

Arab Republic of Egypt



Ministry of Health

The Minister

Decree No. 297 of 2009 on Rules and Procedures of Registering Biological products, Serums,
Vaccines, and Blood derivatives

Having reviewed:

- Law 127/1955 on Practice of Pharmacy.
- Ministerial Decree 94/2004 on modifying some provisions of analysis fees.
- Ministerial Decree 113/2004 on rules and procedures of giving marketing approval for pharmaceutical preparations.
- Ministerial Decree 191/2005 regulating procedures of re-registering pharmaceutical preparations.
- Ministerial Decree 370/2006 re-regulating procedures of registering pharmaceutical preparation,
and according to documents presented by the Minister deputy for pharmaceutical affairs.

The Minister of Health decided the following

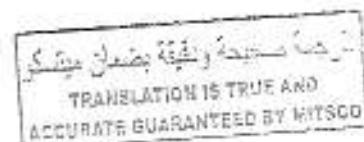
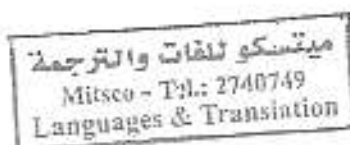
Article (1) Attached provisions shall govern with respect to rules and procedures of registering and reregistering Biological products, serums, vaccines, and blood derivatives.

Article (2) This decree shall be published in the Egyptian Gazette and come into force the day following to its publication. All conflicting decrees shall be repealed.

Minister of Health

Professor Hatem Al-Gabaly

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Rules and Procedures Accompanying Decree 297/2009 of the Minister of Health

Article (1) In interpreting provisions of this decree, the following terms shall have the meaning explained next to them:

- Biological products: preparations made of substances extracted from or produced by living sources, whether they are genetically-modified microorganisms or liquids and tissues extracted from various human or animal sources.
- Locally-manufactured preparations: Biological pharmaceutical preparations which are manufactured in factories located in the Arab Republic of Egypt.
- Imported products: Biological products imported as finished products or manufactured abroad and packed in local factories.

Article (2): Technical Committee for Drug Control shall recommend number of preparations to be registered for each drug group, including the originator preparation of the active ingredient according to patient's needs (Appendix 1). A substantiated report shall be attached to the recommendation which shall be submitted to minister's deputy for pharmaceutical affairs. The minister's deputy shall in turn submit it to the minister for endorsement.

Article (3): Registration applicant must submit a query application about the product concerning the group of alternative drugs to the Central Administration of Pharmaceutical Affairs. The query application shall include active ingredient, concentration, indications, dosage form & the manufacturing company (Appendix 2). This application is recorded

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according to the date & hour of presentation. The query applicant is notified with the product situation within fifteen working days of application receipt.

Article (4): After approving the query application, the following steps are followed:

- 1- Presenting the requested documents for pricing as declared in (Appendix 3) for the local preparations, (Appendix 4) for the imported preparations & preparations manufactured abroad and packed in local factories, these pricing documents are to be presented to the Central Administration of Pharmaceutical Affairs within thirty working days from the date of reply on the query application or else the query entry number is considered cancelled.
- 2- The product is priced – whether local or imported- in a period of maximum sixty working days from the date of receipt of the complete pricing file.

Article (5): After pricing, the preparation is directed to the scientific committees in the following cases:

- 1- If it contains a new active ingredient, a new formulation or doesn't have scientific reference.
- 2- If it has a new indication, a new concentration or a new dosage form.
- 3- If any international warnings were declared concerning the formula presented for registration.

In these cases, the registration applicant is notified to present the scientific studies of the product within thirty working days from the pricing date renewable only once in the case of request of any fulfillments, or else the application entry number is considered cancelled. Submission is made to the scientific committees within sixty working days from the date of receipt of complete scientific file. Procedures of product registration are to be continued in case

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of approval from the scientific aspect. But in the case of disapproval, submission is made to the technical committee of drug control to take the appropriate decision.

Article (6): For locally manufactured products, registration procedures are to be completed after pricing according to the following steps:

- 1- Presenting registration file containing the documents mentioned in (Appendix 5) to the Central Administration of Pharmaceutical Affairs within eight months from the pricing date, or else the application entry number is considered cancelled. The registration applicant is notified with the file situation after fifteen working days from the date of file receipt. In case of presence of any comments on the file from the National organization for drug control and research of biological products or the Central Administration of Pharmaceutical Affairs, the registration applicant should fulfill them within 60 working days from the date of notification, renewable only once. Or else the registration application is considered cancelled.
- 2- Stability study assessment is made by the competent scientific committee within 60 working days from the date of acceptance of complete registration file.
- 3- Preparation of samples for analysis within 30 working days from the date of pricing approval, on condition that it is packed in presence of an inspector from the pharmaceutical inspection of the Central Administration of Pharmaceutical Affairs, so that the inspector keeps the samples & sends them to the National organization for drug control and research of biological products for analysis, accompanied with a copy of the scientific file presented to the registration department in the Central Administration of Pharmaceutical Affairs. The Organization is committed to issue a technical assessment

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report & the analysis results within 60 working days from the date of samples presentation.

Submission is made to the technical committee for drug control within 60 working days from the date of acceptance of stability study results & receipt of the technical assessment report from the National organization for drug control and research of biological products. The technical committee will take the necessary decision concerning product registration. In case the technical committee disapproves registration, the registration applicant is informed by the means of a substantiated letter. On the other hand, in case of approval the product is given a registration certificate valid for a period of five years.

Article (7): For registering imported products or products manufactured abroad and packed in local factories, the product must be freely sold in the country of origin for a period of one year or more, and the product must have a registration & free sales certificate from the European LMEA, American FDA, Australian TGA or Japanese MHLW, or the product should be WHO prequalified, or the drug owning company belongs to one of the members of the International Conference on Harmonization (for regulating drug research & industry) ICH.

The drug control technical committee has the right to request inspection of the factory abroad. It might also exclude some imported products with special importance for the Egyptian patient from this condition according to a recommendation from the competent scientific committee. The recommendation must be submitted to the Minister's deputy for pharmaceutical affairs accompanied with a substantiated report. The minister's deputy shall in turn submit it to the minister of Health for endorsement.

Article (8): For Imported products, registration procedures are to be completed after pricing according to the following steps:

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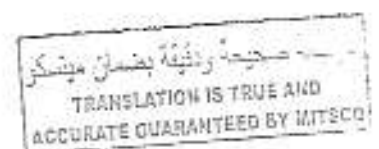
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- 1- Presenting registration file containing documents declared in (Appendix 6) to the Central Administration of Pharmaceutical Affairs within 60 working days from the date of issuance of pricing approval or from the date of scientific committee's approval stated upon in article (5), or else the application entry number is considered cancelled. The registration applicant is notified with the file situation after fifteen working days from the date of file receipt. In case of presence of any comments on the file from the National organization for drug control and research of biological products or the Central Administration of Pharmaceutical Affairs, the registration applicant should fulfill them within 60 working days from the date of notification, renewable only once, or else the registration application is considered cancelled.
- 2- The competent scientific committee assesses the Stability study.
- 3- The pharmaceutical inspection withdraws samples from the product imported from the country of origin, for the purpose of their analysis in the National organization for drug control and research of biological products within 60 working days from the date of pricing approval or the date of scientific committee's approval in the cases stated upon in article (5). The Organization is committed to issue a technical assessment report including the analysis results within 60 working days.

Submission is made to the technical committee for drug control within 60 working days from the date of acceptance of stability study results & receipt of the technical assessment report from the National organization for drug control and research of biological products. The technical committee will take the necessary decision concerning product registration. In case the technical committee disapproves registration, the registration applicant is informed by a substantiated letter. On the other hand, in case of approval the product is given a registration certificate valid for a period of five years.

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Article (9): The biological products, serums & vaccines are re-registered every five years according to a request presented from the product owner to the Central Administration of Pharmaceutical Affairs, including the requested documents in the re-registration file declared in (Appendix 7) & (Appendix 8) during the last year of product's registration validity according to the following procedures:

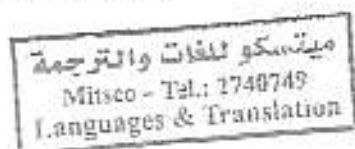
- 1- If no change is made to any of the product components, the registration department studies the formula & the product insert, & assesses the stability study. Then submission is made to the technical committee for drug control within sixty working days. In case of approval, the product is re-registered for a new period with the same registration number.
- 2- If any change is made to the product, all procedures stated upon should be taken according to the regulations approved by the World Health organization (WHO).

The product owner is given a time limit of one year from the date of this decree to present a complete application for re-registration. If this time limit ends or the registration period ends without presenting the mentioned application, the product registration is considered cancelled.

Article (10): Announcement is made concerning the biological products, serums & vaccines having registration numbers in the Ministry of Health's website maximum in the tenth day of the next month from approval issuance. Any relevant party has the right to object to any of the applications whose registration was announced within two months from the announcement date.

The Minister of Health has the right to stop or cancel continuing the registration procedures or withdraw the registration certificate for any Pharmaceutical product he finds harmful to the public health, according to the recommendation of the technical committee of drug control.

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Article (11): The product owner is committed to the following:

- 1- Presenting a representation according to what is mentioned in (Appendix 9) in which he declares his commitment to the terms of the Intellectual property rights protection law No. 82 for the year 2002, And that if his violation to the mentioned law was proven he will bear the complete responsibility. The Central Administration of Pharmaceutical Affairs has the right to cancel the approval on continuing the registration procedures or cancel registration according to the recommendation of the Minister's deputy for Pharmaceutical Affairs & the endorsement of the Minister of Health to this recommendation.
- 2- Writing the name of the manufacturer, the company which owns the product, manufacturing date, expiry date, batch number, barcode, registration number & price on the outer pack. And writing the name of the manufacturer, manufacturing date, expiry date and batch number on the inner pack. And shouldn't perform any change to the product except after obtaining a written approval from the Central Administration of Pharmaceutical Affairs.
- 3- Notifying the Central Administration of Pharmaceutical Affairs with the names of all his accredited distributors & with any change occurring to their data. The product owner should ensure that the accredited distributor applies the good storage procedures & the good dispensing procedures (GSP & GDP).
- 4- Admitting his complete responsibility for storing raw materials, all stages of product manufacturing & the product compliance with technical specifications till distribution is completed.

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In case of toll manufacturing, the factory must be licensed from the ministry of health & must comply with all the obligations mentioned in this decree, with good manufacturing practice rules & all what is mentioned in the ministerial decree 539/2007.

- 5- To make available the products having a previous registration certificate within a year from publishing this decree, also to make available all the products which will have a final registration certificate according to this decree within one year from the date of issuance of the final registration certificate. Or else, the registration certificate is considered cancelled & the product can not to be sold in the market.
- 6- Admitting that the manufacturing site will & the ownership will not be changed without taking the approval of the Central Administration of Pharmaceutical Affairs.
- 7- Admitting that all data presented in the product analysis file to the National organization for drug control and research are identical to what have been presented in the registration file to the Central Administration of Pharmaceutical Affairs, and that all documents & data are correct upon his full responsibility.

Article (12): The registration applicant has the right to complain from the final decision issued by the technical committee for drug control within sixty days from the date of decision issuance. Petition is to be made by presenting a substantiated letter to the committee of petitions, supported with the documents & information he wishes to refer to during studying his petition. A decision is taken in the petition during sixty days from the date of its presentation.

Article (13): Registration certificate is cancelled in the two following cases:

1. If the product was not available in the markets in a continuous manner for one year after the issuance of the final registration certificate. Cancelling is made by a

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decision from the Central Administration of Pharmaceutical Affairs according to a recommendation from the technical committee of drug control.

2. If a change was made to the product before taking the approval of the technical committee of drug control.
3. If the product registration period ends without presenting a re-registration file. Any batch manufactured after that date will be kept with taking the necessary legal procedures in this issue.

Article (14): In emergency cases, any product can be freely sold with exceptions from some of the conditions mentioned in this decree according to a recommendation from the minister's deputy for pharmaceutical affairs, and the minister's endorsement to this recommendation. On condition that the Central Administration of Pharmaceutical Affairs withdraws samples to be analyzed in the National organization for drug control and research of biological products, and the relevant person presents a registration file within two months from the Minister's endorsement.

(The original is signed by the Minister of Health Dr. Hatem Al-Gabaly)

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Appendix (1): Determining the number of alternatives inside each pharmaceutical group:

1. The number of products for each dosage form for the same active ingredient does not exceed 12 products classified as follows:

- The originator product (Brand or innovator)
- 11 Products including maximum one imported product.

Upon completing 12 products from any concentration, no registration applications will be accepted for the remaining concentrations of the same dosage form except in the cases of line extension (adding another concentration from the same company, same dosage form & same active ingredient for the product already available in the local market with a number exceeding 12 alternatives)

2. Concerning products that need a high manufacturing technology not available in the Egyptian factories, the number of products for each active ingredient is 12 products including:

- The Brand or Innovator product.
- A maximum of 5 imported products (generics)

*** Dosage forms:**

- Solid dosage forms (Tab., Caps.)

Solid dosage forms (S.R., C.R., Effervescent powder, effervescent tab., Gums, ...etc.)

-Semisolid preparation (Oint., Cream)

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-Injectable preparation (Ampoule, vial, prefilled syringe, ...)

-Eye/Ear preparation

-Syrup, Suspension

Inhalers.

Appendix (2): Documents requested for the application query:

- Company identification form (Company Profile)

(Presented only once & updated whenever a change is made)

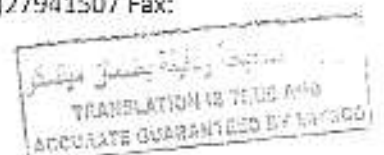
- 1) Query Application form mentioning clearly the name of the active ingredient, concentration, indications & dosage form.
- 2) Copy of the scientific reference for the originator product, The source must be reliable internationally (BNF, PDR, Rote Liste, Compendium Suisse, Vidal)

And concerning the pharmacopoeial products (USP, British or European), a copy of the most recent pharmacopoeia which the product follows.

- 3) Payment receipt of the fees of the query application service.
- 4) Presenting a document proving that the registration applicant is a member of the chamber of pharmaceutical industry.
- 5) Concerning the imported products or manufactured under license from abroad, the following documents will be presented in addition to the previous:

- a- What proves that the product has a registration & free sales certificate from the European EMFA, American FDA, Australian TGA or Japanese MHLW. or the product

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should be WHO prequalified, or the drug owning company belongs to one of the members of the International Conference on Harmonization (for regulating drug research & industry) ICH (www.ich.org)

- b- Free sales certificate in the country of origin or CPP (according to the form of the world health organization) notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad (submit a copy after looking into the original).

Appendix (3): Documents requested for the pricing file for local products:

- 1) Pricing application form clearly mentioning the proposed pack & price, printed on the company paper & sealed with the company seal.
- 2) The approval on the query application.
- 3) Payment receipt of the pricing services fees.
- 4) List of costs, invoices or price offers for each of the active and inactive materials & packaging materials.
- 5) Product's Formula printed on company paper & sealed with the company seal.

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Appendix (4): Documents requested for the pricing file for imported products:

- 1) Pricing application form clearly mentioning the proposed price & pack, printed on the company paper & sealed with the company seal.
- 2) The approval on the query application.
- 3) Payment receipt of the pricing services fees.
- 4) Copy of free sales certificate in the country of origin notarized from the Egyptian embassy abroad.
- 5) List of cost, import price & price in the country of origin (notarized from the Egyptian embassy abroad) (original & copy).
- 6) Prices in other countries including Arabian countries (Pricing form)
- 7) Copy of the product's original pack & insert.

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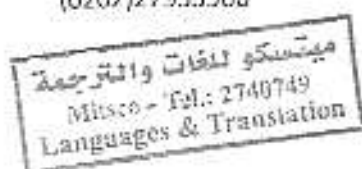
Appendix (5): Documents requested for the registration file of biological products, serums & blood derivatives for local products:

(Both a printed copy & an electronic copy on a CD are to be presented)

First: Administrative information

- 1) Application form for registration.
- 2) The approval on the query application.
- 3) Payment receipt of the registration services fees.
- 4) Authorization letter for the person handling registration, sealed with the company seal.
- 5) A pledge verifying the data sealed with the company seal
- 6) The product insert according to a scientific reference, including the terms mentioned in the registration application, in Arabic & English languages.
- 7) Form of the product's outer & inner packs & inner label.
- 8) In case of manufacturing under license from a foreign company, the following will be presented besides the previous:
 - Manufacturing contract concerning the product, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad (submit a copy after looking into the original), unless there are contradictory international agreements.

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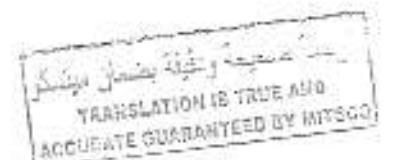
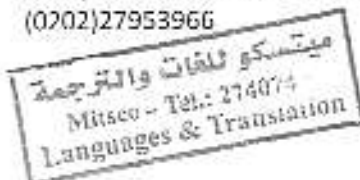
- Original free sales certificate in the country of origin notarized from the Egyptian embassy abroad.
- 9) In case of toll manufacturing, the manufacturing contract concerning the product must be presented, notarized confirming the accuracy of signature.

Second: Materials entering in the product formula

Active ingredients:

- 1) Specifications of the active ingredients & the relevant tests.
- 2) Methods of analysis and validation.
- 3) Certificates of analysis.
- 4) RSF/TSF Freedom certificates for the materials entering in the product formulation.
- 5) If the materials entering in the product formulation are from blood derivatives, the following will be presented besides the previous:
 - Plasma master file including information indicating plasma source starting from the process of collection passing by all steps of manufacture, in process control & viral safety.
 - Official certificates declaring plasma source.
 - HIV-1, HIV-2, HBsAg & HCV freedom certificate for the plasma
- 6) Suppliers' names.

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Inactive ingredients:

- 1) Specifications of the inactive ingredients & the relevant tests.
- 2) Certificates of analysis.
- 3) Methods of analysis and validation.
- 4) BSE/TSE Freedom certificates for the materials entering in the product formulation.
- 5) HIV-1, HIV-2, HBsAg & HCV freedom certificate for the plasma (In the case of using blood derivatives as inactive ingredients)
- 6) Suppliers' names.

Packaging & wrapping materials:

- 1) Type & specifications of the components of Packaging & wrapping materials.
- 2) Suppliers' names

Third: Finished product

- 1) Product's formula including the active & inactive ingredients printed on the company paper & sealed with the company seal.
- 2) Certificate of analysis of the product issued from the factory.
- 3) Finished product specifications.
- 4) The applied methods of analysis of finished product & their validation.

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- 5) Stability study of the product.
- 6) Copy of the factory license indicating production lines convenient with the dosage form.
- 7) Flow chart indicating sites & steps of product manufacture.
- 8) Method of manufacture, clarifying the in process control & validation used during method of manufacture.
- 9) Production site file (Site master file)
- 10) Preclinical studies (If there performance is necessary).
- 11) Clinical studies for the product.
- 12) Description of the applied steps to keep the cooling chain (cold chain).

Appendix (6): Documents requested for the registration file of imported products:

(Both a printed copy & an electronic copy on a CD are to be presented)

First: Administrative information

- 1) Application form for registration.
- 2) The approval on the query application.
- 3) Payment receipt of the registration services fees.
- 4) The original pack of the product (outer & inner packs) & the product insert in Arabic & English languages.

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- 5) List of the countries where the product is registered & sold, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 6) Original Free sale certificate of the product in the country of origin notarized from the Egyptian embassy abroad.
- 7) Clarification of the relation between the manufacturing company, the importing company & the distributor by original certificates notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 8) Agency or distribution contract notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad (submit a copy after looking into the original)
- 9) Concerning products manufactured abroad & packed locally, the following will be presented besides the previous:
 - Local packaging contract between the importing company & the licensed local factory which performs packaging. The foreign companies having a licensed factory are exempted from this condition.
 - Authorization letter from the foreign company abroad to the importing company declaring agreement on registering & packing the product in a licensed local factory inside Egypt. The letter should be notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad
- 10) Authorization letter for the person handling registration, sealed with the company seal.

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- 1) A pledge verifying the data sealed with the company seal

Second: Materials entering in the product formula

Active ingredients:

- 1) Specifications of the active ingredients & the relevant tests.
- 2) Methods of analysis and validation.
- 3) Certificates of analysis.
- 4) BSE/ISL Freedom certificates for the materials entering in the product formulation, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 5) If the materials entering in the product formulation are from blood derivatives, the following will be presented besides the previous:
 - Plasma master file including information indicating plasma source starting from the process of collection passing by all steps of manufacture, in process control & viral safety.
 - Official certificates declaring plasma source notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
 - HIV-1, HIV-2, HBsAg & HCV freedom certificate for the plasma, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad

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Inactive ingredients:

- 1) Specifications of the inactive ingredients & the relevant tests.
- 2) Certificates of analysis.
- 3) Methods of analysis and validation.
- 4) BSL/TSE Freedom certificates for the materials entering in the product formulation, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 5) HIV-1, HIV-2, HBsAg & HCV freedom certificate for the plasma (In the case of using blood derivatives as inactive ingredients) notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad

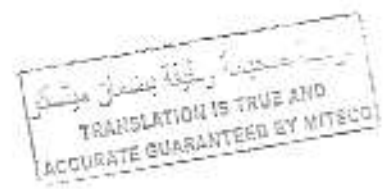
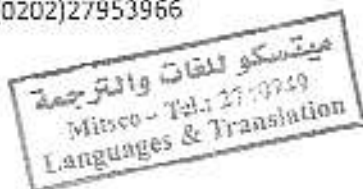
Packaging & wrapping materials:

- 1) Type & specifications of the components of Packaging & wrapping materials.

Third: Finished product

- 1) Product's formula including the active & inactive ingredients printed on the company paper & sealed with the company seal, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 2) Certificate of analysis of the product notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 3) Stability study of the product.
- 4) Factory license or its equivalent notarized from the Egyptian embassy abroad.

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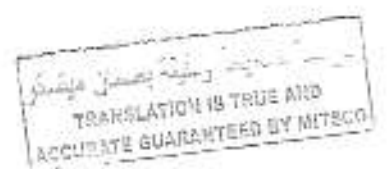
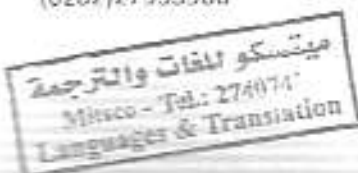


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- 5) Inspection report of the manufacturing site issued from the competent authority & notarized by the Egyptian embassy abroad.
- 6) Good manufacturing practice certificate (GMP) issued from the health authority in country of origin & notarized from the Egyptian embassy abroad.
- 7) Finished product specifications.
- 8) The applied methods of analysis of finished product & their validation.
- 9) Flow chart indicating sites & steps of product manufacture.
- 10) Method of manufacture, clarifying the in process control & validation applied during process of manufacture.
- 11) Production site file (Site master file)
- 12) Preclinical studies (If there performance is necessary).
- 13) Clinical studies for the product.
- 14) Post marketing studies.
- 15) Description of the applied steps to keep the cooling chain (cold chain).
- 16) Summary protocol for three final batches.

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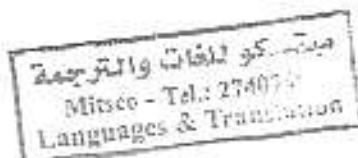
Appendix (7): Documents requested for the re-registration file of local products:

(Both a printed copy & an electronic copy on a CD are to be presented)

First: Administrative information

- 1) Company identification form (Company profile) (presented only once & renewed whenever any change is made)
- 2) Application form for re-registration.
- 3) Product's registration certificate.
- 4) Product's pricing certificate.
- 5) Payment receipt of the re-registration services fees.
- 6) Authorization letter for the person handling registration, sealed with the company seal.
- 7) A pledge verifying the data sealed with the company seal.
- 8) The product insert according to a scientific reference, including the terms mentioned in the re-registration application, in Arabic & English languages.
- 9) The original outer pack, inner pack & inner label of the product.
- 10) In case of manufacturing under license from a foreign company, the following will be presented besides the previous:
 - Manufacturing contract concerning the product, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian

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embassy abroad (submit a copy after looking into the original), unless there are contradictory international agreements.

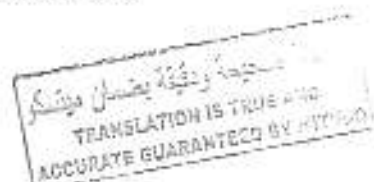
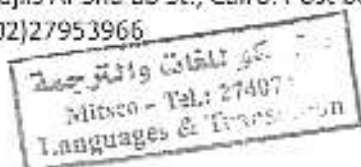
- Original free sales certificate in the country of origin notarized from the Egyptian embassy abroad.
- 11) In case of toll manufacturing, the manufacturing contract concerning the product must be presented, notarized confirming the accuracy of signature.

Second: Materials entering in the product formula

Active ingredients:

- 1) Specifications of the active ingredients & the relevant tests.
- 2) Methods of analysis and validation.
- 3) Certificates of analysis.
- 4) BSE/TSE Freedom certificates for the materials entering in the product formulation.
- 5) If the materials entering in the product formulation are from blood derivatives, the following will be presented besides the previous:
 - Plasma master file including information indicating plasma source starting from the process of collection passing by all steps of manufacture, in process control & viral safety.
 - Official certificates mentioning plasma source.
 - HIV-1, HIV-2, HBsAg & HCV freedom certificate for the plasma

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- 6) Suppliers' names.

Inactive ingredients:

- 1) Specifications of the inactive ingredients & the relevant tests.
- 2) Certificates of analysis.
- 3) Methods of analysis and validation.
- 4) BSE/TSE Freedom certificates for the materials entering in the product formulation.
- 5) HIV-1, HIV-2, HBsAg & HCV freedom certificate for the plasma (In the case of using blood derivatives as inactive ingredients)
- 6) Suppliers' names.

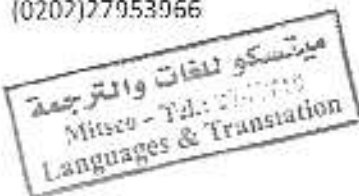
Packaging & wrapping materials:

- 1) Type & specifications of the components of Packaging & wrapping materials.
- 2) Suppliers' names.

Third: Finished product

- 1) Product formula including the active & inactive ingredients printed on the company paper & sealed with the company seal.
- 2) Certificate of analysis of the product issued from the factory.
- 3) Finished product specifications.

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- 4) The applied methods of analysis of finished product & their validation.
- 5) Stability study of the product (Ongoing stability).
- 6) Copy of the factory license indicating production lines convenient with the dosage form.
- 7) Flow chart indicating sites & steps of product manufacture.
- 8) Method of manufacture, clarifying the in process control & validation applied during method of manufacture.
- 9) Production site file (Site master file)
- 10) Preclinical studies (If there performance is necessary).
- 11) Clinical studies for the product.
- 12) Description of the applied steps to keep the cooling chain (cold chain).

Appendix (8): Documents requested for the re-registration file of imported products:

(Both a printed copy & an electronic copy on a CD are to be presented)

First: Administrative information

- 1) Company identification form (Company profile) (presented only once & renewed whenever any change is made)
- 2) Application form for re-registration.
- 3) Product's registration certificate.

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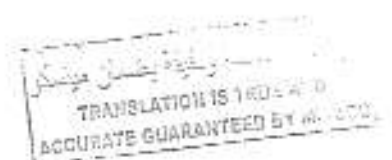
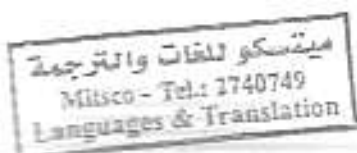
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- 4) Product's pricing certificate.
- 5) Payment receipt of the re-registration services fees.
- 6) The original pack of the product (outer & inner packs) & the product insert in Arabic & English languages.
- 7) List of the countries where the product is registered & sold notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 8) Original Free sale certificate of the product in the country of origin notarized from the Egyptian embassy abroad.
- 9) Clarification of the relation between the manufacturing company, the importing company & the distributor by original certificates notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 10) Agency or distribution contract notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad (submit a copy after looking into the original)
- 11) Concerning products manufactured abroad & packed locally, the following will be presented besides the previous:

Local packaging contract between the importing company & the licensed local factory which performs packaging. The foreign companies having a licensed factory are exempted from this condition.

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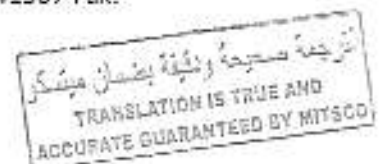
- Authorization letter from the foreign company abroad to the importing company declaring agreement on registering & packing the product in a licensed local factory inside Egypt. The letter should be notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad
- 12) Authorization letter for the person handling registration, sealed with the company seal.
- 13) A pledge verifying the data sealed with the company seal

Second: Materials entering in the product formula

Active ingredients:

- 1) Specifications of the active ingredients & the relevant tests.
- 2) Methods of analysis and validation.
- 3) Certificates of analysis.
- 4) BSL/ISL Freedom certificates for the materials entering in the product formulation, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 5) If the materials entering in the product formulation are from blood derivatives, the following will be presented besides the previous:
 - Plasma master file including information indicating plasma source starting from the process of collection passing by all steps of manufacture, in process control & viral safety.

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- Official certificates declaring plasma source notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- HIV-1, HIV-2, HBsAg & HCV freedom certificate for the plasma, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad

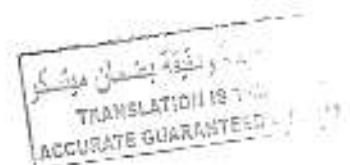
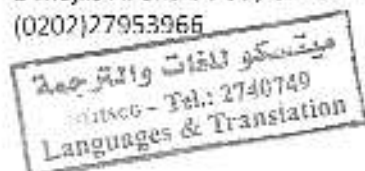
Inactive ingredients:

- 1) Specifications of the inactive ingredients & the relevant tests.
- 2) Certificates of analysis.
- 3) Methods of analysis and validation.
- 4) BSE/TSE Freedom certificates for the materials entering in the product formulation, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 5) HIV-1, HIV-2, HBsAg & HCV freedom certificate for the plasma (In the case of using blood derivatives as inactive ingredients) notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad

Packaging & wrapping materials:

- 1) Type & specifications of the components of Packaging & wrapping materials.
- 2) Names of the suppliers.

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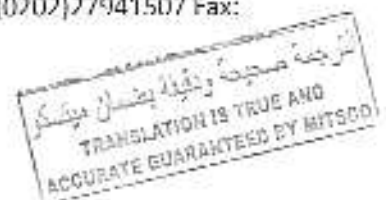
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Third: Finished product

- 1) Product's formula including the active & inactive ingredients printed on the company paper & sealed with the company seal, notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 2) Certificate of analysis of the product notarized from the Chamber of commerce or its equivalent in the country of origin and certified from the Egyptian embassy abroad.
- 3) Stability study of the product (Ongoing stability).
- 4) Factory license or its equivalent notarized from the Egyptian embassy abroad.
- 5) Inspection report of the manufacturing site issued from the competent authority & notarized by the Egyptian embassy abroad.
- 6) Good manufacturing practice certificate (GMP) issued from the health authority in country of origin & notarized by the Egyptian embassy abroad.
- 7) Finished product specifications.
- 8) The applied methods of analysis of finished product & their validation.
- 9) Flow chart indicating sites & steps of product manufacture.
- 10) Method of manufacture, with clarifying the in process control & validation used during process of manufacture.
- 11) Production site file (Site master file)
- 12) Post marketing studies.
- 13) Description of the applied steps to keep the cooling chain (cold chain).

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Appendix (9): Representation form:

I (Chairman of the board/Chief executive officer) holding I.D. No.....
declare & represent that the application for registration of the product doesn't
violate terms of the intellectual property rights protection law 82/2002 & its executive
regulations. And that I bear the legal responsibility if my violation to the mentioned law was
proven.

Name:

Capacity:

I.D. :

Signature:

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