Central Administration for Pharmaceutical Products
General Administration of Veterinary Pharmaceuticals

Guideline

Guidelines on

Registration Procedures of Veterinary Pharmaceuticals

Year 2023

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1. Introduction:

This is a regulatory guideline to clarify the rules and procedures required for registering new veterinary pharmaceutical products.

2. Scope of implementation:

This guideline shall apply to all of the new veterinary pharmaceutical products submitted for registration to be locally marketed.

3. Important definitions:

A 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:

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 Operations 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 ARE under license from a foreign company outside the ARE that owning the product name and composition through a contract between the two companies.

<u>The imported veterinary pharmaceutical products</u>:

They include the following

-[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. Procedures:

<u>First: General rules</u>:

- 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 reasons 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 case of the products has a reference composition but imported from a non-reference country and not marketed in any of the reference countries; the similars box shall be firstly reviewed to know whether or not have an available place, then the products shall be presented to the scientific committee to evaluate the product and consider the possibility of excluding it from the condition of being marketed in one of the reference countries in cases of extreme necessity or that the product is new and has a great therapeutic value. Then the decision of the Scientific Committee shall be presented to the Technical Committee for Drug Control to take the final decision whether to reject or to accept and submit the factory inspection file “Site Master File" to the Central Administration of Operations for evaluation and study in the requiring cases; The Technical Committee for Drug Control has the right to ask for inspection of the factory abroad.

- 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 permitted number of the imported veterinary products received from each company per month shall be only one product.

-It is allowable to submit different concentrations of the same pharmaceutical 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 original product (Brand product) as well two generic products, in accordance with the pharmaceutical forms presented in each similars box of the imported veterinary products approved by the Technical Committee for Drug Control.
-The company shall be obligated 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 shall be obligated to write the factory name and address and he is allowed to write the name of the company owning the right to market instead of the product owner, based on the submitted CPP certificate.

-The company shall be committed to write the Mfg. date, Exp. date, batch number and registration number on the outer package of all products and refrained from making any change in the product except after obtaining an approval of the Central Administration of Pharmaceutical Products.

-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 is committed to inform the Egyptian Pharmacovigilance Center with any serious adverse effects detected resulting from administering the veterinary product within 15 days. It also shall undertake to submit a Periodic Safety Update Report in accordance with the rules, otherwise product registration shall be suspended.

-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.

-To issue a registration certificate for the imported products, it is required to be registered and marketed in the country of origin or any of the approved reference countries for a period exceeding one year.

-The manufacturing or importing shall be carried out within 3 years from the issuance date of the registration certificate. In case of non-compliance, the registration certificate shall be canceled in accordance with the decision of the Technical Committee for Drug Control issued at the session dated on: October 4th, 2018.

-The company shall undertake to refrain from moving the manufacturing place or transferring its ownership except after obtaining an approval from the Central

Administration of Pharmaceutical Products, otherwise the registration certificate shall be cancelled.

-The company shall be committed to refrain from change the source of the active raw materials except after obtaining an approval from the Central Administration of Pharmaceutical Products, otherwise the registration cancelled shall be cancelled.

Second: The mechanism of applying for registration

Procedures of initiating the submission of a registration application of new veterinary pharmaceutical products:

A- For the locally manufactured veterinary products that will be marketed locally:

- The company shall be committed to submit an inquiry request via the electronic platform for registering veterinary products (EVERS) about (being the composition is a referential and possibility of registering the product) in accordance with the Appendix No. (1).

  * The company may submit an additional inquiry request after paying the prescribed service fee, with a maximum of two addition requests over the permitted number.

- The inquiry request shall be revised by the General Administration of Veterinary Products. The company shall be notified of the acceptance or rejection of the inquiry request (in case of rejection the reasons shall be indicated) via the electronic platform for veterinary products registration (EVERS) within a maximum period of five working days from the date in which the inquiry request was submitted.
- In case of there are documents required to be fulfilled in the inquiry request, the company must fulfill them within 3 working days, otherwise the inquiry request shall be null and void.
- In case of inquiry request acceptance, the company must submit a list of proposed names for the product (5 proposed names as a minimum and 20 proposed names as a maximum) within 25 working days from the date in which the inquiry request was accepted via the electronic platform for veterinary products registration (EVERS).

- The proposed names list of the product shall be reviewed and the name will be chosen within 9 working days from the date of submitting the list of the proposed names.
- In case of rejecting the first list of names, the company shall be notified, accordingly, the company must submit a list of other names within 15 working days from the date of notifying the company of the rejection, otherwise the inquiry request shall be cancelled.
- The company is allowed to submit a maximum of four proposed names lists, including the first list. In case of rejection the four submitted lists, the scientific name shall be written next to the company name mentioned in the commercial register.
- 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 date of notifying the company with the product chosen name, otherwise the inquiry request shall be considered null and void.

B- For the imported veterinary products that will be locally marketed:

- The company shall be committed to submit an inquiry request via the electronic platform for registering veterinary products (EVERS) about the composition being referential and the possibility of registering the product in accordance with Appendix No. (2).

  * The company may submit an additional inquiry request after paying the prescribed service fee, with a maximum of two requests over of the permitted number.

- The inquiry request shall be revised by the General Administration of Veterinary Products and the company shall be notified of the inquiry status in term of acceptance or rejection (in case of the rejection the reasons shall be explained) within a maximum period of five working days from the date in which the inquiry request was submitted.
- In case of there are documents required to be fulfilled in the inquiry request, the company must fulfill them within 3 working days, otherwise the inquiry request shall be null and void.
- In case of receiving a response indicating the accepting of the inquiry request, the similars box shall firstly be reviewed by the General Administration of Veterinary Products to know whether or not it has

available place for the imported veterinary product and the company shall be notified of whether or not there is an available place in the similars box within 15 working days starting from the date in which the company was notified of the acceptance of the inquiry request.

- The company shall be committed to submit the scientific file via the electronic platform for registering veterinary products (EVERS) within one month from the date in which it was notified of there is an available place in the similars box for imported veterinary products, otherwise, the inquiry request shall be null and void.

*** Presentation to the Specialized Scientific Committee for Veterinary Medicines 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 No. (3) 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 Medicines 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 Medicines 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, 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 Medicines and Feed Additives shall be issued within 14 working days from the date of the Scientific Committee.
- For the veterinary products that has an expired approval to proceed with the registration procedures, the company's request to complete the registration procedures shall be accepted in case of fulfilling the required registration procedures in terms of analysis in the Central Administration for Drug Control, obtaining a stability report from the General Administration for Stability and approval of the scientific leaflet from the Central Administration of Pharmaceutical Care and submitting the final registration file during the year following the expiration of the approval to proceed with registration procedures in accordance with the decision of the Technical

Committee for Drug Control dated on: May 23rd, 2017 regarding this matter. Noting that no petitions shall be accepted after expiry of the prescribed deadlines.

*** <u>During the validity period of the approval of proceeding with the registration procedures, the company is committed to fulfill the following, otherwise the registration application shall be cancelled</u>**

1- **<u>For locally manufactured products:</u>**

- Producing a pilot batch not less than the minimum of the operating capacity of the production line in the presence of an inspector from the Central Administration of Operations; all registration requirements shall be completed in accordance with the composition form on which the pilot batch was produced and the Central Administration of Operations shall withdraw samples from the pilot batch to be analyzed at the Central Administration for Drug Control.
- The Central Administration for Drug Control shall be addressed for obtaining a conformity report stating the source of the raw material accompanied with the composition form based on which the analysis was performed.
- Submitting the results of the six months accelerated stability study conducted on the pilot batch to be evaluated by the authority concerned with evaluating the stability studies at the Central Administration of Pharmaceutical Products. The stability report of the product stating the source of the raw material shall be obtained and the approved composition form shall be accompanied to.
- Applying to the Central Administration of Pharmaceutical Care after completing the stability and analysis studies or at the beginning of the last year of the validity of the approval of proceeding with the registration procedures, whichever is earlier and approving of the scientific leaflet.
- Submitting the final registration file via the electronic platform for registering the veterinary products (EVERS).

2- **<u>For imported products</u>**:

- The Central Administration of Pharmaceutical Control shall be applied for obtaining a conformity report accompanied by a composition form based on which the analysis was performed.

- The companies obtaining a registration and circulation 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 imported consignment after obtaining the final registration certificate. The competent department shall not release the first imported consignment until after issuance of the conformity result of the analysis.
- The product stability study that was conducted abroad shall be submitted for evaluation by the authority responsible for evaluating of the stability studies at the Central Administration of Pharmaceutical Products; Obtaining of the stability report of the product accompanied with the approved composition form.
- Applying to the Central Administration of Pharmaceutical Care to approve the scientific leaflet after completing the stability and analysis studies or at the beginning of the last year of the validity of the approval of proceeding with the registration procedures, whichever is earlier.
- Submitting the final registration file via the electronic platform for registering the veterinary products (EVERS).

*** <u>Submitting the final registration file and issuing the registration certificate:</u>**

- The final registration file shall be submitted via the electronic platform for registering veterinary products (EVERS) within the specified period in accordance with the Appendix No. (4)
- The file shall be initially evaluated. In case of failure to meet the basic conditions, the file shall be rejected and the uploaded documents shall be cancelled.
- The entire file shall be re-uploaded by the company, in case of the initial acceptance of the file, it shall be reviewed by the General Administration of Veterinary Products and the company shall be notified of the required documents within three months from the date in which the final registration file was submitted. The company shall be committed to submit the required documents within three months from the date in which it was notified with the required documents. This grace period is renewable for once after paying the prescribed service fee, otherwise, the registration application shall be cancelled.

- The required documents shall be revised within one month from the submission date. In case of failure, the company shall be notified via the electronic platform for the veterinary products registration (EVERS) and the company shall be committed to submit the completed and fulfilled required documents within a grace period of one month as a maximum from the date in which it was notified with the required documents, otherwise the registration application shall be cancelled.
- In case of failure to submit the required document again, the prescribed service fee shall be paid and the required documents shall be resubmitted within a period of one month as a maximum from the date in which the company was notified of the required documents. The required documents may be submitted for twice as a maximum, otherwise the registration application shall be cancelled.
- After fulfilling the registration file, it shall be presented to the Technical Committee for Drug Control in order to take the appropriate decision regarding whether or not to register the product. In case of approval by the Technical Committee for Drug Control, the final registration certificate valid for a period of ten years shall be issued.
- The decisions of the Technical Committee for Drug Control shall be issued within 14 working days from the date of the Committee.
- In case of non-approval, a letter of non-approval shall be issued to the company indicating the rejection reasons. The company may submit a petition to reconsider the Technical Committee for Drug Control final decision within 60 working days from the issuance date of the decision, provided that the petition shall fulfill all the technical justifications on which the petition is based as well as the petition shall be supported with the documents and information on which the company rely on when considering its petition.

5. Appendixes

Appendix No. (1)

1. A scanned copy of the original inquiry receipt (1,000 LE) stating the active ingredient, concentration and pharmaceutical form of the submitted product and indicating that it is a "new veterinary inquiry request", provided that the company's full name shall match the company name mentioned on the Toll Card or manufacturer's license.
2. A scanned copy of the original payment receipt of the fees for submitting an additional inquiry request (5,000 LE). The copy shall state the active ingredient, concentration and pharmaceutical form of the submitted product and indicating that it is a "new veterinary inquiry request", provided that the company full name shall match the company name mentioned on the Toll Card or manufacturer's license (up to two requests over the permitted number as a maximum).
3. A recent scientific reference proving that the composition is a referential (attached to the original certified translation whenever requested).

* The products registered in the Egyptian Drug Authority shall be relied on as a scientific reference for the submitted composition in case of the generic reference products' are not available.

* A copy of the most recent pharmacopeia to which the product belongs (in the case of the pharmacopeia products).

4. The Certificate of Pharmaceutical Product (CPP) (in case of the products manufactured locally under license from abroad.
5. A copy of the factory license of the registrant (for Local/F-Toll products).
6. A copy of the Toll manufacturing card. (For Toll products).
7. A copy of the commercial register (in case of the products submitted by factories under construction).
8. A copy of the registration license or Scientific Committee approval (in the case of the submitted products are (Line Extension).
9. A list showing the products of the toll companies and factories under construction.

Appendix No. (2)

1. A scanned copy of the original inquiry receipt of (1,000 LE) stating the active ingredient, concentration and pharmaceutical form of the submitted product and indicating that it is a "new veterinary inquiry request", provided that the company full name shall match the company name mentioned in the commercial registry.
2. A scanned copy of the original payment receipt of the fees for submitting an additional inquiry request of (5,000 LE). The copy shall state the active ingredient, concentration and pharmaceutical form of the submitted product and indicating that it is a "new veterinary inquiry request", provided that the full company name shall match the company name mentioned in the commercial register (maximum of two requests over the permitted number).
3. A recent scientific reference proving that the composition is a referential attached to the original certified translation whenever requested. (In case of the products imported from non-reference countries).
4. The Certificate of Pharmaceutical Product (CPP).
5. In case of the veterinary products (brand products), a proof by the responsible health authority proving that the submitted product is the "Innovator product", shall be provided.

Appendix No. (3)

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

For local products:

- Original fee payment fees receipt. (yellow).
- 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:

- 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:

- Original fees payment receipt (yellow).
- 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 (original and copy) 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' register for the imported products.
- A copy of the company's commercial register.

Appendix No. (4)

List of documents required to submit the final registration file for a veterinary product (local)

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. Fee payment receipts.
7. 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.
8. Certificate of product specifications on the factory letterhead signed and stamped by the responsible person in the factory.
9. 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.
10. 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.
11. 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.
12. An 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.

13. An undertaking to re-analyze the product (Evaluation and Accreditation Department) in case of the stability composition form differs from the composition form attached to the report of the Central Administration for Drug Control and on which the analysis was conducted in terms of inactive ingredients, stamped and signed by the chairman of the board of directors of the company owning the product or his representative under an official authorization.
14. A copy of a recent authorization for the company representative certified by a valid bank signature.

For local products:

- A copy of the license of the factory with suitable production line for manufacturing the product.

For Toll product:

- A 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 Legal Affairs Department (stipulating the validity period of the manufacturing contract).
- A copy of the factory license that has an appropriate production line for manufacturing the product.

For F-Toll products

- An authenticated and approved by Legal Affairs Department manufacturing contract and an appendix stating the product name, composition form and pharmaceutical form recent, notarized and approved by Legal Affairs Department. (A copy of the manufacturers' tax card).
- 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 license of the factory manufacturing the product that has an appropriate production line for producing the product.
- A copy of the license of the factory owning of the product.
- A valid storage contract, notarized and approved by Legal Affairs Department

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 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, Toll Under License.
- An appendix to the manufacturing contract stating the product name, composition form and pharmaceutical form, recent, notarized and approved by Legal Affairs Department (stipulating the validity period of the manufacturing contract) for Toll Under License products.
- An authenticated and approved by Legal Affairs Department 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 Legal Affairs Department, for F-Toll Under License products.

List of documents required for a veterinary product registration 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.
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. Reception and registration receipts.
7. 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.
8. Certificate of product specifications signed and stamped by the factory and on its letterhead.
9. 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.
10. A declaration to re-analyze the product (Evaluation and Accreditation Department) in case of the stability composition form differs from the composition form attached to the report of the Central Administration of Pharmaceutical Control, on which the analysis was conducted in terms of inactive ingredients. The declaration shall be stamped and signed by the Chairman of the company's Board of Directors or his representative under an official authorization.
11. Register of drug importers.

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.