one month (renewable for once after paying the prescribed service fee) from the date in which it was notified of the postponement reasons. Then the registration application shall be represented to the Specialized Scientific Committee for Veterinary Pharmaceuticals and Feed Additives.

In case of failure to fulfill the required documents within the specified period the registration application shall be cancelled

- In case of non-approval, the registration application shall be presented to the Technical Committee for Drug Control to express the final decision. In case of the decision was affirmed, a non-approval letter of proceeding with the registration procedures shall be issued for the company, the rejection reasons shall be indicated.
- In case of approval, an approval valid for a period of three years from the date of the Scientific Committee shall be issued to proceed with the registration procedures, the company shall submit a request within three months of the authorization's expiration to extend the validity for one year, including the reasons for exceeding the deadline and payment of the prescribed service fee. This extension is granted only upon the approval of the General Administration of Veterinary Pharmaceuticals.
- Note that products that obtained authorization to proceed with registration procedures prior to the implementation of this regulatory guide are exempt from the three-month deadline for submitting the extension request
- taking into consideration this approval shall not be considered a final registration approval, but it shall subject to review and amending by the Central Administration of Pharmaceutical Products whenever necessary until obtaining the final registration certificate.
- The decisions of the Specialized Scientific Committee for Veterinary Pharmaceuticals and Feed Additives shall be issued within 14 working days from the date of the Scientific Committee.

The mechanism of applying for registration Procedures of initiating the submission of a registration application of new veterinary pharmaceutical products submitted for export only or for export and tenders

The company shall be committed to submit the scientific file via the electronic platform for registering the veterinary products (EVERS) within one month from the approval date; otherwise, the inquiry request shall be considered void. The product name shall be reviewed upon submission of the scientific file.

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

- The scientific file shall be submitted via the electronic platform for registering of veterinary products (EVERS) within the specified period in accordance with Appendix in order to be reviewed. In case of there are documents required to be fulfilled, the company shall be notified via the electronic platform for registering of veterinary products (EVERS) within ten working days from the date of submitting the scientific file.
- The company shall be committed to submit all the required documents within a period of two months as a maximum from the date of notifying it of such documents.
- The required documents shall be revised within 7 working days from its submission date. In case of there are failure, the company shall be notified via the electronic platform. The company shall be committed to submit all of the required documents within period of one month from the date of notifying the company of such documents, In case of failure to submit the required documents again, the documents shall be resubmitted within a maximum period of one month from the date of notifying the company of these documents provided that the prescribed service fee shall be paid and the resubmission of required documents shall be accepted.
- After fulfilling the scientific file, the product shall be presented to the Specialized Scientific Committee for Veterinary Pharmaceuticals and Feed Additives to express an opinion on the registration application and approve the preliminary scientific data of the product.
- In case of there are clarifications and documents contributing to make the final decision required by the Scientific Committee from the company, the registration application shall be postponed and the company shall be notified of the postponement reasons. The company must submit the clarifications and documents required by the committee within one month from the date in which it was notified of the postponement reasons. Then the registration application shall be represented to the Specialized Scientific Committee for Veterinary Pharmaceuticals and Feed Additives.
- In case of non-approval, the registration application shall be presented to the Technical Committee for Drug Control to express the final decision. In case of the decision was affirmed, a non-approval letter of proceeding with the registration procedures shall be issued for the company, the rejection reasons shall be indicated.

- In case of approval, an approval valid for a period of three years from the date of the Scientific Committee shall be issued to proceed with the registration procedures, the company shall submit a request within three months of the authorization's expiration to extend the validity for one year, including the reasons for exceeding the deadline and payment of the prescribed service fee. This extension is granted only upon the approval of the General Administration of Veterinary Pharmaceuticals.
- Note that products that obtained authorization to proceed with registration procedures prior to the implementation of this regulatory guide are exempt from the three-month deadline for submitting the extension request
- taking into consideration this approval shall not be considered a final registration approval, but it shall subject to review and amending by the Central Administration of Pharmaceutical Products whenever necessary until obtaining the final registration certificate.
- The decisions of the Specialized Scientific Committee for Veterinary Pharmaceuticals and Feed Additives shall be issued within 3 working days from the date of the Scientific Committee.
- In case of exceeding any of the prescribed deadlines for fulfill the aforementioned required documents, the company shall submit an appeal for an equivalent additional grace period to complete the required task. This appeal must include the reasons for exceeding the set deadline, provided that the service fee for granting the additional equivalent grace period is paid.

***During the validity period of the approval to proceed with the registration procedures, the company is obligated to complete the following; otherwise, the registration request will be considered null and void:**

1-Regarding local products:

- "Production of a pilot batch shall be carried out using at least the minimum operating capacity of the production line, in the presence of an inspector from the Central Administration of Inspection on Pharmaceutical Institutions. All registration procedures and requirements must be completed in accordance with the composition statement (formula) used to produce the pilot batch and approved by the inspector of the Central Administration of Inspection on Pharmaceutical Institutions, as well as the raw material source used for producing the pilot batch. The Central Administration of Inspection on Pharmaceutical

Institutions shall draw samples from the pilot batch for analysis at the Central Administration of Drug Control."

- The submission to the Central Administration of Drug Control to obtain a compliance report, stating the source of the raw material, with an attached composition statement based on which the pilot batch was produced and analyzed.
- Submission of the accelerated and long-term stability study results for one pilot batch over a six-month period to the General Administration of Stability, to obtain the product's stability report, stating the source of the raw material, and attached with the composition statement based on which the pilot batch was produced.
- Submission to the Central Administration of Pharmaceutical Care after completing the stability and analysis studies, or at the beginning of the final year of the workflow approval validity, whichever comes first, for the approval of the scientific leaflet.
- Submission of the final registration file via the electronic platform for veterinary products registration (EVERS).

2-Regarding imported products

- Submit to the Central Administration for Drug Control and obtain a conformity report accompanied by a statement of the composition on which the analysis was based.
- Companies that have obtained a registration and trading certificate from one of the reference countries approved by the Technical Committee for Drug Control may conduct the analysis at the Central Administration for Drug Control for the first incoming shipment after obtaining the final registration certificate , The competent administration shall not release the first .incoming shipment until the analysis result is issued confirming conformity
- Submission of the product's stability study conducted abroad for evaluation by the General Administration of Stability, and to obtain the product's stability report attached with the approved composition statement.
- Submission to the Central Administration of Pharmaceutical Care after completing the stability and analysis studies, or at the beginning of the final year of the workflow approval validity, whichever comes first, for the approval of the scientific leaflet.

- Submission of the final registration file via the electronic platform for veterinary products registration (EVERS).

***Submitting the final registration file and issuing the registration notification:**

- The final registration file shall be submitted within the specified deadline according to Annex No. (4) via the electronic platform for veterinary products registration (EVERS).
- The file shall be initially evaluated, and in case the essential requirements are not met, the file will be rejected and the uploaded documents will be canceled, provided that the complete file is re-uploaded by the company.
- If the file is initially accepted, it will be reviewed by the General Administration of Veterinary Pharmaceuticals . The company shall be notified of the required completions within three month from the date of submission of the final registration file. The company shall provide the required ,completions within three months from the date of notification to the company of the completions which shall be renewed once after payment of the service fee for otherwise the registration request .shall be considered void
- The completions shall be reviewed within one month from the submission date. In case of any errors, the company shall be notified via the electronic platform for veterinary products registration (EVERS). The company is committed to submit the required completions fully and satisfying all requirements within a maximum period of one month from the company's notification date; otherwise, the registration request shall be considered null and void.
- In case of repeated errors in the submitted completions, the prescribed service fee shall be paid, and the completions shall be re-submitted within a maximum period of one month from the company's notification date, with a maximum of two times; otherwise, the registration request shall be considered void.
- In the event of repeated errors in the submitted completions, a fee will be paid, and the completions will be resubmitted within a maximum period of one month from the date of notifying the company

of the required completions, with a maximum of two times, otherwise the registration request will be considered void.

- Presentation to the Technical Committee for Drug Control (TCDC) after satisfying the registration file requirements, in order to take the appropriate decision regarding the registration or non-registration of the product. In case of approval by the Technical Committee for Drug Control, a final registration certificate shall be issued, valid for ten years starting from the committee's approval date.
- In case of non-approval, a non-approval letter including the reasons for rejection shall be issued to the company. The company may submit an appeal for reconsideration of the Technical Committee for Drug Control's final decision within 60 working days from the date the applicant is notified, provided that the appeal satisfies all supporting technical justifications and is supported by the documents and information the company wishes to rely upon when reviewing its appeal.
- Decisions of the Technical Committee for Drug Control shall be implemented within 14 working days.

Second: Procedures for registering veterinary products submitted for export only, or for export and tenders:

***Registration Application Mechanism:**

- The company is committed to submitting an inquiry request regarding (formula reference and the possibility of registering the product) according to Annex No. (1) via the Electronic Veterinary Registration System (EVERS).
- The inquiry request is reviewed by the General Administration of Veterinary Pharmaceuticals, and the company is notified of the acceptance or rejection (with clarification of the reasons for rejection) within a maximum of three working days from the date of submission.
- In the event of a request to complete certain requirements in the inquiry, the company must fulfill them within 3 working days; otherwise, the inquiry request will be canceled.
- If the inquiry is approved, the company is committed to submitting the scientific file via the EVERS platform within one month from the date of acceptance; otherwise, the inquiry request will be considered void. Note that the product name will be reviewed at the time the registration request (scientific file) is submitted.

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

- The scientific file shall be submitted via the electronic platform for registering of veterinary products (EVERS) within the specified period in accordance with Appendix in order to be reviewed. In case of there are documents required to be fulfilled, the company shall be notified via the electronic platform for registering of veterinary products (EVERS) within ten working days from the date of submitting the scientific file.
- The company shall be committed to submit all the required documents within a period of two months as a maximum from the date of notifying it of such documents.
- The required documents shall be revised within 7 working days from its submission date. In case of there are failure, the company shall be notified via the electronic platform. The company shall be committed to submit all of the required documents within period of one month from the date of notifying the company of such documents, In case of failure to submit the required documents again, the documents shall be resubmitted within a maximum period of one month from the date of notifying the company of these documents provided that the

prescribed service fee shall be paid and the resubmission of required documents shall be accepted.

- After fulfilling the scientific file, the product shall be presented to the Specialized Scientific Committee for Veterinary Pharmaceuticals and Feed Additives to express an opinion on the registration application and approve the preliminary scientific data of the product.
- In case of there are clarifications and documents contributing to make the final decision required by the Scientific Committee from the company, the registration application shall be postponed and the company shall be notified of the postponement reasons. The company must submit the clarifications and documents required by the committee within one month from the date in which it was notified of the postponement reasons. Then the registration application shall be represented to the Specialized Scientific Committee for Veterinary Pharmaceuticals and Feed Additives.
- In case of non-approval, the registration application shall be presented to the Technical Committee for Drug Control to express the final decision. In case of the decision was affirmed, a non-approval letter of proceeding with the registration procedures shall be issued for the company, the rejection reasons shall be indicated.
- In case of approval, an approval valid for a period of three years from the date of the Scientific Committee shall be issued to proceed with the registration procedures, the company shall submit a request within three months of the authorization's expiration to extend the validity for one year, including the reasons for exceeding the deadline and payment of the prescribed service fee. This extension is granted only upon the approval of the General Administration of Veterinary Pharmaceuticals.
- Note that products that obtained authorization to proceed with registration procedures prior to the implementation of this regulatory guide are exempt from the three-month deadline for submitting the extension request
- taking into consideration this approval shall not be considered a final registration approval, but it shall subject to review and amending by the Central Administration of Pharmaceutical Products whenever necessary until obtaining the final registration certificate.
- The decisions of the Specialized Scientific Committee for Veterinary Pharmaceuticals and Feed Additives shall be issued within 3 working days from the date of the Scientific Committee.

- In case of exceeding any of the prescribed deadlines for fulfill the aforementioned required documents, the company shall submit an appeal for an equivalent additional grace period to complete the required task. This appeal must include the reasons for exceeding the set deadline, provided that the service fee for granting the additional equivalent grace period is paid.
- **In the case of products submitted for export only, the company is obligated within the validity period of the approval to proceed with the registration procedures, to complete the following; otherwise , the registration application will be considered void**
 - Production of a research batch R&D and completion of all registration requirements .according to the composition statement on which this batch was produced
 - Submit to the Central Administration for Drug Control and obtain a conformity report .accompanied by a statement of the composition on which the analysis was based
 - Submitting the results of the accelerated six-month stability study for evaluation by the General Administration of Stability; and obtaining a stability report for the product .accompanied by a statement of the approved composition
 - Apply to the Central Administration for Pharmaceutical Care after completing the stability- and analysis studies or at the beginning of the final year of The validity of the approval of the ,process, whichever is earlier for the approval of the scientific leaflet
 - Submitting the final registration file via the electronic platform for registering veterinary products (EVERS).

In the case of products submitted for export and tenders, the company is obligated, within the validity period of approval to proceed with registration procedures, to complete the following .otherwise , the registration application will be void

- Production of -a pilot batch with a minimum capacity for operating the production line, in the presence of an inspector from the Central Administration of Inspection on Pharmaceutical Institutions. All registration procedures and requirements must be completed according to the composition statement on which the pilot batch was produced and which was approved by the inspector from the Central Administration for Inspection of Pharmaceutical Institutions as well as the source of the raw material used in the production of the pilot batch . The Central Administration of Inspection on Pharmaceutical Institutions will withdraw samples from the pilot batch for analysis at the Central Administration for Drug Control.
- Submit to the Central Administration for Drug Control and obtain a conformity report stating the source of the raw material and attaching a statement of the composition on which the pilot batch was produced and the analysis was based
- Submission of the accelerated and long-term stability study results for one pilot batch over a six-month period for evaluation by the General Administration of Stability, and to obtain the product's stability report, stating the source of the raw material, and attached with the composition statement based on which the pilot batch was produced.
- Apply to the Central Administration for Pharmaceutical Care after completing the stability and analysis studies or at the beginning of the final year of The validity of the approval of the process, whichever is earlier, for the approval of the scientific leaflet
- Submitting the final registration file via the electronic platform for registering veterinary products (EVERS)

- **Submitting the final registration file and issuing the registration license**

- The final registration file shall be submitted within the specified deadline according to Annex No. (3) via the electronic platform for veterinary products registration (EVERS), to be reviewed by the General Administration of Veterinary Pharmaceuticals, and the company shall be notified of the required completions within 10 working days from the final registration file submission date. The company is committed to submit the required completions within three months from the company's notification date
 - The completions shall be reviewed within 7 working days from the submission date. In case of any errors, the company shall be notified via the electronic platform for veterinary products registration (EVERS). The company is committed to submit the required completions fully and satisfying all requirements within a maximum period of one month from the company's notification date. In case of repeated errors in the submitted completions, a fee shall be paid, and the re-submission of completions shall be accepted.
- In the event that any of the deadlines set for completing any of the previously mentioned required completions are exceeded, the company may submit an appeal for an additional deadline of a similar period to complete the required completion, including the reasons that led to exceeding the specified deadline, provided that a fee for the additional similar deadline is paid
- Presentation to the Technical Committee for Drug Control as soon as the registration file is complete, in order to make the appropriate decision regarding whether or not to register the product. If the Technical Committee for Drug Control approves, a final registration license is issued that is valid for ten years
- In case of non-approval, a non-approval letter including the reasons for rejection shall be issued to the company. The company may submit an appeal for reconsideration of the Technical Committee for Drug Control's final decision within 60 working days from the date the applicant is notified, provided that the appeal satisfies all supporting technical justifications and is supported by the documents and information the company wishes to rely upon when reviewing its appeal.

***Central Administration of Pharmaceutical Policies and Market Access**

-Regarding Importation and Medical Customs Release

Companies are permitted to import raw materials and packaging materials used in the manufacturing of locally produced pharmaceutical products (whether for research and development (R&D) batches, pilot batches, or production batches, according to each case), medical customs release shall be granted for incoming shipments of imported veterinary pharmaceutical products, raw materials, and packaging materials in accordance with the decision of the EDA Chairman No. (444) of 2023 and the regulatory guideline governing the rules and procedures for importation and medical customs clearance of pharmaceutical products, their raw materials, and packaging materials, along with any subsequent updates thereto.

Central Administration of Inspection on Pharmaceutical Institutions

1. Requests for Manufacturing Pilot Batches

First: Method of Submission for Request to Attend Production of Pilot/Production Batches of Pharmaceutical Products

The product-owning company shall submit a request to General Administration for Factory Inspection to attend production, using the approved form, and proceed with payment of the service fee, then upload it via the designated electronic link for receiving pilot batch requests:

https://docs.google.com/forms/d/1gkCpStOkYDICOdQUkEi55NfFYqMG0_4c842hSA1YHsg/prefill

Approval shall be issued after payment of the service fee and completion of the required documents stated in the application form, and shall be sent to the company via the official email within three working days, provided that production is carried out within three months from the date of approval, with adherence to the timeline specified in the approval to proceed with procedures issued for the product.

In the case of **Normal Track**, the company is permitted to manufacture pilot/production batches after ten days from the date of fulfilling the submitted request for manufacturing approval.

In the case of **Fast Track**, the company is permitted to manufacture pilot/production batches within three days from the date of fulfilling the submitted request for manufacturing approval.

Pilot/production batches shall be manufactured in the presence of inspectors from the Central Administration of inspection on pharmaceutical institutions

, with review of batch records and approval of the formulation composition upon which manufacturing was conducted.

The inspector shall approve two original copies of the formulation composition (one original attached to the inspection report and one original delivered to the company).

Samples shall be withdrawn from the pilot/production batch for analysis at the Central Administration of Drug Control.

2. Handling of Bulk Shipments

The inspector shall proceed to the company warehouse after the factory submits a visit request through the designated electronic link.

The inspector shall review the shipment documents and verify their conformity with the containers present at the factory. After confirming that the documents match the containers and ensuring their integrity, the inspector shall issue a report for opening (unsealing) the bulk consignments imported directly by the company.

Samples shall be withdrawn for analysis from the first three consignments at the laboratories of the Egyptian Drug Authority. The company is allowed to proceed with the remaining production steps of the bulk product, provided that the company undertakes not to release the final product until receipt of a conformity decision from the Central Administration of Drug Control (CADC) for the bulk samples and the finished product samples, where applicable.

A report shall be issued indicating compliance, completion, or continuation of analysis for any sample, based on correspondence received from CADC.

In the event of non-compliance of any bulk or finished product, samples shall be withdrawn from three additional consecutive batches from the same supplier for which non-compliance was issued. Release shall only take place after obtaining conformity results, after which random sampling shall be resumed.

3. Sampling/Distribution of the Finished Veterinary Pharmaceutical Product (for the first three batches / random sampling)

The inspector shall proceed to the product manufacturing site after a visit request is submitted via the designated electronic link.

The inspector shall review the product-related documents, and samples shall be withdrawn and secured for submission to the Central Administration for Drug Control (CADC).

The batch shall not be released except upon receipt of a conformity decision from CADC and obtaining approval of the studies stated in the registration certificate.

4. Mechanism for Travel to Inspect Manufacturing Sites Outside the Arab Republic of Egypt for products imported from non-reference countries and not marketed in reference countries, whether finished products or bulk to be packaged in Egypt.

A travel request shall be submitted through the electronic link of the General Administration for Factory Inspection for overseas inspection. Re-inspection shall be conducted in accordance with the Risk-Based Inspection Plan issued by the General Administration for Factory Inspection, in line with the decisions of the Chairman of the Egyptian Drug Authority No. (157) of 2021 and No. (150) of 2022.

The request shall include the following:

1. A letter containing the proposed travel dates (including three proposed dates within the intended month of travel).
2. A commitment letter from the company to pay the service fees for inspection as specified in the annex attached to the Chairman of the Authority's Decree No. (157) of 2021, along with an undertaking by the company to bear all travel and transportation expenses for the committee.
3. The final report shall be issued by the Egyptian Drug Authority inspection committee to the factory within 45 days
4. The factory shall commit to submitting the corrective and preventive action plan (CAPA) within 30 days.
5. The matter shall be presented to the competent committees for approval or rejection of the factory.

Central Administration of Pharmaceutical Care

General Administration of Pharmacovigilance

During the validity period of veterinary product registration license:

- The company is obliged inform the General Administration of Pharmacovigilance of any serious adverse reactions observed for the product within 15 days, and to report any non-serious adverse reactions within 90 days.
- The company is committed to monitoring and reporting safety signals.

All companies must submit a Pharmacovigilance System Description (PVSD) before the end of 2026.

Upon re-registration of products registered after the issuance of this decision:

The company must submit a pharmacovigilance file that includes all of the following requirements:

- A product safety report (Benefit-Risk Assessment Report) covering the entire registration period of the product.
- The company's status regarding submission of the Pharmacovigilance System Description, along with its summary. (Additionally, the submission status of the Pharmacovigilance Sub-System Description for the company's office or local agent in Egypt, along with its summary, must be provided (in the case of reregistration of the imported products / locally manufactured products under license from a foreign company / local products belonging to international companies).

In case of incomplete submission of the documents:

The Pharmacovigilance Administration shall refer the matter to the Technical Committee for Drug Control to take the appropriate decision as deemed necessary.

General Administration of Pharmaceutical References and Leaflets

Applications for leaflet approval must be submitted to the General Administration of Pharmaceutical References and Leaflets – Central Administration of Pharmaceutical Care for products that have obtained a Scientific Committee Approval from the Central Administration of Pharmaceutical Products starting from 04/09/2022. Evaluation must be conducted in accordance with the current operating procedures, during the validity period of the Scientific Committee Approval for registration procedures, after completion of the required studies or at the beginning of the last year of the validity of the Scientific Committee Approval, whichever comes first, prior to submission of the registration/final file to the Examination Unit.

According to the leaflet template available at the following link:

<https://docs.google.com/forms/d/e/1FAIpQLSd3jBVOLOfICUqhBuNDttUWNzsaQAOi73GKVRTixTn7JgYyKw/closedform?pli=1>

1. The veterinary product leaflet submission should be done according to the current work mechanisms, during the validity period of the approval of the registration procedures and after the completion of the required studies or at the beginning of the last year of validity of the approval of proceeding with the registration procedures, whichever is earlier, before submitting the final registration or file.

2. according to the leaflet form listed on the following link.

<https://docs.google.com/forms/d/e/1FAIpQLSd3jBVOLOfICUqhBuNDttUWNzsaQAOi73GKVRTixTn7JgYyKw/closedform?pli=1>

Central Administration of Drug Control

- The company must submit an application for analytical file review via the link of the Evaluation and Approval Administration after payment of the approved service fee.
- The completeness of the file contents must be verified in accordance with the approved checklist.
- The file must be technically reviewed, and the response shall be sent electronically to the company via email.
- The company is granted a period not exceeding three months to respond to the Examination requirements.
- In case the company fails to fulfill the requirements within the specified period, it may submit a request to extend the Examination period after payment of the approved service fee.
- The company's request must be reviewed after assessing the reasons for the delay.
- After completion of requirements, the company must submit an application for submission of the analytical file, samples, and testing requirements via the designated link.
- In case the company delays submitting the file and samples for analysis after completion of requirements for more than three months, the company may submit a request for extension of the deadline with justification, after payment of the approved service fee.
- The Central Administration of Drug Control has the right to request additional testing requirements not available in the laboratories during the review/analysis of the product file when necessary, and it also has the right to request additional samples if needed.
- If an official letter is issued to the company during analysis, the company must respond within a period not exceeding three months.
- In case of delay in responding to the letter beyond three months, the company has the right to submit a request for extension of the deadline with justification, after payment of the approved service fee.
- The final report must be issued indicating the name of the raw material supplier and attached with the composition statement on which the analysis was conducted.

6. Annexes:

Annex (1)

1. A scanned copy of a recent payment receipt for the inquiry request fees.
2. A scanned copy of a payment receipt for additional inquiry request fees.
3. A recent scientific reference proving the formula reference (attached with an original certified translation if required).

* Existing registered products may be used as a scientific reference for the submitted formula only if identical reference products are unavailable, provided that the registered product is still valid.

* A copy of the latest pharmacopoeia the product follows (for pharmacopoeial/compendial products).

4. A Certificate of Pharmaceutical Product (CPP) for the product (in the case of products manufactured locally under license from abroad).
5. A copy of the Technical License for Operation for the factory submitting the registration request (for **Local** or **F-Toll** products).
6. A copy of the registration in the Contract Manufacturing Register (**Toll Card**) (for **Toll** products).
7. A copy of the Commercial Register (in the case of products submitted by factories under construction).
8. A copy of a valid Registration License or a valid Scientific Committee approval (in the case of products submitted as a **Line Extension**).
9. A list showing the products belonging to both **Toll** companies and factories under construction.

Annex (2)

1. A scanned copy of a recent payment receipt for the inquiry request fees.
2. A scanned copy of a payment receipt for additional inquiry request fees.
3. A recent scientific reference proving the formula reference, attached with an original certified translation if required (specifically for products imported from **non-reference countries** that are not currently marketed in a reference country.)
4. A Certificate of Pharmaceutical Product (**CPP**) for the product.
5. In the case of **Innovator Products** :evidence from the responsible health authority confirming that the submitted product is indeed the "Innovator" product.

Annex (3)

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

For local products:

- Scanned copy of the receipt for payment of fees.
- Certificate of preliminary scientific data of the product, signed, stamped and supported by the necessary references.
- A signed and stamped declaration of the sizes of packages to be registered on the company letterhead in case of injection.

In the case of manufacturing under license, the previous documents shall be submitted in addition to the following:

- Scanned copy of the receipt for payment of fees.
- An under-license manufacturing contract authenticated by the Chamber of Commerce and the Egyptian Embassy abroad, unless otherwise stated by international agreements.
- An official authorization for registration/ manufacturing under license authenticated by the Chamber of Commerce and the Egyptian Embassy abroad.
- A signed and stamped product composition form on the company letterhead, indicating the active and inactive ingredients, their concentrations, functions and specifications, according to the latest edition of the pharmacopeia.
- A copy of the Toll manufacturing card for the products (Toll Under License)

- An authenticated and Notarized by Legal Affairs Department manufacturing contract and an annex stating the product name, composition form and pharmaceutical form F- Toll/ Toll Under License.

For imported products:

- Scanned copy of the receipt for payment of fees.
- A signed and stamped product composition form on the company letterhead, indicating the active and inactive ingredients, their concentrations, functions and specifications, according to the latest edition of the pharmacopeia.
- Certificate of preliminary scientific data of the product, signed, stamped on the company letterhead (supported by the necessary references).
- A signed and stamped declaration of the sizes of packages to be registered on the company letterhead in case of injection.
- Agency contract or official authorization authenticated by the Chamber of Commerce and the Egyptian Embassy abroad for review and verification.
- A copy of the Good Manufacturing Practices (GMP) certificate of the factory abroad (in case of it is not indicated in the product CPP).
- A copy of the pharmaceutical importers' registers for the imported products.
- A copy of the company's commercial register.
- Certified translation of the product information leaflet as published in the country of origin's database (if available).
- Original leaflet or labels used in the country of origin.
- Authenticated CPP (Certified Product Profile) certificate for the product.

Annex (4)

The required documents to submit the final registration file for a veterinary product (Manufactured locally)

1. A data certificate for a veterinary product (local) stamped and signed by the chairman of the company's board of directors or his representative under an official authorization.
2. A copy of the approval to proceed 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. Sample withdrawal report for finished product (Pilot batch) issued by the inspection department, accompanied by a composition statement.
7. Pilot Batch Manufacturing Attendance Report
8. Fee payment receipts.
9. Hard File Fees Extra (If exceed due date).
10. A composition form stamped and signed by the responsible person on the company letterhead owning the product. The composition form shall state the manufacturer name, functions and specifications for the active and inactive ingredients, according to the most recent edition of the pharmacopeia.
11. Certificate of product specifications on the factory letterhead signed and stamped by the responsible person in the factory.
12. The scientific leaflet on the letterhead of the company owning the product stamped and signed by the responsible person. This scientific leaflet shall match the scientific leaflet approved by the Central Administration of Pharmaceutical Care and the packages and storage conditions indicated in it shall match data mentioned in the stability report.
13. The specifications of non-pharmacopeia active ingredients (In-House Spec) signed and stamped on the manufacturer letterhead. In case of the pharmacopeia active ingredient, the results mentioned in (In-House Spec) must be within the permissible range mentioned in the pharmacopeia.

14. A declaration by the company stating the factory name that manufactures the raw (active) material on the company letterhead, stamped and signed by the chairman of the board of directors of the company owning the product or his representative under an official authorization.
15. A valid analysis certificate of the raw (active) ingredient issued by the factory that manufactures the active ingredient, stamped and signed by the chairman of the board of directors of the company owning the product or his representative under an official authorization.
16. A copy of a recent authorization for the company representative certified by a valid bank signature.
17. A declaration to provide accelerated and long-term stability studies for evaluation by the General Administration of Stability, covering the first three production batches within five years from the production date of each batch. This shall be monitored by the Central Administration of Inspection on Pharmaceutical Institutions. Furthermore, [the company] undertakes to conduct an "In-use stability" study or Impurity Analysis if requested in the approval issued by the General Administration of Stability.

For local products:

- A copy of the Technical Operating License of the factory with suitable production line for manufacturing the product.

For Toll product:

- A valid Toll manufacturing card containing the factory name manufacturing of the product and the storage site.
- An annex to the manufacturing contract stating the product name, composition form and pharmaceutical form, recent, notarized and approved by General administration of Legal Affairs (stipulating the validity period of the manufacturing contract).
- A copy of the Technical Operating License of the factory that has an appropriate production line for manufacturing the product.

For F-Toll products

- An authenticated and approved by General administration of Legal Affairs manufacturing contract and an appendix stating the product name, composition form and pharmaceutical form recent, notarized and approved by General administration of Legal Affairs.
- A copy of the manufacturers' commercial register, taking into account that the product owner shall be indicated in the manufacturer's commercial registry. (Article of Toll Manufacturing)
- A copy of the manufacturers' tax card.
- A copy of the Technical Operating License of the factory manufacturing the product that has an appropriate production line for producing the product.
- A copy of the Technical Operating License of the factory owning of the product.
- A valid storage contract, notarized and approved by General administration of Legal Affairs

For the products (Under License)

- An under-license manufacturing contract authenticated by the Chamber of Commerce and the Egyptian Embassy abroad, unless otherwise stated by international agreements.
- An official authorization for registration/ manufacturing under a certified license issued by the Chamber of Commerce and the Egyptian Embassy abroad.
- An original certificate of pharmaceutical product (CPP) from the origin country, issued by the Ministry of Health or the Ministry of Agriculture and authenticated by the Egyptian embassy abroad.
- A copy of the Technical Operating License of the factory manufacturing the product that has an appropriate production line for producing the product.
- A Toll manufacturing record containing the factory name manufacturing of the product and the name of the store for the products for Toll Under License.
- An appendix to the manufacturing contract stating the product name, composition form and pharmaceutical form, recent, notarized and approved by General administration of Legal

Affairs (stipulating the validity period of the manufacturing contract) for Toll Under License products.

- An authenticated and approved by General administration of Legal Affairs manufacturing contract and an appendix stating the product name, composition form and pharmaceutical form for F-Toll Under License products.
- A storage contract valid, notarized and approved by the General administration of Legal Affairs, for F-Toll Under License products.

List of documents required for a veterinary product registration final file (imported)

1. Data certificate of a veterinary product (imported).
2. A copy of the approval of proceeding with the registration procedures.
3. A copy of the report of the Central Administration for Drug Control (if present).
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. Hard File Fees Extra (If exceed due date).
8. 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.
9. Certificate of product specifications signed and stamped by the factory and on its letterhead.
10. The scientific leaflet on the letterhead of the company owning the product abroad stamped and signed by the Central Administration of Pharmaceutical Care. This scientific leaflet shall match the scientific leaflet approved by the Central Administration of Pharmaceutical Care and the packages and storage conditions indicated in it shall match the data indicated in the report of the General Administration of Stability.
11. Register of drug importers (if present).

12. An original certificate of pharmaceutical product (CPP) from the country of origin, issued by the Ministry of Health or Ministry of Agriculture and authenticated by the Egyptian embassy abroad.
13. A copy of the Good Manufacturing Practices (GMP) of the factory abroad (in case it is not indicated in the CPP of the product).
14. An agency contract or official authorization for registration. It shall be authenticated by the Chamber of Commerce and the Egyptian Embassy abroad.
15. A copy of a recent authorization for the company's representative certified by a valid bank signature.
16. The company's commercial register.
17. If the products are imported from non-reference countries, a recent statement issued by the CAO indicating the factory's inspection status will be required.