Guideline

Central Administration for Pharmaceutical Products
General Administration For Veterinary Pharmaceuticals

Guidelines on Procedures for Re-registering Veterinary Pharmaceuticals According to the Chairman of Egyptian Drug Authority's Decision No. (434) Year 2022

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1. Introduction

The guidelines include the rules and procedures for re-registering veterinary pharmaceuticals according to the decision of the Chairman of the Egyptian Drug Authority (EDA) No. 434 of 2022.

2. Scope

The guidelines apply to locally manufactured or imported veterinary pharmaceuticals submitted to be re-registered for local marketing purposes.

3. Definitions

Veterinary pharmaceutical:

-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

<u>Locally manufactured veterinary pharmaceutical products</u>:

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

First: General rules

* This guideline applies to veterinary pharmaceuticals that are locally manufactured in factories inside the Arab Republic of Egypt, imported fully manufactured from abroad, or manufactured abroad and packaged in licensed facilities inside the Arab Republic of Egypt for local marketing.

* Locally manufactured or imported veterinary pharmaceuticals are re-registered every 10 (ten) years, provided that the company commits to submitting the scientific file via the Egyptian Veterinary Electronic Registration System (EVERS) platform during the last year of the validity of the registration certificate. Otherwise, the product will be cancelled.

* If the re-registration deadline is exceeded, the company will pay prescribed service fee for accepting the product file submission after the deadline. The prescribed service fee will be set according to the number of months of delay (3 months, 6 months, 9 months, or 12 months) and a maximum one year from the expiration date of the registration certificate.

* A product is granted approval to initiate the re-registration procedures, valid for a maximum period of 4 (four) years, starting from the expiration date of the registration certificate or from the date of approval to initiate the re-registration procedures, whichever is the later. This is intended to fulfil and complete the technical studies, requirements, approvals and attachments necessary to complete the re-registration procedures and submit the final re-registration file. During the aforementioned period, import, production, and trading may be permitted and authorized in accordance with the regulatory rules, unless any regulation, update, or decisions to the contrary are issued.

* If the approval for re-registration procedures expires, the validity may be extended for a maximum period of an additional year from the date of expiration. The extension can be granted upon submission of a request by the company, accompanied by an explanation for the reasons leading to the deadline extension. However, this extension is

subject to the company paying the required service fee for each six-month period that the extension covers.

* In case that all deadlines for approval to initiate re-registration procedures are exceeded without submitting the final re-registration file, a comprehensive report will be submitted. This report will include a study of the reasons for exceeding the deadline and an assessment of the completion of technical studies, requirements, approvals, and attachments necessary to obtain the final re-registration certificate. This report will be presented to the EDA Chairman for individual consideration through the GAVP within the CAPP to consider stopping the production of locally manufactured products or the import of imported products until the final registration certificate is obtained. Only production and import will be allowed to complete the re-registration procedures.

* All relevant regulatory divisions within EDA, each in its field of specialization, are obligated to providing information, through the application links, about the attachments necessary for the submission of applications and studies required to complete and submit the final re-registration file.

- Without prejudice to the original time limit specified for the validity of the approval to initiate the re-registration procedures, each head of a competent central administration is responsible for setting specific timeframes for the receipt, assessment, and submission of documents to various committees within their respective jurisdictions. Additionally, they will define the time limits granted to the company to fulfil necessary requirements and completions based on the nature of the procedure. To facilitate this process, each competent department will provide a checklist outlining the application process for the required service. This checklist will include information about necessary documents, procedures, specified dates and deadlines, application links, and applicable fees for scheduled services when required.

- Companies are obligated to apply for the registration at relevant central administrations in advance, aiming to fulfil the requirements and assess the technical studies necessary to submit the final re-registration file. This must be done well before the expiration of the approval to initiate the re-registration procedures. The process aims to ensure there is ample time for evaluation and necessary completions in accordance with the dates, deadlines and procedures specified by the relevant central administrations to receive files, evaluate studies, and present them to various committees.
- In case that any of the deadlines set for completing any of the procedures required by any of the relevant central administrations are exceeded, the company may submit to the relevant central administration a petition to grant an additional grace period. The petition must include the reasons that led to exceeding the deadline and the suggested corrective measures. If the application is accepted, the applicant will be required to pay fees for each additional period corresponding to each delayed month. However, the number of delayed months should not exceed the original time limit set for the validity of the approval to initiate re-registration procedures. Otherwise, the company must first submit a request to extend the validity of the approval to initiate the re-registration procedures to the CAPP. Once approved and after completing its procedures, the company can then submit a request to the competent central administration for an additional period to complete the required procedure.

* The company is required to include the following information on the outer packaging of the product:

1. The name and address of the factory, as specified in the factory license.
2. The name of the product owner.

For imported products, the applicant must include the name and address of the factory. It is permissible to use the name of the marketing authorization holder instead of the product owner, based on the submitted Certificate of Pharmaceutical Product (CPP).

* The company is committed to writing 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 must inform the Egyptian Pharmacovigilance Centre (EPVC) of any serious adverse effects detected on the veterinary product within 15 (fifteen) days. The company also undertakes to submit a Periodic Safety Update Report in accordance with the rules. Otherwise, the registration of the product will be stopped.

* The company is committed to ensuring that all data submitted in the product analysis file at the Central Administration for Drug Control are in conformity with what was submitted in the registration file at the CAPP and that all documents and data are correct and under its full responsibility.

* The applicant must commit to production or import within 3 (three) years from the issue date of the registration certificate. In case of non-compliance, the registration certificate shall be cancelled in accordance with the decision of the Technical Committee for Drug Control issued on October 4th, 2018.

* To issue a registration certificate for imported products, the product must be registered and marketed in the country of origin or any of the approved reference countries.

* The company is committed not to change manufacturing site or transfer ownership except after the CAPP approval. Otherwise, the registration certificate will be cancelled.

* The company is committed not to change the source of active raw materials except after the CAPP approval. Otherwise, the registration certificate will be cancelled.

Second: Re-registration application mechanism with relevant central administrations

Central Administration of Pharmaceutical Products (CAPP):

General Administration of Veterinary Pharmaceuticals (GAVP)

- The company is obligated to pay for the prescribed service fee for re-registering veterinary pharmaceuticals before submitting the scientific file via the EVERS platform.
- The scientific file is reviewed by the GAVP and the file's completions are sent to the company within one month from the date of submitting the scientific file via the EVERS platform, in accordance with Appendix 1.
- The company is required to provide the required completions in full via the EVERS platform within a maximum period of two months from the date of sending the completions, which can be renewed once after paying the prescribed service fees.
- Completions will be reviewed within one month from the date of submission. In case of an error, the company will be notified via the EVERS platform. The company is required to provide the needed completions in full within a maximum period of one month from the date of notifying the company of the completions.
- If there are repeated errors in the submitted completions, the prescribed service fees will be charged. The company will then be allowed to resubmit the corrected completions within a maximum period of one month from the date of notifying the company of the necessary completions.
- If any of the deadlines for completing the required procedures and submissions are exceeded, the company may submit a request for an additional similar period to fulfil the necessary procedure, including reasons for the delay. Payment of prescribed service fees for an additional similar period will be required.
- If the previous composition statement is not available, or in case of an amendment to the composition statement involving only inactive substances, the rules and standards for variation of registered veterinary pharmaceuticals will be applied.

The company must adhere to the obligations and deadlines provided to fulfil those requirements.

- Once the scientific file is complete, the product is submitted to the Specialized Scientific Committee for Veterinary pharmaceuticals and Feed Additives to provide an opinion on the re-registration request and approve the preliminary scientific data for the product. Reference products, which are in conformity with a reference product registered in one of the reference countries approved by the Technical Committee for Drug Control in terms of their active substances, concentrations, and pharmaceutical form, may be exempted from referral to the Scientific committee. This exemption is applicable if there is a registration certificate for the product, accompanied by the previously approved scientific data by the Scientific Committee, and the presence of updated scientific references for that data.
- If the Scientific Committee requests the company to provide some clarifications and completions for the final decision, the decision can be postponed and the company will be informed via the electronic platform of the reasons for the postponement. The company must submit the completion required by the committee within a month from the date of informing the company of the postponement decision, which can be renewed once after paying the prescribed service fee. The product is then re-referred to the Scientific Committee

* If the specified period is exceeded without completion, the company may submit a request for an additional similar period to complete the required procedure, including the reasons that led to exceeding the deadline. Payment of prescribed service fees for additional similar period will be required.

- If the scientific committee does not approve the re-registration, the request will be forwarded to the Technical Committee for Drug Control for a final decision. If the decision is upheld, a non-approval decision will be issued, outlining the reasons for rejection. The company has the option to submit a petition to reconsider the

final decision of the Technical Committee for Drug Control within 60 (sixty) working days from the issue date. The petition must include all technical justifications and be supported by the necessary documents and information. A decision on the petition will be made within 60 (sixty) working days from the day of its submission.

- If the scientific committee approves the re-registration, an approval will be issued to initiate the re-registration procedures. It's important to note that this approval is not considered final but is subject to review and potential amendment by the CAPP until the final re-registration certificate is obtained.
- The scientific committee decisions are issued within 14 (fourteen) working days from the date of the Scientific Committee's decision.
- The company is committed to submitting the final re-registration file within the specified period, fulfilling all requirements for re-registration, taking into account the following:

* Submitting a long-term stability study for re-registration. Products are exempt from submitting the aforementioned stability study if the following conditions are met:

- The product had been re-registered at least once and obtained a stability study evaluation report for re-registration by the specialized scientific committee to evaluate stability studies. The previously issued stability approval must be completed for all data necessary to complete the product re-registration file, with a commitment to applying the rules followed in the case of making any change in the product according to the mechanism of the general administration of stability.
- The source of the raw material on which a re-registration stability study was conducted must be adhered to when submitting the final registration file. If the company wishes to add other sources of raw material, it will be required to submit a request to the Variation Department to obtain approval.

* The applicant shall update the analysis file at the Central Administration of Drug Control and complete the requirements for variation in case the product's composition is unrecognized or if the composition or specifications modification. A request should be submitted to the Variation Department to obtain a transfer letter to update the analysis file after obtaining approval to initiate the re-registration process.

* If the applicant company has submitted a final re-registration file for its products to the examination unit before the decision is issued, it has the option to submit a transfer letter to update the analysis file. The company must also provide a declaration expressing its commitment to updating the analysis file with Central Administration of Drug Control after the issuance of the registration certificate. This commitment becomes a prerequisite for the release of the first production batch.

* Submission to the Central Administration of Pharmaceutical Care (CAPC) to approve the scientific leaflet.

- The final re-registration file should be submitted within the specified period in accordance with Appendix 2 on the EVERS platform.
- The file is initially evaluated. If the basic conditions are not met, the file will be rejected and the uploaded documents will be cancelled. The company have to re-submit the entire file again.
- If the file is initially accepted, it will be reviewed by the GAVP, and the company will be notified of the required completions within three months from the date of submitting the final re-registration file. The company has to submit the required completions within three months from the date of notifying the company of the completions, and this period can be renewed once after paying the prescribed service fee.
- The completions will be reviewed within one month from the date of submission. If any errors are identified, the company will be notified through the EVERS platform. The company is obligated to submit the required completions within a

maximum period of one month from the date of notification regarding the identified errors.

- If there are repeated errors in the submitted completions, the company has to pay the prescribed service fee. Subsequently, the company must resubmit the completions within a maximum period of one month from the date of being notified about the required completions.
- If the company exceeds any of the deadlines set for completing the required procedures and completions, it has the option to submit a petition requesting an additional similar deadline. This petition should include the reasons for surpassing the specified deadline, and the company is required to pay the prescribed service fee of obtaining the additional similar deadline.
- The product undergoes evaluation by the Technical Committee for Drug Control after the completion of the re-registration file. If the committee approves, the product is re-registered for an additional 10 (ten) years using the same registration number. A registration certificate is issued for the remaining period, calculated from the expiration date of the registration certificate. An extra registration period of 10 (ten) years may also be granted, provided that the prescribed fees for re-registration are paid, and if the remaining registration period is five years or less.
- If the Technical Committee for Drug Control does not approve the re-registration, the company will be issued a letter of non-approval explaining the reasons for rejection. The company has the opportunity to submit a petition to reconsider the final decision within 60 (sixty) working days from the date of issuance. The petition must include all necessary technical justifications and be supported by relevant documents and information. A decision on the petition will be made within 60 (sixty) working days from the date of its submission.
- The decisions of the Technical Committee for Drug Control are issued within 14 (fourteen) working days from the date of committee

General Administration of Stability

- Products under re-registration are exempted from submitting the stability study required for re-registration, on the condition that the stability study conducted on the production batches of this product has previously been evaluated by the competent committee for evaluating stability studies.
- The previously issued stability approval for the purpose of re-registration is considered to contain all the data necessary to complete the product re-registration file, with a commitment to the applicable rules in case of any change in the product, according to the following:

A. The product must have obtained a previous re-registration certificate

B. The full name of the product, the names of the active ingredients, their concentrations and the amount of equivalent salt, if any, the dosage form, the name of the company submitting the re-registration application, and the name of the manufacturer.

- If the above-mentioned is not met, a referral will be made to the Department of Regulatory Affairs for Veterinary Products at the GAVP for the company to submit a declaration on the company's letterhead from its legal representative, signed and detailing the required data.

C. Name of the active raw material supplier

- If the above-mentioned requirements are not met, the case will be referred to the Department of Regulatory Affairs for Veterinary Products at the GAVP. The company will be required to submit a declaration on the company's letterhead from its legal representative, signed and indicating the name of the factory that produced the active raw material used in manufacturing the production batches for which the stability study for re-registration was conducted. Additionally, the company should submit evidence proving the manufacturing of the product from that source, such as an inspection report.

D. Physical properties, the packaging in detailed form and in various sizes, if any, showing all the manufacturing materials, including primary and secondary packaging materials, the decision of the specialized scientific committee to evaluate stability studies, explaining the shelf life and complete storage conditions according to the pharmaceutical form, in accordance with the stipulated rules for stability studies. The purpose of the study should be re-registration.

- In use shelf, diluent, solvent and its volume, storage conditions, dilution or reconstitution, shelf life after opening, etc.
- If the above is not completed, go to the General Administration of Stability to complete the required data.

E. A composition statement attached to the stability approval

- If the above-mentioned information is not complete, go to the General Administration of Stability to complete the required data.

F. A composition statement on which a stability study was conducted, showing the specifications for both active and inactive materials for approvals issued beginning in 2018 only, and a finished product specification certificate for approvals issued beginning in 2018.

- If the above-mentioned are not met regarding the approvals issued beginning in 2018, the company will head to the General Administration of Stability to complete the required data.
- If the requirements mentioned above are not met for approvals issued before 2018, the company should approach the Department of Regulatory Affairs for Veterinary Pharmaceuticals at the GAVP. The company is required to submit a declaration on its letterhead, signed by its legal representative, providing the necessary data. Additionally, the company should attach a certificate of updating the analysis file with the following attachments (a final analysis report for the product, the approved final composition statement, and a certificate of product

specifications) from the Central Administration for Drug Control laboratories at the EDA.

- It is the company's responsibility to ensure that the stability approval issued for the purpose of re-registration has been fulfilled for all data as stated above before submitting the final re-registration file to the GAVP.

Central Administration for Drug Control (CADC)

- The company that owns the product under re-registration is required to submit a request to the Variation Department of registered veterinary pharmaceuticals at the GAVP to update the analysis file. This request is necessary to obtain the essential transfer letter.
- The CADC shall study the status of the product to issue a certificate of updating the analysis file for a registered veterinary product, which shall be accompanied by the final analysis report for the product and a statement of the final composition approved by the EDA's laboratories as well as the specifications of the final product.
- In cases that require analysis at the Evaluation and Accreditation Department, and before the final re-registration certificate is issued, samples obtained from the product are delivered for analysis to the CADC at the Evaluation and Accreditation Department through Central Administration of Operations, without stopping the release of the production batch from which it was withdrawn based on a written declaration from the company's legal representative on the company's letterhead, signed and indicating the company's full responsibility. The Central Administration of Operations shall follow up on this process.
- If the company wishes to apply for fulfilling the re-registration requirements with the CAPP, using a final report issued by the Evaluation and Accreditation Department within one calendar year from the date of approval of the CADC final report, the company that owns the product may submit a request to obtain a statement from CADC, indicating that the final report on the product issued by

the Evaluation and Accreditation Department was updated as part of the procedures for examining the product file before analysis.

- **Central Administration of Operations (CAO)**

General Administration for Inspection of Veterinary Pharmaceutical Factories

- With regard to products imported from a non-reference country and not markted in a reference country, whether they are finished or in the bulk form packaged in Egypt, the company is obligated to approach the General Administration for Inspection of Veterinary Pharmaceutical Factories to set the next inspection dates in accordance with the risk-based inspection planning.

5. Appendixes

Appendix No. 1

A list of documents required to submit the scientific file to re-register a local veterinary pharmaceutical product:

1. A copy of the previous registration certificate,
2. Proof of production of the product,
3. A statement of the previously registered composition approved by the CADC or CAO,
4. A copy of the previous CADC report,
5. An original payment receipt for the re-registration service fee for a local product,
6. A composition statement on the letterhead of the company that owns the product, stating the name of the manufacturer, including the active and inactive ingredients, their concentrations, functions, and specifications, according to the latest edition of the Pharmacopoeia, signed and stamped,
7. A certificate of preliminary scientific data for the product on company letterhead, signed and stamped, supported by the necessary references,
8. A declaration indicating the volumes of injection packages to be registered, signed and stamped on company letterhead,
9. A signed and stamped letter from the company, explaining the method of calculating the salt and base equivalent, if any, supported by references (pharmacopeia of the active ingredient),
10. A recent scientific reference proving the reference formula, if available, with an attached certified translation, if required.

The following are also required:

Local products and F-Toll:

- A copy of the manufacturing license of the applicant.

In the case of manufacturing under license, the following will be required, in addition to the above:

- A manufacturing contract with a license authenticated by the Chamber of Commerce and the Egyptian embassy abroad, unless there are international agreements to the contrary,
- Official authorization for registration/manufacturing with a license authenticated by the Chamber of Commerce and the Egyptian embassy abroad,
- A CPP from the country of origin issued by the Ministry of Health or the Ministry of Agriculture and notarized by the Egyptian embassy abroad,
- A copy of the Toll card of the product (Toll under License),
- A manufacturing contract and an Appendix stating the product's name, composition and pharmaceutical form, notarized and approved by the Legal Affairs Toll/F-Toll Under License.

If the product is manufactured by a third party, the following will be required, in addition to the above:

- A copy of the registration license in the Toll company's registry.

List of documents required to submit a scientific file with the purpose of re-registering an imported veterinary pharmaceutical

1. A copy of the previous registration certificate,
2. Proof of import of the product,

3. A statement of the previously registered composition approved by the CADC or CAO,
4. A copy of the previous CADC report,
5. An original payment receipt of re-registration service for an imported product,
6. A composition statement on the foreign company's letterhead, indicating the factory name, active and inactive ingredients, their concentrations, functions, and specifications, according to the latest edition of Pharmacopeia, signed and stamped,
7. A certificate of preliminary scientific data for the product on company letterhead, signed and stamped, supported by the necessary references,
8. A declaration of the volumes of the injection packages to be registered, signed and stamped on company letterhead,
9. A CPP from the country of origin issued by the Ministry of Health or the Ministry of Agriculture and notarized by the Egyptian embassy abroad,
10. A contract of agency or official authorization notarized by the Chamber of Commerce and the Egyptian embassy abroad,
11. A copy of the Good Manufacturing Practice (GMP) certificate of the factory abroad, if it is not indicated in the CPP of the product,
12. A copy of the drug importer's register for imported products, if any.
13. A copy of the company's commercial register.

Appendix No. 2

List of documents required to submit the final file to re-register a "local" veterinary pharmaceutical

1. A data certificate for a local veterinary pharmaceutical, signed and stamped by the Chairman of the Company's Board of Directors or his/her representative with official authorization,
2. Copies of the previous registration certificate,
3. A copy of Scientific approval,
4. A copy of the General Administration of Stability's report or a previous stability approval issued for the purpose of re-registration, containing all the necessary data,
5. Previous report of central administration of drug control (CADC) and the original previously registered composition statement,
6. A copy of the Variation Committee's approval of registered pharmaceutical products, accompanied by a copy of the approved composition statement, if any,
7. A copy of a document proving that the requirements for the variations, if any, have been done,
8. A copy of the certificate of updating the analysis file for a registered veterinary Medicinal product, accompanied by the final analysis report for the product,
9. Receipts for registration,
10. A composition statement on the company letterhead, signed and stamped by the person in charge, stating the name of the manufacturer, the product's functions, and specifications of active and inactive ingredients, according to the latest Pharmacopeia edition,
11. A certificate of specifications for the product on factory letterhead, signed and stamped by the person in charge,

12. The scientific leaflet on the company letterhead, signed and stamped by the person in charge. It should be in conformity with the scientific leaflet approved by the Central Administration for Pharmaceutical Care, stating the packages and storage conditions in conformity with the content of the stability report,
13. In-house specifications for non-pharmacopeia active substances on factory letterhead, signed and stamped. In case the active substance is pharmacopeia, the results mentioned in the In-House Specifications must be within the permissible range mentioned in the constitution,
14. A declaration from the company stating the name of the factory that manufactures the raw active material on the company's letterhead, signed and stamped by the Chairman of the Board of Directors of the company that owns the product or his/her authorized representative,
15. A certificate of analysis of the raw active material from the factory that manufactures the active material, signed and stamped by the Chairman of the Board of Directors of the company that owns the product or his/her authorized representative,
16. A copy of a recent delegation for the company's representative, authenticated as having a valid bank signature. In case of delegating another person to sign on behalf of the Chairman of the Board of Directors, the delegation must be sent with a valid bank signature on the file papers.

For local products, the following are required:

- A copy of the factory's license indicating the appropriate production line that manufactures the product.

For Toll products, the following are required:

- A Toll card stating the name of the factory that manufactures the product and the storage site,

- A recent annex to the manufacturing contract stating the product's name, composition, and pharmaceutical form (or the registration number for the product), notarized and certified by Legal Affairs Department, including the date of the original contract and its validity period, with the necessity that any amendment to the annex to be stamped and signed by the factory official,

**If the company desires to make a manufacturing transfer, the manufacturing transfer request must be submitted to the Variation Departement before uploading the file via the EVERS platform so that the file is not considered submitted on improper factory letterhead and thus the file is rejected.

- A copy of the factory's license indicating the appropriate production line for manufacturing the product.

As for F-Toll products, the following are required:

- A manufacturing contract and an annex stating the product's name, composition and pharmaceutical form, notarized and certified by Legal Affairs Department,
- A copy of the manufacturers' tax card,
- A copy of the commercial register of the two factories, taking into consideration that the owner of the product's commercial register mentions the third-party manufacture category,
- A copy of the license of the factory that manufactures the product and has the appropriate production line to manufacture the product,
- A copy of the license of the factory who owns the product,
- A valid storage contract, notarized and certified by Legal Affairs Department.

Regarding under-license products, the following are required:

- A manufacturing contract with a license notarized by the Chamber of Commerce and the Egyptian embassy abroad, unless there are international agreements stating otherwise,

- Official delegation for registration/manufacturing with a license notarized by the Chamber of Commerce and the Egyptian embassy abroad,
- An original CPP from the country of origin issued by the Ministry of Health or the Ministry of Agriculture and notarized by the Egyptian embassy abroad,
- A copy of the license of the factory that manufactures the product and has an appropriate production line to manufacture the product,
- The Toll Manufacturing card stating the name of the factory that manufactures the product and the name of the storage site for Toll under-license products,
- An annex to the manufacturing contract stating the product's name, composition and pharmaceutical form, notarized and certified by the Legal Affairs Department (stating the validity period of the manufacturing contract) for Toll under-license products,
- A manufacturing contract and an annex stating the product's name, composition and pharmaceutical form, notarized and certified by the Legal Affairs Department for the F-Toll under-license products.
- A valid storage contract, notarized and certified by Legal Affairs Department for the F-Toll under-license products.

List of documents required to submit the final file to re-register an imported veterinary pharmaceutical

1. A veterinary pharmaceutical data certificate for re-registration of an imported product,
2. A copy of the previous registration certificate,
3. A copy of the scientific committee approval,
4. A copy of the General Administration of Stability's report or a previous stability approval report issued for the purpose of re-registration, includes all the necessary data,
5. Previous report of central administration of drug control (CADC) and the original previously registered composition statement,
6. A copy of the Variantion Committee's approval of registered pharmaceutical products, accompanied by a copy of the approved composition statement, if any,
7. A copy of a document proving that the requirements for the variation, if any, have been done,
8. A copy of the certificate of updating the analysis file for a registered veterinary Medicinal product, accompanied by the product's final analysis report, the final approved composition statement, and the product's certificate of specifications issued by the CADC laboratories,
9. Receipts of reception and registration,
10. A composition statement on the letterhead of the company that owns the product abroad, signed and stamped, stating the manufacturer's name, as well as the functions and specifications of the active and inactive ingredients, according to the latest Pharmacopeia edition, indicating the name of the factory if different from the license holder,

11. A certificate of specifications for the product on factory letterhead, signed and stamped by the factory,
12. A leaflet on the letterhead of the company that owns the product abroad, signed and stamped and in conformity with the leaflet approved by the Central Administration for Pharmaceutical Care, stating the containers and storage conditions and is in conformity with the General Administration of Stability's report,
13. A copy of the drug importers' register,
14. An original CPP from the country of origin issued by the Ministry of Health or the Ministry of Agriculture and authenticated by the Egyptian embassy abroad,
15. A copy of the GMP of the factory abroad, if not indicated in the product's CPP,
16. An agency agreement or an official authorization of registration notarized by the Chamber of Commerce and the Egyptian embassy abroad,
17. A copy of a recent authorization for the company's representative certified by a valid bank signature,
18. The company's commercial register,
19. 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.

6. Versions

Version	Issue date	Places of amendment
First version	7/8/2022	
Second version	10/2023	- General rules - Application via the electronic platform EVERS - Transfer letter for updating analysis file - Central Administration for Drug Control (CADC) - Central Administration of Operations (CAO) - Appendixes