Central Administration of Pharmaceuticals Products
General Administration of Veterinary Pharmaceuticals

Notice to Applicant on Submitting the Final (Registration/ Re-registration) File for the year 2023

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1- Introduction:

The final file of (registration/ re-registration) shall be submitted via the electronic system of EVERS platform.

2- General Requirements:

- Adherence to uploading the exactly required documents; nothing more, nothing less.

- The file shall be initially reviewed by junior pharmacists to ensure that it fulfills all the required documents until file reception is accepted.

- Making sure, when uploading the file to the platform, that the reference name is correctly written in the field designated therefor and that it is in conformity with the reference name mentioned in the country of origin, along with mentioning the concentration of the product in the case that there is more than one concentration in the country of origin.

- Selecting the country of origin of the reference product from the drop list of the reference country.

- Adherence to precisely selecting the name of the factory that manufactures the raw material from the drop list of the suppliers in a way that is exactly in conformity with the certificate of analysis of the raw material attached to the file. In case the name does not match the name mentioned in the certificate of analysis of the raw material, contact shall be made first with the General Administration of Veterinary Pharmaceuticals **before uploading the file** so that we can add the name to the drop list.

- In case the company desires to apply for manufacturing site change, a cover letter requesting an under-registration manufacturing transfer shall be uploaded with the file, provided that a modification of the under-registration manufacturing transfer shall be submitted **after the file is uploaded to the platform**.

Guideline on Submitting the Final Registration File (New Registration)

The document required to be submitted	Requirements to be observed

1- A data certificate of a veterinary product	* The certificate shall be in case the template of the registration type (local/ imported). * The data certificate shall be printed on the company's letterhead, compiled on one page, signed and stamped by the chairperson of the company's board of directors or his representative with an official authorization to sign. * The product name and pharmaceutical form shall be in conformity with the Scientific Committee approval. * The company name shall be in conformity with the factory license/toll card, being mindful of the need to ensure that that it matches the name registered in the company profile * The factory name shall be in conformity with the name mentioned in the Central Administration of Drug Control Report or uploading a proof of the product manufacturing site change, while verifying that the factory is enrolled in the toll card. * The Storage site shall be the one indicated in the toll card. In case that the contract period expires, a new, valid contract which is certified by the legal counsel shall be uploaded. (This does not apply to expired storage contracts with factories). * The shelf life, storage conditions, and packaging shall be in conformity with the stability report. In case that a modification exists, any previously submitted modifications shall be uploaded to the General Administration of Stability or a modification with the requested variation(s) shall be submitted. * The reference name shall be written in accordance with any of the following: - The reference provided in the inquiry request, if it is valid. - The reference provided in the scientific file for being presentation to the scientific committee, if it is valid. - Any reference that is in conformity with the composition and pharmaceutical form, while making sure that it is valid and its country of origin is selected.

	* In case that a current reference is not available, a modification shall be submitted to complete the registration procedures without a reference after being reviewed by the junior pharmacist.
2- A copy of the scientific committee approval for proceeding with registration procedures.	* It is required also to submit the leaflet attached thereto.
3- A copy of the report of the Central Administration for Drug Control.	* It is required also to send the composition form attached thereto.
4- A copy of the report of the General Administration of Stability	* It is required also to send the certificate of analysis and the composition form attached thereto.
5- The scientific leaflet approved by the Central Administration of Pharmaceutical Care.	* It is required also to upload it in the same field designated for uploading the product's Scientific Committee approval on the platform. (The same PDF with the Scientific Committee approval issued by the General Administration of Veterinary Pharmaceuticals)
6- Payment receipts of hard file fees (mandatory/extra)	* Medical stamp receipt (the white one) + deadline extension receipt, in case it may be requested, along with writing the receipt number in the designated field on the platform.
7- The composition form printed on the letterhead of the product-owning company, and stating the manufacturer name, the specifications, and the functions of both active and inactive ingredients in their latest versions signed and stamped by the person in charge.	* The name of the factory and the company shall be written in accordance with the rules previously explained in the requirements to be observed in the data certificate. * USP/BP/EP specifications shall be written only in the table in the case of pharmacopeia active or inactive materials, being mindful of writing the phrase "According to the latest edition" at the bottom of the table. * In case there is a discrepancy in the inactive ingredients despite complying with the composition form attached to the stability approval, a declaration shall be uploaded to re-analyze the product from the first production batch. * In case that there is a discrepancy between the composition form of the stability and that of the laboratories, a modification explaining the reasons for the discrepancy shall be submitted in order to write to the party in which the modification shall be made.

8- A Certificate of Analysis of the Product/Finished Product Specifications, which certificate shall be printed on factory letterhead, signed and stamped by the factory.	* Making sure that the certificate is printed on the letterhead of the manufacturing factory, not on the letterhead of the product-owning factory in the case of F-Toll products. * Making sure that the product name and pharmaceutical form are written on the certificate. * In case of requesting a modification in the certificate of analysis of the product specifications, a new certificate shall be brought from the factory stamped and signed by the factory. Modification cannot be made in the certificate by the product-owning company. * In case that there is a discrepancy between the product specification certificate of analysis attached to the stability report and the Central Administration of Drug Control Report, a modification explaining the reasons for the discrepancy shall be submitted in order to write to the party in which the modification shall be made.
9- The signed and sealed scientific insert leaflet, which is printed on the product-owning company letterhead, and which is approved by the Central Administration of Pharmaceutical Care.	* The dose of the active ingredient shall be removed from the leaflet. * The storage and packaging conditions mentioned in the stability report shall be adhered to. * The name of the factory and the company shall be written in accordance with the rules previously explained in the requirements to be observed in the data certificate.
10- In-House Specifications of active ingredients (non-pharmacopeias) that are printed on the factory letterhead, signed and stamped. In case that the substance is in pharmacopeias, the results mentioned in in-house specifications must be within the permissible range mentioned in the pharmacopeias.	* Making sure that the specifications are printed on the letterhead of the manufacturing factory, not on the letterhead of the product-owning factory in the case of F-Toll products, being mindful of the rules previously explained in the product specifications certificate. * The approved pharmacopeias of the active ingredient shall be attached for perusal and revision in case that the substance is in pharmacopeias.
11- A declaration by the company stating the name of the factory that manufactures the raw (active) material printed on the company's letterhead, stamped and signed by the	*The declaration shall be directed to the Egyptian Drug Authority, adhering to the following formula: • The company shall also undertakes to provide a copy of the GMP certificate and the certificate of analysis of the raw material,

chairperson of the board of directors of the product-owning company or his representative with an official authorization.	when applying for importing the raw material to the Egyptian Drug Authority (Central Administration for Pharmaceutical Policies and Market Access).
12- A certificate of analysis of raw (active) materials from the factory that manufactures the active material stamped and signed by the chairperson of the board of directors of the product-owning company or his representative with an official authorization.	* The certificate shall be signed and stamped from abroad, taking into account the following: * The supplier's GMP shall be attached in case that the country of origin is not mentioned in the certificate. * Making sure that the pharmacopeia mentioned in the composition form is among the pharmacopeias to which the certificate belongs. * In case that the certificate belongs to the in-house specifications as well as the approved pharmacopeias, the additional in-house tests shall be stated in the certificate.
13- A declaration of product re-analysis (at the administration of evaluation and approval) in case that the composition form of stability differs from the composition form attached to the Central Administration of Drug Control Report on which the analysis has been conducted.	* The declaration shall be uploaded only if the composition form of stability differs from the composition form attached to the Central Administration of Drug Control Report on which the analysis has been conducted.
14- A copy of a recent delegation for the company representative authenticated by a valid bank signature.	* The signature delegation authenticated by a valid bank signature shall be uploaded in case that another authorized person signs the file papers, noting that the delegation validity period is only one year from the date of its signature.
For local products: - A copy of the manufacturer license with a suitable production line that is appropriate for producing the product.	

For toll products: - A toll manufacturing card that includes the name of the factory that manufactures the product and the name of the store. - A recent, notarized manufacturer contract annex, which is approved by the legal affairs and which states the name of the product, composition and pharmaceutical form, and the validity period of the manufacturing contract. - A copy of the manufacturer license with a suitable production line that is appropriate for manufacturing the product.	* Making sure that the toll card is valid in accordance with the regulatory guide of the requirements for registering companies in the registry of toll manufacturing companies. * The following sentence shall be written: This is an annex of the manufacturer contract dated on ..... and valid for a period of ....., and this annex is effective as of the manufacturer contract. It is required that this modification shall be stamped by the signature and the seal of the manufacturer. * No amendment to the date of the contract or the annex is accepted (no deletion or crossing out is permitted).
For F-Toll products: A manufacturing contract with an annex stating the name of the product to be manufactured, which annex shall be authenticated and approved by the legal researcher. - A copy of the manufacturers' tax card. - A copy of the manufacturers' commercial register. - A copy of the license of the manufacturer of the product and that has the production line that is appropriate for producing the product. - A valid storage contract authenticated and approved by Legal Affairs.	The following requirements shall be taken into account in the case of F-Toll products - A copy of the license of the manufacturer of the product shall be attached. - The commercial register of the product-owning manufacturer shall indicate the item of toll manufacturing.
For under-license products:	Documents required according to the type of the product registration:

- A manufacturing under-license agreement attested by the Chamber of Commerce and notarized by the Egyptian Embassy abroad, unless provided otherwise in the international agreements. - An official agency agreement / power of attorney for registration/ manufacturing under-license agreement that is attested by the Chamber of Commerce and notarized by the Egyptian Embassy abroad. - An original certificate of pharmaceutical product (CPP) from the country of origin issued by the Ministry of Health or the Ministry of Agriculture and notarized by the Egyptian embassy abroad. - Documents required according to the type of the product registration shall also be observed.	<u>In case of local under-license:</u> Manufacturer License <u>In case of Toll under-license:</u> Toll Card Manufacturer Contract Annex <u>In case of F-Toll under-license:</u> Manufacturing Contract with annex Storage Contract
<u>For imported products:</u> - A formulation composition printed on the letterhead of the product-owning company abroad, stating the name of the manufacturer in case the manufacturer is different from the license holder, and stating the functions and specifications of the active and inactive ingredients. - A finished product Specifications, printed on the letterhead of the manufacturer abroad, signed and stamped by the manufacturer. - The scientific insert leaflet, which is printed on the letterhead of the	* The register of importers shall be valid and shall state the name of the warehouse. * The company shall have a commercial register that states the activity of registering medical products, or it shall provide a declaration that it shall add this activity within six months from the date of issuing the license.

product-owning company abroad, and which states the name of the manufacturer in case the manufacturer is different from the license holder. - Register of importers. - An original certificate of pharmaceutical product (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 GMP of the factory abroad (if it is not indicated in the CPP of the product) - An official agency agreement / power of attorney for registration that is attested by the Chamber of Commerce and notarized by the Egyptian Embassy abroad. - A copy of a recent delegation for the company representative, which company representative delegation shall be authenticated by a valid bank signature. - The company's commercial register.	

Guideline on Submitting the Final File of (Re-registration)

The document to be submitted	Requirements to be observed
1. A data certificate of a veterinary product.	* The certificate shall be in case the template of the registration type (local/ imported). * The data certificate shall be printed on the company's letterhead, compiled on one page, signed and stamped by the chairperson of the company's board of directors. * The product name and dosage form shall be in case the scientific committee approval. * The company name shall be in conformity with the factory license/toll card, keeping in consideration the need to ensure that it matches the name registered in the company profile * The factory name shall be in conformity with the name mentioned in the Central Administration of Drug Control Report or uploading a proof of the product manufacturing site change, while verifying that the factory is enrolled in the toll card. * The storage site shall be the one indicated in the toll card. In case that the contract period expires, a new, valid contract which is certified by the legal counsel shall be uploaded. (This does not apply to expired storage contracts with factories). * The shelf life, storage conditions, and packaging shall be in conformity with the stability report. In case that a modification exists, any previously submitted modifications shall be uploaded to the General Administration of Stability or a modification with the requested variation(s) shall be submitted. * The reference name shall be written as it was provided in the inquiry request / presentation to the scientific committee or in any reference that is in conformity with the composition and pharmaceutical form, while making sure that it is valid and its country of origin is selected. In case that a current reference is not available, a

	modification shall be submitted to complete the registration procedures without a reference after being reviewed by the junior pharmacist.
2. A copy of the previous old registration certificate.	* This copy shall be attached to composition form + approved leaflet (if present)
3. A copy of the scientific committee approval for proceeding with re-registration procedures.	* It is required also to submit the leaflet attached thereto.
4. A copy of the General Administration of Stability report or a previous stability approval that is issued for the purpose of re-registration and that fulfills all required data.	* In case that the company brings a stability approval for any of the variations that the product has undergone and the company is desirous to consider it a stability approval for the purpose of re-registration, the company shall address the General Administration of Stability to submit a petition and bring a proof of such approval.
5. The Central Administration for Drug Control Report (NODCAR Report) along with the previously registered composition form.	* Or a statement indicating that there is no evidence of conformity or composition form from the Central Administration for Drug Control.
6. A copy of registered pharmaceutical products' Variation Committee approval with a copy of approved composition form (if present)	* Documents proving that variation requirements are fulfilled shall be uploaded.
7. A copy of analysis file update certificate attached to the final product analysis report, the approved final composition form, and the product specifications certificate from the Authority's laboratories at the Central Administration for Drug Control. Analysis file update certificate or/Variation transfer letter with declaration of re-analysis.	* The request for analysis file update shall be submitted to the Department of Variation before submitting the registration file. * Products that submitted a request for re-registration before the issuance of Decree No. (434) may submit a transfer letter to update the analysis file with an attached declaration to update the analysis file and to conduct withdrawal for the analysis from the first production batch as a condition for releasing the batch (taking into consideration that the declaration shall be uploaded in the same Attachment of the transfer letter)

8. The scientific leaflet approved by the Central Administration of Pharmaceutical Care.	* It is also required to upload it in the same field designated for uploading the product's Scientific Committee approval on the platform. (The same PDF with the Scientific Committee approval issued by the General Administration of Veterinary Pharmaceuticals)
9. Receipts of reception and registration. Hard File Fees are mandatory.	* Medical stamp receipt (the white one). In case that the remaining period of registration license is (five years or less), the company is allowed to submit a Cover Letter to extend the license period along with paying the prescribed fees (along with submitting the number of the re-registration renewal receipt in the designated field).
10- The formulation composition printed on the letterhead of the product-owning company, and stating the manufacturer name, the specifications, and the functions of both active and inactive ingredients according to the latest edition signed and stamped by the person in charge.	* The name of the factory and the company shall be written in accordance with the rules previously clarified in the requirements to be observed in the data certificate. * USP/BP/EP specifications shall only be written in the table in case of pharmacopeia active or inactive materials, keeping in consideration writing the phrase "According to the latest edition" at the bottom of the table.
11. A Certificate of Analysis of the Product/Finished Product Specifications printed on factory letterhead, signed and stamped by the factory.	* Making sure that the certificate is printed on the letterhead of the manufacturing factory, not on the letterhead of the product-owning factory in the case of F-Toll products. * Making sure that the product name and pharmaceutical form are written on the certificate. * In case of requesting a modification in the certificate of analysis of the product specifications, a new certificate shall be brought from the factory with the original stamp and seal of the factory. Modification cannot be made in the certificate by the product-owning company.
12. The scientific insert leaflet, which is printed on the product-owning company letterhead, signed and stamped by the person in charge, and approved by the	* The dose of the active ingredient shall be removed from the leaflet.

Central Administration of Pharmaceutical Care.	* The storage and packaging conditions mentioned in the stability report shall be adhered to. * The name of the factory and the company shall be written in accordance with the rules previously clarified in the requirements to be observed in the data certificate.
13. In-House Specifications of active ingredients (non-pharmacopeias) that are printed on the factory letterhead, signed and stamped. In case that the substance is in pharmacopeias, the results mentioned in in-house specifications must be within the permissible range mentioned in the pharmacopeias.	* Making sure that the specifications are printed on the letterhead of the manufacturing factory, not on the letterhead of the product-owning factory in the case of F-Toll products, being mindful of the rules previously explained in the product specifications certificate. * The approved pharmacopeias of the active ingredient shall be attached for perusal and revision in case that the substance is in pharmacopeias.
14. A declaration by the company stating the name of the factory that manufactures the raw (active) material printed on the company's letterhead, stamped and signed by the chairperson of the board of directors of the product-owning company or his representative with an official authorization.	*The declaration shall be directed to the Egyptian Drug Authority, adhering to the following formula: • The company shall also undertakes to provide a copy of the GMP certificate and the certificate of analysis of the raw material, when applying for importing the raw material to the Egyptian Drug Authority (Central Administration for Pharmaceutical Policies and Market Access).
15. A certificate of analysis of raw (active) materials from the factory that manufactures the active material stamped and signed by the chairperson of the board of directors of the product-owning company or his representative with an official authorization.	* The certificate shall be signed and stamped from abroad, taking into account the following: * The supplier's GMP shall be attached in case that the country of origin is not mentioned in the certificate. * Making sure that the pharmacopeia mentioned in the composition form is among the pharmacopeias to which the certificate belongs. * In case that the certificate complies with in-house specifications as well as the approved pharmacopeias, the additional in-house tests shall be stated in the certificate.
16. A copy of a recent delegation for the company representative authenticated by a valid bank signature.	* The signature delegation authenticated by a valid bank signature shall be uploaded in case that another authorized person signs the file papers, noting that the delegation

	validity period is only one year from the date of its signature.
For local products: - A copy of the manufacturer license with a suitable production line that is appropriate for manufacturing the product.	
For toll products: - A toll manufacturing card that includes the name of the factory that manufactures the product and the name of the store. - A recent manufacturer contract annex stating the name of the product and notarized by the legal affairs. - A copy of the manufacturer license with a suitable production line that is appropriate for producing the product.	* Making sure that the toll card is valid in accordance with the regulatory guide of the requirements for registering companies in the registry of toll manufacturing companies. * If the contract annex is issued within a period of more than six months, the following sentence shall be written: This is an annex of the manufacturer contract dated on ..... and valid for a period of ....., and this annex is effective as of the manufacturer contract. It is required that this modification shall be stamped by the signature and the seal of the manufacturer. * No amendment to the date of the contract or the annex is accepted (no deletion or crossing out is permitted).
For F-Toll products: A manufacturing contract with an annex stating the name of the product to be manufactured, which annex shall be authenticated and approved by the legal researcher. - A copy of the manufacturers' tax card. - A copy of the manufacturers' commercial register. - A copy of the license of the manufacturer that manufactures the product and that has the production line that is appropriate for producing the product.	The following requirements shall be taken into account in the case of F-Toll products - A copy of the license of the product owning manufacturer shall be attached. - The commercial register of the product-owning manufacturer shall indicate the item of toll manufacturing.

- A valid storage contract authenticated and approved by Legal Affairs.	
For under-license products: - A manufacturing under-license agreement attested by the Chamber of Commerce and notarized by the Egyptian Embassy abroad, unless provided otherwise in the international agreements. - An official agency agreement / power of attorney for registration/ manufacturing under-license agreement that is attested by the Chamber of Commerce and notarized by the Egyptian Embassy abroad. - An original certificate of pharmaceutical product (CPP) from the country of origin issued by the Ministry of Health or the Ministry of Agriculture and notarized by the Egyptian embassy abroad. - Documents required according to the type of the product registration shall also be observed.	Documents required according to the type of the product registration: In case of local under-license: Manufacturer License In case of Toll under-license: Toll Card Manufacturer Contract Annex In case of F-Toll under-license: Manufacturing Contract with annex Storage Contract
For imported products: - A formulation composition printed on the letterhead of the product-owning company abroad, stating the name of the manufacturer in case that the manufacturer is different from the license holder, and stating the functions and specifications of the active and inactive ingredients. - A Certificate of Analysis of the Product Specifications printed on the letterhead	* The register of importers shall be valid and shall state the name of the warehouse. * The company shall have a commercial register that states the activity of registering medicinal products, or it shall provide a declaration that it shall add this activity within six months from the date of issuing the license.

of the manufacturer abroad, signed and stamped by the manufacturer. - The scientific insert leaflet, which is printed on the letterhead of the product-owning company abroad, and which states the name of the manufacturer in case that the manufacturer is different from the license holder. - Register of importers. - An original certificate of pharmaceutical product (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 GMP of the factory abroad (if it is not indicated in the CPP of the product) - An official agency agreement / power of attorney for registration that is attested by the Chamber of Commerce and notarized by the Egyptian Embassy abroad. - A copy of a recent delegation for the company representative authenticated by a valid bank signature. - The company's commercial register.	