Administration of Pharmaceutical Products
General Administration for Herbal Products Registration

Guideline

Executive Procedures of the Decree of Egyptian Drug Authority's President No. (572) of 2022 on Regulating Procedures of Registration/Re-registration of the Complementary Medical Products

(2022)

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Introduction

All complementary medical products locally manufactured, manufactured under license from abroad, imported as well as products intended for export only must register in Egyptian Drug Authority and shall subject to the following procedures.

Scope of Implementation

Registration of complementary medical products in the General Administration for Herbal Products Registration affiliated to the Central Administration of Pharmaceutical Products at Egyptian Drug Authority (the links designated for that purpose on the website shall be used).

Abbreviations

CPP: Certificate of Pharmaceutical Product.

Free sale: Free circulating and selling certificate.

Toll: A local product manufactured by third party.

F-Toll: A local product manufactured by third party.

Under license: A product has permission from abroad to be locally manufactured.

Definitions

Complementary medical product:

It is a medical product that contains an ingredient or a group of active ingredients that have a complementary medical effect and is used for the purpose of helping to treat, prevent, restore, correct or modify physiological functions.

The term "product" wherever mentioned herein shall have the meaning of "complementary medical product".

Company:

It is the company requesting to register the product and owning all of the product legal rights.

Manufacturer:

It is a factory designated for manufacturing of the pharmaceutical products, licensed in accordance with the applicable laws and conforms to the good manufacturing requirements approved by Egyptian Drug Authority.

Certificate of Pharmaceutical Product (CPP) / Free circulating and selling certificate (Free sale):

They are certificates that include data on the product to be exported and is issued by the competent authority in the exporting country in order to address the importing country.

Reference countries:

They are a group of countries determined by a decision issued for them by the Technical Committee for Drug Control.

White List:

It includes active ingredients registered in Egyptian Drug Authority which were previously approved by specialized scientific committees during the past twenty years. It also includes a list of vitamins and minerals registered in the Canadian Monograph which is updated periodically in accordance with the decisions of the specialized scientific committees and in accordance with developments of the international references.

Complementary medical products locally manufactured. It include the following:

Local:

It is a product owned by a company owning a factory licensed by Egyptian Drug Authority where this product is manufactured in the same factory.

Toll- Locally manufactured by third party:

It is a product owned by a company registered in the third-party manufacturing register of Egyptian Drug Authority. This product is manufactured in a factory licensed by Egyptian Drug Authority and has a production line via a manufacturing

contract.

F-Toll: Locally manufactured by others:

It is a product owned by a company owning a factory licensed by Egyptian Drug Authority. This product is manufactured by a factory to factory contract in another factory has a production line and licensed by Egyptian Drug Authority.

Products locally manufactured under a license from abroad:

It is a product produced and manufactured in a factory licensed by Egyptian Drug Authority under license from a foreign company owning the product name and composition in one of the reference or a non-reference countries. This product circulated in a reference country under a contract between the foreign company abroad and the company granted the right for registration and manufacturing in the Arab Republic of Egypt, provided that the products locally manufactured under license shall meet the following conditions:

1. The product composition form submitted for registration shall match the product composition form circulated in the reference country. In case of the composition form was modified, the modification shall be carried out in accordance with the applied rules in Egyptian Drug Authority.
2. The pharmaceutical raw materials contained in the product composition shall be supplied from the same source of the product circulated in the reference country, otherwise the company granted the right for registration and manufacturing under license in the Arab Republic of Egypt must have an authorization to supply the raw materials from another source has the same properties of the pharmaceutical raw materials.
3. The product submitted for registration must have the same name under which the product is circulated in the reference country, provided that there is no confliction between the product name and another product name circulated in the local market.

4. Submitting a Certificate of Pharmaceutical Product (CPP) or a Free circulating and selling certificate (free sale) issued from the country of origin or from a reference country in case of the country of origin is a non-reference country, provided that the CPP shall be issued by a competent authority in the reference country, authenticated and certified by the Egyptian embassy or consulate, as the case may be in the reference country and all data indicated in the CPP shall be adhered to. That CPP shall include the product composition form circulated in the reference country and/or the packaging of the product.

Imported complementary medical products. It includes the following:

Imported (Bulk):

It is a product that is manufactured outside the Arab Republic of Egypt in one of the reference countries or in one of non-reference country, provided that it shall be circulated in a reference country and packaged and/or packaged in a factory licensed by Egyptian Drug Authority.

Imported (Finished):

It is a product manufactured, packaged and packaged outside the Arab Republic of Egypt, and it is imported as a finished product from one of the reference countries or from a non-reference country provided that it shall be circulated in a reference country.

The imported products shall meet the following conditions:

1. The product composition form submitted for registration shall match the product composition form circulated in the reference country. In case of the composition form was modified, the modification shall be carried out in accordance with the applied rules in Egyptian Drug Authority.

2. The product submitted for registration must have the same name under which the product is circulated in the reference country, provided that there is no confliction between the product name and another product name circulated in the local market.
3. Submitting a Certificate of Pharmaceutical Product (CPP) or a Free circulating and selling certificate (free sale) issued from the country of origin or from a reference country in case of the country of origin is a non-reference country, provided that the CPP shall be issued by a competent authority in the reference country, authenticated and certified by the Egyptian embassy or consulate, as the case may be in the reference country and all data indicated in the CPP shall be adhered to. That CPP shall include the product composition form circulated in the reference country and/or the packaging of the product.

Complementary medical products locally manufactured intended for export only:

It is a product owned by a company owning a factory or company registered in the third-party manufacturing register in Egyptian Drug Authority, and is manufactured in a factory licensed by Egyptian Drug Authority for the purpose of export only.

Central Administration of Pharmaceutical Products

All the complementary medical products locally manufactured, locally manufactured under license from abroad, imported as well as the locally manufactured products for the purpose of export only, shall subject to registration in Egyptian Drug Authority according to the following procedures (the links designated for that purpose on the website shall be used).

Registration procedures of a new product

1. Submitting an inquiry request to obtain an approval of proceeding with the registration procedures:

A- The company shall submit an inquiry request for registering the product in the competent department in the following cases:

- The composition contains an active ingredient/s included in the White List.

- In case of there are required documents, the company shall be granted a grace period of 15 days from the date in which the letter was issued, otherwise the request shall be null and void.

- The composition contains an active ingredient is not included in the White List or contains a herbal substance.

- The references proving safety and effectiveness shall be submitted to be presented to the Specialized Scientific Committee.

- In case of the committee required documents for the submitted studies, the company shall be granted a grace period of 90 days from the date in which the letter was issued, provided that the studies shall be re-presented to the same committee for adjudication.

B- In case of acceptance, a valid for two years approval for proceeding with the registration procedures shall be issued (within 10 working days).

C- In case of rejecting, a reasoned letter of rejecting shall be issued to the company.

2. Initiating the registration procedures:

The company shall be committed to submit the following documents within 3 months from the issuance date of the approval of proceeding with registration procedures for products submitted for local circulation:

A- Documents required to revise the product trade name within 5 working days.

B- Documents required to price the product within 5 working days.

3. Completing the registration procedures:

The company shall complete the registration procedures of the following cases as indicated below:

First: Locally manufactured products, locally manufactured under license from abroad or those products subject to the Article of export and tenders.

The company may choose one of the following two track:

The first track: In which the company is committed to the following:

A. Submitting an accelerated stability study conducted on research samples for evaluation by the competent department within the first 12 months from the issuance date of the approval of proceeding with the registration procedures.

B. Completing all registration requirements in accordance with the approved composition form issued in the approval of proceeding with the registration procedures and on which a stability study was conducted.

C. Submitting the analysis file of the first production batch after obtaining the registration notification to be registered at the Central Administration of Pharmaceutical Control in accordance with the applied rules, provided that the conformity analysis result shall be a required condition for release.

Note: It is permissible, based on the request submitted by the company that desire to manufacture a production batch for the purpose of analysis for registration- before the issuance of the registration notification, to manufacture that batch, provide that the company shall specify the storage conditions, expiration date and conditions of use on the company's responsibility as well as the company shall undertake to destroy that production batch in case of results of the stability study was failed, rejected or changed in the way that requires modifying the storage conditions and expiration date. This production batch shall be allowed to be circulated provided that the registration notification and the results of analysis and conformity shall be obtained from the Central Administration of Pharmaceutical Control and fulfilling all the required conditions and obligations, provided that follow-up shall be carried out by the Central Administration of Operations.

The second track: In which the company is committed to the following:

A. Submitting the analysis file of the experimental or production patch for registration at the Central Administration of Pharmaceutical Control in accordance with the applied rules within the first 12 months from the date in which the approval of proceeding with registration procedures was issued.

B. Obtaining the analysis result stating the conformity accompanied by the composition form on which the analysis was conducted.

C. Submitting an accelerated stability study conducted on a pilot or production batch for evaluation by the competent department within the first 12 months from the date in which the approval of proceeding with registration procedures was issued.

D. Completing all registration requirements in accordance with the issued approved composition form on which the stability study was conducted stating the approval of proceeding with the registration procedures.

Second: Imported products

The company shall be committed to submit the following within the first 12 months from the issuance date in which the approval of proceeding with the registration procedures was issued:

A. The product stability study conducted abroad to be evaluated by the competent department in order to obtain an approval for the stability study. The stability study shall be accompanied to the approved composition form.

B. The analysis file conducted on an imported consignment of the imported product to be registered at the Central Administration of Pharmaceutical Control in accordance with the applied rules. The analysis may also conducted on the first imported consignment after obtaining the registration notification, provided that the release shall take place after obtaining the analysis result stating the conformity.

Third: Locally manufactured products intended for export only

A. The company shall submit the of analysis conducted on the research samples to be registered at the Central Administration of Pharmaceutical Control in accordance with the applied rules within the first 12 months from the date in which the approval with registration procedures was issued.

B. The analysis result stating the conformity, shall be obtained accompanied by the composition form on which the analysis was conducted.

C. The company shall submit an accelerated stability study on research samples to be evaluated by the competent department within the first 12 months starting from the date in which the approval of proceeding with registration procedures was issued.

D. Completing all registration requirements in accordance with the issued approved composition form on which the stability study was conducted and stating the approval to proceed with the registration procedures.

Note: The company may submit the required studies conducted on samples from a pilot or production batch based on a request submitted by the company.

4- Submission the final registration file to obtain the registration notification:

A. The company shall apply to set a date to submit the final registration file within 3 months as a maximum from the date in which the analysis result indicating the conformity/the decision of the Scientific Committee for Stability was issued whichever is later.

B. The company shall submit the final registration file on the specified date. In case of there are required documents, the company shall obtain a grace period of 30 days to submit them.

5- Presentation to the Technical Committee for Drug Control:

The product shall be presented to the Technical Committee for Drug Control within 10 working days from the date of completing the final registration file in order to take the final decision.

A. In case of the committee approved the product registration, the following procedures shall be carried out:

1. The competent department shall issue a registration notification. The validity of the registration notification shall be 10 years from the date in which the approval of the Technical Committee for Drug Control was issued for local products and 3 years for imported products as a transitional phase until they are re-registered as local products.
2. The registration notification shall fulfill the following when applying for re-registration:

– Conducting the analysis required for registration on the first production batch at the Central Administration of Pharmaceutical Control in accordance with the applied rules in case of the first track of registration of the locally manufactured products, locally manufactured under license from abroad and locally circulated or the products subject to the Article of export and tenders or conducting the analysis on the first imported consignment after obtaining the registration notification for the imported product in case of failure to analyze before issuing the registration notification, provided that the release shall take place after obtaining the analysis result stating the conformity.

– Completely submitting a long-term stability study for locally manufactured products, locally manufactured under license from abroad and locally circulated or the products subject to the Article of export and tenders.

– Completely submitting of the pharmacovigilance report in accordance with the applied rules.

B. In case of the product registration was refused by the committee, a reasoned letter of refusal shall be issued to the company.

Re-registration procedures

1. The products registered at the Central Administration of Pharmaceutical Products (have a valid registration notification at the time of issuance of the decision) and subject to registration requirements of complementary medical products:

A. The re-registration shall be carried out in accordance with the procedures specified hereto during the last year of the registration notification's validity based on a request submitted by the company owning the product. That request shall include the documents required for the re-registration file.

– In case of there are documents required to be fulfilled, the company shall be given a grace period of 30 days to submit them in order to fulfill the re-registration file. The products shall be evaluated in accordance with the applied decisions on the date thereof.

B. The product shall be presented to the Technical Committee for Drug Control in order to take the final decision regarding whether or not to re-register the product as a complementary medical product.

– **In case of approval to re-register the product by the committee:**

1. A new registration notification shall be issued for the product with a new registration number as a complementary medical product. That registration notification shall be valid for a period of 10 years, starting from the expiry date of the previous registration notification.
2. It is required for issuance of the registration notification, fulfilling the pharmacovigilance evaluation report in accordance with the applied rules in this regard in the event that it has not been submitted previously, provided that it shall be submitted at applying for re-registration.

– In case of the product registration was refused by the committee, a reasoned letter of refusal shall be issued to the company.

The companies may apply to convert the registration notification to a complementary medical product in accordance with the rules, in case of the

registration notifications issued by the Central Administration for Pharmaceutical Products were valid and subject to the classification of a supplementary medicinal product.

2- **The pharmaceutical products registered as a complementary medical product**:

A. The re-registration shall be carried out during the last year of the registration notification's validity based on a request submitted by the company. That request shall include the documents required for re-registration file.

– In case of there are documents required to be fulfilled, the company shall be given a grace period of 30 days to submit them in order to fulfill the re-registration file. The products shall be evaluated in accordance with the applied decisions on the date thereof.

B. The product shall be presented to the Technical Committee for Drug Control in order to take the final decision regarding whether or not to re-register the product.

▪ In case of approval by the committee to re-register the product, a new registration notification shall be issued for the product under the same registration number. That registration notification shall be valid for a period of 10 years, starting from the expiry date of the previous registration notification.

– In case of the product registration was refused by the committee, a reasoned letter of refusal shall be issued to the company.

Names, cards and leaflets

Names:

A list of names consisting of 20 trade names shall be presented and revised according to the database in terms of pronunciation and writing in Arabic and English. The general form, pronunciation and timbre shall differ from the names registered in Egyptian Drug Authority. Taking into consideration that the scientific name of the active ingredient can be used following by the company name in the case of its existence separately. As for imported products, the name shall be reviewed according to the data included in the CPP certificate. In case of the imported product name conflicted with other products names enrolled in Egyptian Drug Authority database, it shall be presented to the Technical Committee for Drug Control.

Cards:

All data shall be written in Arabic and English on the outer and inner cover of the package, which include: the trade name, active ingredients, pharmaceutical form, number of units composing the package, storage conditions, company and factory name, address and telephone, company logo, registration number in Egyptian Drug Authority (in addition to) batch number, manufacturing date and expiry date as well as writing the price on the outer cover. It is allowed to lay drawings on the cover, and it is sufficient to write the product name, the pharmaceutical form and the company name or logo in the case of the inner cover made from aluminum.

In the case of finished imported products: the packaging shall be revised according to the data mentioned in the CPP in addition to submit an undertaking to add the importer’s name, address and telephone number in Arabic language, the price and registration number in Egyptian Drug Authority in addition to batch number, manufacturing date and expiry date.

Leaflets:

The company shall submit the product leaflet, which shall contain the following: the dosage, indications, side effects, warnings and contraindications, along with submitting the product file, provided that the leaflet shall be revised before

obtaining the registration notification.

Pricing

Pricing shall rely on the price proposed by the company, as the company shall submit a request to price the product obtaining an approval to proceed with the registration procedures as a complementary medical product in the competent administration. The price request shall include the public selling price, as well as the pharmacist's profit and the distributor's profit shall be determined in accordance with the applicable laws and decisions.

Reliability study for re-registration

The products fulfilling the following conditions shall be exempted from submitting a stability study for re-registration:

1. The product shall be previously has been re-registered at least once and obtaining a stability study evaluation report for re-registration.
2. fulfilling the previously issued stability approval for all the data necessary to complete the file of the product re-registering.

In case of the company has not completed the stability study required for re-registration:

A re-registration notification may be issued (based on a request submitted by the company), provided that a stability study for re-registration shall be submitted for evaluation by the Specialized Scientific Committee to evaluate the stability study within a maximum period of 3 years from the issuance date of the registration notification. Otherwise, production shall be suspended until completing the evaluation of the stability study required for re-registration.

Variables

Variable rules and standards shall apply to the registered pharmaceutical products.

Modify the composition form

1. In case of making any modification in the active ingredients in term of quantity or quality, all registration procedures as a new complementary

medical product shall be taken. In case of the modification relied on the decisions of the Specialized Scientific Committees or the decisions of the Technical Committee for Drug Control, the product shall be excluded from re-registration as anew complementary medical product. In case of requiring additional studies, the company shall be given a grace period to complete them.

2. In case of modifying the inactive ingredients, the rules and standards for variants shall be applied to the registered pharmaceutical products in terms of obligations and deadlines granted for completing them.

The re-registration notification shall be issued in accordance with the applied rules and procedures stated in the approved composition form that fulfilled all studies in case of lack to a decision from the Technical Committee for Drug Control to cancel one of the substances and excluding it from the production by using it, provided that all studies required on the new composition form after issuing the notification in accordance with the specified deadlines shall be completed.

Petitions

The company may file an appeal against the final decision issued by the Technical Committee for Drug Control within 60 days from the issuance date of the decision. The petition shall be filled based on a reasoned request supported by the documents and information that the committee wishes to rely upon when considering the petition, provided that it shall be presented to the Technical Committee to take the appropriate decision.

Intellectual property

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

Adverse effects

The company shall be committed to inform the Central Administration of Pharmaceutical Care of any serious adverse effects observed from the product

within 15 days. It shall also undertake to submit the Periodic Safety Update Report (PSUR) in compliance with the decisions of the Egyptian Pharmacovigilance Center.

Reconciliation of the situation

The complementary medical products submitted for redressing their situations, shall be submitted to the Central Administration for Pharmaceutical Products to study its status on a case-by-case basis.

Cancellation

In case of the locally manufactured products obtaining a registration notification are not manufactured for local circulation or the imported products obtaining a registration notification are not imported into the Egyptian markets within 18 consecutive months from the issuance date of the registration notification, the registration notification is canceled by a decision of Egyptian Drug Authority's President, based on a reasoned report submitted by the Central Administration of Pharmaceutical Products' Chairman after being presented to the Technical Committee for Pharmaceutical Control based on a report submitted by the Central Administration of Operations.

Appendixes

Central Administration of Pharmaceutical Policies and Market Access

It shall be applied to obtain an import approval/import plan and customs medical release letter in accordance with the "Regulatory Guideline of the Rules and Procedures Organizing the Process of Import and Customs Medical Release for Medical Products, their Raw Materials and Packaging Supplies", as follows with regard to complementary medical products.

Products under registration:

- In case of raw materials/packing supplies imported for the purpose of research or for manufacturing a pilot batch, the company shall apply to obtain the letter of sealed customs medical release letter for the imported items pursuant to the approval of proceeding with the registration procedures.
- In the case of raw materials/packing supplies imported to manufacture a production batch to conduct the analysis required for registration before the issuance of the registration notification, the company shall apply to obtain an import approval of the items imported valid for the total shipment pursuant to the approval to proceed with the registration procedures.
- In case of bulk/finished imported products, the company shall apply to obtain the sealed customs medical release letter obtained for the products submitted for registration and imported for the purpose of analysis or registration, pursuant to the approval of proceeding with the registration procedures.

Registered products submitted for re-registration:

- In case of raw materials, the company shall apply to obtain the annual import approval for raw materials imported for the purpose of production pursuant to the product registration notification.
- In case of Bulk/Finished imported products, the company shall apply to

obtain the annual import plan for Finished/Bulk registered products pursuant to the product registration notification.

Central Administration of Operations

First: Documents required for release of the used raw materials:

1. Customs release invoice bearing the stamp of Egyptian Drug Authority (in case of imported raw materials).
2. Import approval or annual import plan issued by Egyptian Drug Authority (in case of imported raw materials).
3. Analysis certificate of the raw material from the supplier and from the company.
4. The product registration file (registration notification/composition form or approval of proceeding with registration procedures).

Second: Documents required for perusal when withdrawing samples for analyzing from the production or pilot batch:

1. Record of raw material withdrawal for analyzing at Egyptian Drug Authority laboratories.
2. A composition form approved by the Central Administration of Pharmaceutical Products or by the Central Administration for Operations' inspector.
3. The company’s analysis certificate for the production or pilot batch and the raw material used in manufacturing.

Third: The phase of proceeding with the registration procedures:

In case of obtaining a product registration notification by the company, the requirements stipulated in the registration notification shall be applied in terms of withdrawal and studies required to be conducted on the products and circulation.

Fourth: Implementing the random withdrawal plan:

The random withdrawal plan shall be applied to the product after issuance of the conformity and expiration decision of the first three production batches, pursuant to the evaluation of the production line on which the product is manufactured.

Fifth: Re-registration phase:

In case of obtaining a re-registration notification by the company for the product, the provisions stipulated in the re-registration notification and the studies required to be conducted on the products to allow circulating shall be applied.

Sixth: Cases of amending the composition form/source of the raw material/place of manufacturing the product/adding a place for manufacturing:

The stipulated requirements in the approval of the product variants shall be applied

Central Administration for Drug Control

First: Locally manufactured products submitted for registration for the first time:

1. The company shall submit a request to examine the analysis file through the link of the Evaluation and Accreditation Department after paying the prescribed fees.
2. The approval of proceeding with the registration procedures shall be revised in terms of the active ingredients and it shall be compared with the approved composition form.
3. The revision shall be carried out in accordance with the approved examination mechanisms for each pharmaceutical form.
4. The completing of the file contents shall be verified according to the approved list, See Table (1).
5. After fulfilling the file to be submitted for examination, the approved number of samples for each pharmaceutical form shall be adhered to, See Table (2).

6. After completion, the company shall submit a request to deliver the analysis file, samples and analysis requirements via the link designated for that purpose.
7. After completing the analysis, the final report shall be issued stating the product owner name, factory name and names of the suppliers of raw materials recorded in the withdrawal report. The final report shall accompany to the composition form on which the analysis was conducted.

Second: Imported products submitted for registration for the first time:

1. The inspection and analysis shall be carried out according to approved inspection mechanisms in line with the specifications of the final product.
2. The file contents completion shall be verified according to the approved list, See Table (1).

Third: Products submitted for re-registration:

1. The company shall submit a request to examine the analysis file via the link of the Evaluation and Accreditation Department after paying the prescribed fees.
2. The re-registration notification and the approved composition form shall be revised.
3. The revision shall be carried out in accordance with the approved examination mechanisms for each pharmaceutical form.
4. The file contents completion shall be verified according to the approved list, See Table (1).
5. After fulfilling the file to be submitted for examination, the approved number of samples for each pharmaceutical form shall be adhered to, See Table (2).
6. After completion, the company shall submit a request to deliver the analysis file, samples and analysis requirements on the link designated for that purpose.

7. After completing the analysis, the final report shall be issued stating the product owner name, factory name and names of the suppliers of raw materials recorded in the withdrawal report. The final report shall accompanied to the composition form on which the analysis was conducted.

Table (1) The approved list of the analysis file	
Locally Manufactured Products	
Regulatory Folder	Approval of proceeding with the registration procedures for products submitted for registration for the first time.
	Re-registration notification of the products submitted for re-registration.
	An approved composition form of the products submitted for registration for the first time bearing the stamp of the company.
	An approved composition form by the Central Administration of Pharmaceutical Products for the products submitted for re-registration.
	An application form for registering a pharmaceutical product stating the registrant company name, the name of the final product manufacturer and the type of packaging of the final product
	Form of delivering samples and withdrawal record for the sealed samples showing the active ingredients used in manufacturing the final products and their batch numbers.
	Analysis certificate of the raw materials used in manufacturing.
	Payment receipt (check) indicating the product name.
	In case of completion, a letter shall be sent accompanied to the response of the requirements and a copy of the e-mail sent in order to facilitate the revision.
	Undertaking of the correctness of data submitted of the examined file.
	Safety undertaking for the samples submitted for analysis.
	Undertaking to retrieve the column of chromatography (if delivered) within one month from the issuance date of the final report.

	Documenting the (batch formula from batch record) after being inspected by the inspector of the Central Administration of Operations.
Technical Quality Folder	Final Product Specifications.
	Final Product Analysis Certificate.
	The used analysis methods and the results of verifying (in case of submitting analysis methods have been developed).
Imported Products	
Regulatory Folder	An approved composition form along with an approval of proceeding with the registration procedures.
	An application form for registering a pharmaceutical product stating the registrant company name, the name of the final product manufacturer and the packaging type of the final product.
	Form of delivering samples and withdrawal record for the sealed samples.
	Analysis certificate of raw materials used in manufacturing.
	Payment receipt (check) indicating the product name
	In case of there are required documents, a letter shall be sent accompanied to the response of the requirements and a copy of the e-mail sent in order to facilitate the revision.
	Undertaking of the correctness of data submitted of the examined file.
	Safety undertaking for the samples submitted for analysis.
	Undertaking to retrieve the column of chromatography (if delivered) within one month from the issuance date of the final report.
Technical Quality	Final Product Specifications.
	Final Product Analysis Certificate

Folder	The used analysis methods and the results of verifying (in case of submitting analysis methods have been developed).

Table (2) number of required samples for analysis according to the pharmaceutical form	
Tablets	60 tablets
capsules	60 capsules
Oral liquids	30 bottles
powder	60 sachets

In case of submitting a pharmaceutical form not enrolled in the table, the examining and analyzing of that pharmaceutical product shall be guided by approved mechanisms for examining and analyzing of the pharmaceutical products.

Central Administration of pharmaceutical Care

First: During the validity period of the products registration notification:

The company shall be committed to the following:

- Send the data of the qualified person for pharmacovigilance to the General Administration of Pharmacovigilance immediately after obtaining the registration notification via the following e-mail:

pv.complementary@edaegypt.gov.eg.

- Submitting the Periodic Benefit Risk Evaluation Reports in accordance with the rules, as the company shall follow the periodic dates indicated in the latest version of the European Union reference date list (EURD List). In case of lack to the material(s) of the company's product, the company should refer to the list published on the official website of Egyptian Drug Authority. In case of the

material(s) not found in any of these lists, the company shall submit a proposal to the Administration of Pharmacovigilance specifying the periodicity and date of submission. The proposal shall be submitted immediately after granting the product license to the company.

The General Administration of Pharmacovigilance shall be informed of any serious adverse effects observed of the product within 15 days, report any non-serious adverse effects of the product within 90 days and report any safety urgent information within 5 days as a maximum from the date of becoming aware of it.

Second: When re-registering:

The company shall be committed to submit the pharmacovigilance file that includes all requirements based on the principles of good pharmacovigilance practice. The following documents shall be submitted:

- Risk management plan, clinical information attachment document describing the company's pharmacovigilance system and its summary.
- Submitting a document of describing the pharmacovigilance subsystem and its summary to the company office or local agent in the Arab Republic of Egypt in case of re-registration of imported products/ locally manufactured products under license from a foreign company/ local product of the international companies.

Note: To find out all the documents required for applying to the General Administration of Pharmacovigilance and the requirements of the re-registration file, refer to the updated checklist via the following link:

https://sites.google.com/view/pvcenter/epvc-reception

In case of the submitted pharmacovigilance file is not approved or the required documents are not completed, the Central Administration of Pharmaceutical Products shall be contacted to take a reasoned decision regarding it.