Regulatory Guideline on

Organizing the Rules and Procedures of Registration of Human Pharmaceutical Products in Accordance with the Different Cases Based on Egyptian Drug Authority Chairman Decree No. (450) of 2023

Code: Gl.CAPP.027
Version No.: (2)
Issue Date: November, 9th 2023
Effective Date of the Decree: November, 9th 2023

Contents

Introduction

- This guideline is concerned with regulating the rules and procedures of the registration of human pharmaceutical products in the different cases in the Egyptian Drug Authority in accordance with the law of establishing the Authority promulgated by Law No. 151 of 2019. This guideline shall apply to the human pharmaceutical products manufactured locally in factories inside the Arab Republic of Egypt for the purpose of local marketing, tender and export or for export only, or imported finished products or those that are manufactured abroad and are packed and packaged in licensed factories inside the Arab Republic of Egypt.
- The Heads of the competent central administration shall determine the grace periods necessary for the procedures of receiving, evaluating and presenting to the various committees, each in their respective jurisdictions, without prejudice to the original grace periods stipulated for registration, provided that each competent administration shall issue a list that includes the method of application for getting the requested service, the required documents and procedures, the specified dates and grace periods, the submission links and the services consideration, when required.
- All relevant regulatory divisions of the Egyptian Drug Authority, each in its jurisdictions, are committed to announcing on the submission links: About
  All attachments necessary to receive the applications and studies necessary to complete and submit the registration file.

Scope

The decree shall apply to organizing registration rules and procedures for human pharmaceutical products, which include:

1- Innovator products Approved by one of the stringent regulatory authorities (SRAs), included in the list of reference countries approved by the Technical Committee for Drug Control or WHO prequalified products.
2- Generics having a reference similar product has been approved by stringent regulatory authority (SRAs) included in a list of the reference countries approved by the Technical Committee for Drug Control or WHO prequalified products.
3- Generics that differ from the reference product in the dosage form, concentration or route of administration after presentation to the scientific committees and approval of the technical committee of drug control.

This decree shall not apply to the registration of biological/herbal/veterinary products or the products containing new active chemical entities.

Reliance Evaluation Route

Egyptian Drug Authority adopts Good Reliance Practices in the evaluation of safety, efficacy and quality data of human pharmaceutical products registered in stringent control authorities (SRAs) included in a list of the reference countries approved by the Technical Committee for Drug Control or WHO prequalified to grant the MA License, which includes:

1. Verification Evaluation Route

2. Abridged Evaluation Route

Evaluation Route	Eligibility Criteria	Requirements
Verification (An Administration process not a scientific assessment to reach a regulatory decision. Verification may be on the basis of assessment reports, GMP inspection reports and/or a certificate of pharmaceutical product of a Stringent Regulatory Authority or WHO prequalification).	Product that has been approved by at least two stringent regulatory authorities or one reference and WHO prequalification	1. Valid Certificate of Pharmaceutical Product 2. Complete CTD dossier 3. Verification of Sameness* (for example sameness letter) 4. Unredacted Assessment report (otherwise justified with evidence) 5. Proof of approval from at least two stringent regulatory authorities or one reference and WHO prequalification.
Abridged (A limited assessment of suitability of use under local conditions and regulatory requirements, while relying on assessment reports, and good manufacturing practices (GMP) inspection reports of one of Stringent regulatory authorities or WHO prequalification, plus specific parts of the Common Technical Document (CTD) (This might include a review of the pharmaceutical quality (CMC) data in relation to climatic conditions).	Product that has been approved by at least one stringent regulatory authority or WHO prequalification	1. Valid Certificate of Pharmaceutical Product 2. Complete CTD dossier 3. Verification of Sameness* (for example sameness letter) 4. Unredacted Assessment report (otherwise justified with evidence) 5. Proof of approval from least one stringent regulatory authority or WHO prequalification

***Sameness:** Ensuring similarity of products (or that where differences exist, these are clearly stated) which are submitted to Egyptian Drug Authority compared to the reference Stringent Regulatory Authority (SRAs), regardless of the approaches or assessment activities conducted by the SRAs. The same pharmaceutical product is defined as characterized by:

- The same qualitative and quantitative formulation.
- The same manufacturing site(s) for the drug substance and finished product, including specific block(s)/unit(s), manufacturing chain, processes, control of materials and finished product.
- The same specifications for the excipient(s), drug substance and finished product.
- The same essential elements of product information for pharmaceutical products.

***Sameness letter**: is an authorized document issued by the License Holder to assure the same quality of the product and to provide transparency about any potential differences compared to the reference Stringent Regulatory Authority (SRAs).

Box

The number of similars in the box consisting of a group of pharmaceutical forms shall be determined starting from the innovator product of the active ingredient as indicated in Appendix No. (1) in accordance with the rules specified in detail in the regulatory guideline issued for implementation of this decree's provisions and after being presented to the EDA Chairman, provided that the Pharmaceutical forms in the box indicated in the Appendix No. (2) shall be updated in the event of the emergence of a new pharmaceutical form and after being presented to the Technical Committee for Drug Control.

Regulating Rules of the Line Extension:

- Line Extension is the addition of another concentration for the same company with the same pharmaceutical form or in different pharmaceutical forms within the same box of the same active ingredients for the registered products that have a valid marketing authorization license or for the under-registration products whose registration procedures are in progress.
- When applying for registering a Line Extension in the same month in which the basic request is submitted, it shall not be counted among the number of registration requests available for submission per month.
- In the event that the company is desirous to submit a registration request for a Line Extension of a basic product, which product was applied for it in a previous month, in excess of the number of registration requests allowed to be submitted per month, the companies shall be permitted to submit ten registration requests for human pharmaceutical products as Line Extensions per month; provided that the service consideration specified for each additional registration request shall be paid.
- The registration request approval of the Line Extension shall be issued on the same Case and Track, provided that the specified service consideration shall be paid and the registration procedures of the same Case and Track on which the basic registration request is accepted shall be implemented.

Company Commitments

The company shall be committed to do the following:

1. Compliance with the provisions of Law No. (82) of 2002 on the Intellectual Property Protection and its executive regulation without any responsibility on the part of the Egyptian Drug Authority.
2. Printing the manufacturer's name and address, production date, expiry date, batch number, registration number and price on the outer package. The rest of the required data shall be adhered to in accordance with the rules regulating the work of the Evaluation unit of Trade Names and mockup of Human pharmaceuticals in the General Administration of Human Pharmaceutical Registration. Any change on the product shall be prohibited except after getting an approval of the Egyptian Drug Authority.
3. Notifying the Egyptian Drug Authority of the names of all its authorized distributors, its storage locations, and any change in the data. The Central Administration of Operations shall follow up this commitment.
4. Manufacturing the product in the same source of the active pharmaceutical ingredient from which the pilot batch(es) / production batch(es) / R&D batch(es) were manufactured in accordance with the different registration cases and on which all the required studies have been conducted. This applies to products manufactured locally and presented for local marketing or for tender and export, or for export only, for which the marketing authorization license is issued. In the event that the company needs to add one or more suppliers, the company shall submit a request to the General Administration of Human Pharmaceutical Registration to determine the required studies.
5. A declaration that it shall not make any change except after the approval of Central Administration of Pharmaceuticals Products, otherwise the marketing authorization license shall be canceled based on a report issued by the Central Administration of Operations.
6. Acknowledging full liability for the storage of the active pharmaceutical ingredients, all the manufacturing phases of the product, the product conformity to the technical specifications and for storing the product up to its complete distribution. In the case of locally manufactured products intended for local marketing, for tender and export, or for export only, the manufacturer shall be required to be licensed by the Egyptian Drug Authority and to adhere to all the obligations contained in this guideline, the rules of Good Manufacturing Practice (GMP) and the provisions of the Ministerial decree No. (777) of 2020 article no. (17)
7. Adherence of the company to the clauses mentioned in Article Twelve in the Egyptian Drug Authority's decree 450/2023.
8. The products registered for export only or for tender and export are not subjected to the grace periods of production and importation.
9. In case of registering the innovator product (whether it was imported or locally manufactured under a license from abroad), the company shall be exempted from

applying to the Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals, where safety and efficacy studies shall be submitted within the complete registration dossier.

10. Adherence of the company to submitting a report on the safety, quality and efficacy of the registered product during the last three months of the fifth year from the date of marketing authorization license. In the event of non-compliance with that procedure, the marketing of the product shall be suspended based on a report issued by the relevant central administrations.

The First Case

In this case, the company applies for registering human pharmaceutical products **as per the number allowed in the box**, provided that the complete registration dossier shall be submitted as a condition for completing the final registration dossier, fulfilling the registration procedures for human pharmaceutical products submitted in accordance with the First Case, fulfilling the requirements and completing the required technical studies and getting the necessary approvals for registration in accordance with the procedures listed in this regulatory guideline.

(A) For locally manufactured human pharmaceutical products

First: Submitting a registration request for a human pharmaceutical product

❖ **Submitting a registration request for human pharmaceutical product locally manufactured for the purpose of local marketing**

- Two registration requests for each manufacturer and one registration request for each Toll company shall be received per month.
- The company shall be obligated to submit a registration request in accordance with the regulatory guides of the General Administration of Human Pharmaceuticals Registration published on Egyptian Drug Authority website. This request shall be registered in accordance with the date and time of its submission in complete and correct form, provided that the company shall receive a confirmation of the initial acceptance of the registration request within 3 working days from the date of receiving the completed request in accordance with the regulating rules. The company shall be notified of the status of the product within a maximum of 18 working days from the date of confirming the initial acceptance of the fulfilled registration request **in accordance with the regulating rules**:

▪ **In the event that there is availability in the box**: In the case there are documents required to be fulfilled, the company shall be obligated to complete any required documents within a maximum of 3 months from the date of being notified. The registration request approval shall be issued within 10 working days from the date of receiving the fulfilled required documents. The company shall be obligated to pay the service consideration of product registration before heading for receiving the registration

request approval, provided that the company shall receive the registration request approval within 30 working days from the date of its issuance, otherwise the registration request shall be cancelled.

- **In the event that there is no availability in the box**: The fulfilled registration request shall be registered in the waiting list record as per the regulating rules in accordance with the date and time of its submission until the product has availability in the box for whatever reason. The company whose turn comes in the waiting list shall be granted the approval of the box. In the case that there are documents required to be fulfilled, a grace period shall be given to the company whose turn comes in the waiting list to fulfill these required documents within 3 months from the date of being notified of the required documents to be fulfilled. In the case of failure to fulfill the required documents within this specified grace period, the company's request shall be considered cancelled and the company whose turn is next shall be addressed.

❖ **Submitting a registration request for registering locally manufactured human pharmaceutical products intended for tender and export or for export only**

The company shall submit a request for starting the product registration procedures to the General Administration of Human Pharmaceuticals Registration in accordance with the regulating rules of the General Administration of Human Pharmaceuticals Registration published on the Egyptian Drug Authority's website, Appendix No. (4). The company shall be notified of the status of the product within 15 working days from the date of receiving the fulfilled and correct registration request. In the case of acceptance, the General Administration of Human Pharmaceuticals Registration shall issue an approval letter for the request submitted by the company. The company shall be obligated pay the service consideration of product registration before receiving the registration request approval, provided that the company shall receive the registration request approval within 30 working days from the date of its issuance, otherwise the registration request shall be cancelled.

Note:

The registration request approval shall state whether the product has a scientific reference or not in accordance with the documents submitted by the company and on its own responsibility taking into consideration that the company shall adhere to the active ingredient, the pharmaceutical form, and the concentration mentioned in the scientific reference which it has sent.

❖ **Locally manufactured human pharmaceutical products that do not have a scientific reference**

If the product does not have a scientific reference with the same pharmaceutical form, dose or route of administration, the company shall submit the scientific files of the product to the specialized scientific committees within 30 working days from the date of issuing the registration request approval, otherwise the registration request shall be canceled. The product

shall be presented to the specialized scientific committees within 60 working days from the date of receiving the completed scientific file.

- **In the event of the approval on a scientific basis:** The company shall be notified of the approval and it shall complete the product registration procedures. In the event that the studies submitted by the company are required to be fulfilled, the company shall be granted a grace period of 30 working days to submit the fulfilled required documents. The matter shall be re-presented to the specialized scientific committees within 30 working days from the date of accepting the fulfilled required documents, otherwise the registration request shall be cancelled.
- **In the event of the non-approval on a scientific basis:** The General Administration of Human Pharmaceuticals Registration shall present the matter to the Technical Committee for Drug Control to take the decision it deems appropriate and to state the reasons in the case of rejecting the registration request and a letter shall be issued to the company by the specialized scientific committees. In the case of non-approval, the company is permitted to submit an appeal against the final decision issued by the Technical Committee for Drug Control based on a reasoned request supported by the documents and information on which the company desires to rely. The decisions of the specialized scientific committees shall be used as a guidance in the study of the registration requests to be submitted later.

Note:

- **In the event that a scientific reference for the product emerges before applying for the scientific committees or before presenting the issue thereto or in the event that the company submits a different scientific reference that matches the product submitted in the registration request approval,** a study of this reference shall be conducted and a statement shall be issued by the Evaluation unit of Scientific data and drug Development without being presented to the scientific committees. Accordingly, the Evaluation unit of registration request of human products shall be addressed to amend the registration request approval with the scientific reference.
- **In the event that a scientific reference for the product emerges after the product is rejected by the scientific committees and the Technical Committee for Drug Control**, Evaluation unit of registration request of human products shall be addressed to get a new registration request approval.

Second: Approvals required to be obtained after the registration request approval or after the issuance of the scientific committee approval

❖ **For under-registration locally manufactured human pharmaceutical products, the company shall apply in parallel to the following entities:**

(a) Evaluation Unit for Trade names and Mockup for Human Pharmaceuticals:

- The company shall submit a list of 15 proposed trade names for the product to the Evaluation Unit for Trade Names and Mockup for Human Pharmaceuticals within a

maximum period of 30 working days from the issuance date of the registration request approval or from the issuance date of approval of the scientific committees, otherwise the registration request shall be cancelled.

- The Evaluation Unit for Trade Names and Mockup for Human Pharmaceuticals shall review the list of trade names submitted by the company within 15 working days from the date of receiving the list of names from the company. A letter shall be issued to the company stating the approval of the product name or the rejection of the first list of names that are previously submitted.
- In the case of rejection, the company shall be obligated to submit another list within a maximum of 20 working days from the date of issuing the rejection letter of the first list of names that are previously submitted.
- The company shall be permitted to submit a maximum of four lists of the proposed names, including the first list of names, provided that the evaluation and approval shall be issued as mentioned above.
- In the case of rejecting the four lists submitted by the company, an approval will be issued with the scientific name alongside the company name.

(b) Central Administration of Drug Policies and Market Access / General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration:

- The documents required for pricing the local products and the imported products shall be submitted (as per Appendix No. 5).
- The documents shall be submitted within 30 working days from the issuance date of the registration request approval or from the issuance date of approval of the scientific committee, otherwise the registration request shall be canceled based on a report submitted by the relevant central administration, provided that the products shall be priced within a maximum period of 90 working days from the date of receiving the complete pricing file.
- For locally manufactured products intended for export only or for tender and export they shall be exempted from applying to the Central Administration of drug Policies and Market Access / General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration.

(c) Central Administration for Pharmaceutical Care / General Administration of Pharmaceutical vigilance

The documents necessary to fulfill the Pharmacovigilance requirements as per the regulatory rules of the General Administration of Pharmaceutical vigilance (Appendix No. 6), shall be Submitted within 30 working days from the issuance date of the registration request approval

or from the issuance date of approval of the scientific committee, otherwise the registration request shall be canceled based on a report submitted by the relevant central administration. The documents submitted by the company shall be evaluated within a maximum of 60 working days from the date of receiving of the fulfilled pharmacovigilance documents (provided that the document describing the Pharmacovigilance system of the company shall be completed upon evaluation).

- **In the event of the approval of the General Administration of Pharmaceutical vigilance**: The company shall be notified of the approval and the product registration procedures shall be completed. In the event that the company is required to fulfill other documents, the company shall be given a period of a maximum of 30 working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance). The evaluation shall be finished by the General Administration of Pharmaceutical vigilance within 30 working days from the date of receiving the required documents.
- **In the event of non-approval or non-fulfillment of the documents**: The registration request shall be presented to the Technical Committee for Drug Control by the General Administration of Pharmaceutical vigilance to take the decision it deems appropriate and to state the reasons in the case of rejecting the registration request.

Note:

In the event of exceeding any of the specified grace periods regarding submitting the lists of trade names, pricing or pharmaceutical vigilance the company may submit a reasoned request in this regard to the competent central administration within 60 days from the expiration date of these grace periods. In the event of approval, a grace period not exceeding 30 days from the issuance date of the approval shall be given. The service consideration specified for each grace period shall be paid separately.

❖ **Studies and approvals required in the procedures of registering human pharmaceutical products:**

(a) For Locally manufactured human pharmaceutical products for the purpose of local marketing, the registration procedures shall be completed according to the following steps:

1. **Commencement of manufacturing of the pilot batch:**
   - Importation and custom release General Administration shall be addressed to apply for importing the active ingredient / packaging material as per the registration request approval, pursuant to the regulatory guideline along with its continuous updated versions issued by the Importation and custom release General Administration at the Central Administration of Drug Policies and Market Access.
   - Before production, the company shall apply to the Central Administration of Operations as per the regulatory guideline of the General Administration of Factories Inspection (Appendix No. 7) in order to manufacture a pilot batch (the pilot batch size shall

correspond to at least 10% of the production batch, exceeding the minimum production capacity of the manufacturing line) in the presence of an inspector from the Central Administration of Operations, provided that this batch shall never be marketed in the local market. The company shall be permitted to produce according to the approval issued by the relevant central administration concerning the active ingredient used in the product in the presence of an inspector from the Central Administration of Operations to ensure that the pilot batch is produced on the same production lines located in the factory.

2. **The inspector shall attach the composition according to which the production is made and this composition shall be signed by the manufacturer representative and shall be sealed and signed by the inspector in an inspection report indicating the source of the active ingredient, provided that the registration procedures shall be fulfilled as per the composition according to which the production is made and they shall be implemented in the following steps:**

A. Samples shall be taken through the Central Administration of Operations from the pilot batch for analysis at the Central Administration for Drug Control in accordance with the regulating rules and deadlines as per the regulatory guideline of the Central Administration of Operations. The Central Administration for Drug Control shall review the analysis file and issue the analysis result in the Administration of Evaluation and Approval as per the executive guideline for reviewing the files, (Appendix No. 8). The result shall state the source of active ingredient, the batch number, the batch type, the manufacturer name, and the product name and its data.

B. Accelerated stability study for a period of 6 months on the pilot batch shall be submitted to the General Administration of Stability to be evaluated and shall be accompanied with the composition, according to which the production was made, and signed and sealed by the inspector of the Central Administration of Operations, provided that the evaluation shall take place within 60 working days from the date of submitting the complete stability study file. The source of the active ingredient, the batch number, the batch type, the name of the manufacturer, the name of the product and its data and complete storage conditions based on the pharmaceutical form shall be indicated in accordance with the provisions stipulated in the applicable rules for stability studies.

(E.g.: Diluent, Solvent, & it's volume (for injectable products), In–use shelf life & shelf life after opening / dilution or reconstitution & storage conditions, etc…)

** In addition to fulfilling long term stability study for at least one year on the same pilot batch in order to grant the product a validity period of two years.

C. The company shall address The Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals to which it shall submit a request

with the attached composition on which the production is made, and signed and sealed by the inspector of the Central Administration of Operations in order to determine the status of the product in terms of the type of the study required. The company shall be obligated to send a commitment stating the presence or absence of any other concentrations of the same active ingredient in the same pharmaceutical form (be under registration or registered). In the event that there are other concentrations, the company shall submit the compositions approved by EDA for these concentrations so that the company's request can be adjudicated. The Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals shall notify the company of the type of the required study.

- In the cases that require conducting a study of bioavailability, bioequivalence, or comparative dissolution in accordance with the rules and procedures regulating the conduction of studies of bioavailability, bioequivalence, or comparative dissolution, samples shall be taken by the Central Administration of Operations and the matter shall be stated in an inspection report dated and signed by the manufacturer's representative and the inspector of the Central Administration of Operations. These samples shall be sent to the bioavailability and bioequivalence centers that are licensed by the Egyptian Drug Authority. The study shall be submitted to the Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals to be evaluated within 60 working days from the date of submitting the fulfilled study in accordance with the rules and procedures applied in this regard.
- In case of registering the locally manufactured products intended for export only, the company may submit a request to be exempted from conducting the studies of bioavailability, bioequivalence and comparative dissolution for human pharmaceuticals within the Arab Republic of Egypt, provided that the company shall submit the study upon conducting it abroad. This procedure is stated as a condition in the marketing authorization license.

Note:

- The company may apply to the General Administration of Human Pharmaceuticals Registration with a request to permit the manufacture of a production batch(s) instead of a pilot batch(s) and to conduct all the studies required to get the marketing authorization license on these production batches, while stating the reasons in it, and to be presented to the Head of the Central Administration of Pharmaceutical Products with a detailed report stating the reasons after paying the service consideration.

3. The company shall adhere to submit the file as per the complete registration dossier to the Administration of Technical Affairs after getting the approval of study of bioavailability and bioequivalence of human pharmaceuticals and the approval of stability study and CADC report, provided that the evaluation and issuance of the technical report shall be issued within 28 working days.

4. The company shall be obligated to apply to the General Administration of Pharmaceutical References and Medical inserts at the Central Administration for Pharmaceutical Care for approving the medical leaflet in accordance with the regulatory rules of the General Administration of Pharmaceutical References and Leaflets (Appendix No. 9), after approving the stability study. The company shall also be obligated to apply to Evaluation unit for Trade Names and Mockup for Human Pharmaceuticals in the Central Administration of Pharmaceutical Products for approving the internal and external mockups.

- Companies shall be permitted to approve the medical leaflet as well as the internal and external mockups of the product by the relevant central administrations before approving the stability study in the event that the production is carried out on a production batch.

(b) For locally manufactured human pharmaceutical products for export only, the following procedures shall be applied:

1. The company shall be obligated to submit accelerated stability study for a period of six months or long term on one or three (R&D) / pilot / production batches to be evaluated by the General Committee to assess Stability Studies within 60 working days from the date of submitting the complete stability study file.

2. The analysis file of the samples shall be submitted to the Central Administration for Drug Control in accordance with the regulatory guideline of the Central Administration for Drug Control.

Third: Submission of registration dossier

- The company shall be obligated to submit the complete **registration dossier** including the required documents through the submission links announced on Egyptian Drug Authority's website to Administration of Regulatory Affairs at the General Administration of Human Pharmaceuticals Registration in accordance with the aforementioned deadlines by EDA Chairman Decree.
- The final review of the dossier shall be carried out by the Administration of Regulatory Affairs and its affiliated units. The company shall be notified of the status of the dossier within 45 working days from the date of receiving the complete registration dossier, and the fulfilled required documents shall be submitted within 60 working days from the date of notifying the company to be evaluated within 15 working days from the date of submitting the required documents. In the event that the deadline for completing the fulfilled required documents is exceeded, the company may apply to the General Administration of Human Pharmaceuticals Registration for extending the deadline of completing the fulfilled required documents after paying the service consideration

In the event of the approval by the Technical Committee for Drug Control	In the event of the rejection by the Technical Committee for Drug Control
A final marketing authorization license shall be issued, provided that the company shall comply with the requirements mentioned in the marketing authorization license and the Central Administration of Operations shall follow up the company compliance.	The company shall be notified of the rejection by virtue of a letter containing the decision of the Technical Committee for Drug Control. The reasons of rejection shall be indicated. The company may submit a grievance to the General Administration of Human Pharmaceuticals Registration against the final decision issued by the Technical Committee for Drug Control within 60 working days from the issuance date of the decision, by virtue of a reasoned request to be submitted to the Technical Committee for Drug Control, supported by the documents and information that the company is desirous to rely on when its grievance is being considered. The matter shall be presented to the Technical Committee for Drug Control within 60 working days from the date when the grievance is submitted.

- The matter shall be presented to the Technical Committee for Drug Control within 30 working days from the date of the company's complete fulfillment of the dossier, so that the Technical Committee shall take the appropriate decision whether to register the product or not.

❖ **Required procedures to be implemented after the issuance of the marketing authorization license:**

- Production of the locally manufactured products that are intended for local marketing that has a final marketing authorization license in the Egyptian market within eighteen months from the issuance date of the final marketing authorization license, otherwise the marketing authorization license shall be cancelled based on a report issued by the Central Administration of Operations.
- The company shall adhere to submit accelerated and long-term stability studies for the first three production batches for the locally manufactured products within five years from the issuance date of the final marketing authorization license in accordance with the report submitted by the Central Administration of Operations; otherwise, the marketing authorization license shall be cancelled.

- **For the imported finished products, manufactured abroad and locally packed or packaged:**
  - **Imported human pharmaceutical products submitted for registration and imported from the reference countries or marketed in one of the reference countries**

First: The procedures of getting a registration request approval

1- The company shall be obligated to submit a registration request of the product in accordance with the regulating rules of the General Administration of Human Pharmaceuticals Registration published on the Egyptian Drug Authority website, the same appendix No. (3). The company shall receive a confirmation of the initial acceptance of the registration request within 3 working days from the date of receiving the fulfilled request in accordance with the regulating rules.

2- The company shall be notified of the status of the product within a maximum of 18 working days from the date of confirming the initial acceptance of the fulfilled registration request in accordance with the regulating rules:

a. **In the event that there is availability in the box**:

The company shall be granted a grace period of a maximum of 3 months to submit the required documents in accordance with to the stipulated regulating rules of the General Administration of Human Pharmaceuticals Registration published on the website of the Egyptian Drug Authority, (the same appendix No. 3) and to have the registration request approval issued, provided that it shall be issued within 10 working days from the date of receiving the fulfilled required documents. The company shall be obligated to pay the fees/service consideration of product registration before heading for receiving the registration request approval, provided that the company shall receive the registration request approval within 30 working days from the date of its issuance, otherwise the registration request shall be cancelled.

b. **In the event that there is no availability in the box**:

The registration request which is fulfilled as per the regulating rules shall be registered in the waiting list record in accordance with the date and time of its submission until it has availability in the box for whatever reason. A grace period shall be granted to the company whose turn comes in the waiting list to submit the fulfilled required documents within 3 months from the date of being notified that there is availability in the box. In the event that company does not adhere to the specified deadline, the request of this company shall be considered cancelled and the company that has the next turn shall be addressed.

Second: Applying to the Evaluation unit for Trade Names and Mockup for Human Pharmaceuticals for getting name approval:

The company shall be obligated to apply to the Evaluation unit for Trade Names and Mockup for Human Pharmaceuticals within 30 working days from the date of the registration request approval for getting approval for the product name, provided that name approval shall be

issued within 15 working days from the date when the company applies to the Evaluation unit for Trade Names and Mockup for Human Pharmaceuticals.

Third: Applying to Central Administration of drug Policies and Market Access / General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration:

Applying to the Pricing Policies and Pharmacoeconomics Administration within a maximum of 30 working days from the issuance date of the registration request approval otherwise the registration request shall be cancelled based on a report submitted by the relevant central administration, provided that the products shall be priced within a maximum period of 90 working days from the date of receiving the complete pricing file.

Fourth: Applying to the Central Administration for Pharmaceutical Care/General Administration of Pharmaceutical vigilance:

- The documents necessary to fulfill the Pharmacovigilance requirements as per the regulatory rules of the General Administration of Pharmaceutical vigilance (Appendix No. 6), shall be Submitted within 30 working days from the issuance date of the registration request approval, otherwise the registration request shall be canceled based on a report submitted by the relevant central administration. The documents submitted by the company shall be evaluated within a maximum of 60 working days from the date of receiving of the fulfilled pharmacovigilance documents (provided that the document describing the Pharmacovigilance system of the company shall be completed upon evaluation).

- **In the event of the approval of the General Administration of Pharmaceutical vigilance**: The company shall be notified of the approval and the product registration procedures shall be completed. In the event that the company is required to fulfill other documents, the company shall be given a period of a maximum of 30 working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance). The evaluation shall be finished by the General Administration of Pharmaceutical vigilance within 30 working days from the date of receiving the required documents.
- **In the event of non-approval or non-fulfillment of the documents**: The registration request shall be presented to the Technical Committee for Drug Control by the General Administration of Pharmaceutical vigilance to take the decision it deems appropriate and to state the reasons in the case of rejecting the registration request.

Fifth: procedures for receiving and reviewing the complete registration dossier and issuing the marketing authorization license:

1. The company shall submit the complete registration dossier containing the required documents after the following:

   (a) Getting the registration request approval and the name approval.

(b) Applying to the pricing and pharmaceutical vigilance Administrations.

This complete registration dossier shall be initially reviewed by representatives of the Administration of the Regulatory Affairs along with its affiliated units, within 20 working days. In case of documents were required to be submitted by the company, the company shall be granted a grace period of 30 working days as a maximum.

2. The Administration of the Regulatory Affairs along with its affiliated units shall send the complete registration dossier to the different divisions to initiate the technical evaluation within 45 working days and notify the company with the dossier status. In case of documents were required to be submitted by the company, the company shall be granted a grace period of three months as a maximum.
3. Upon fulfilling all the requirements, the time set for the product registration shall be resumed and all the approvals shall be issued within a maximum of 10 working days.
4. **Module 1** shall be updated after getting the approvals, pricing certificate and pharmacovigilance approval within six months from the date of issuance of the first pricing certificate of the product or from the issuance date of the approval of the General Administration of Pharmaceutical vigilance whichever is later. The final review of the dossier shall be carried out by the Administration of the Regulatory Affairs and its affiliated units and the company shall be notified of the status of the dossier within 45 working days from the date of receiving the complete registration dossier. In case of documents were required to be submitted by the company, the company shall be granted a grace period of 60 days as a maximum from the date of notifying the company, provided that the required submitted documents shall be evaluated within 15 working days from the date of submission of the required documents. The matter shall be presented to the Technical Committee for Drug Control within 30 working days from the date when the company fulfills the complete dossier, so that the Technical Committee shall take the appropriate decision whether to register the product or not.

   ** In case of exceeding the grace period of fulfilling required documents, the company may submit a request to the General Administration of Human Pharmaceuticals Registration to extend the grace period after paying the service consideration.

Note:

- For the products which have a Certificate of Pharmaceutical Product (CPP) from one of the reference countries approved by the Technical Committee for Drug Control or the products which are marketed in one of the reference countries, the analysis file shall be submitted to the Central Administration for Drug Control, including the documents and attachments required for the analysis file of the first received shipment after the issuance of the final marketing authorization license. The first received shipment shall not be released until the analysis result is issued from the Central Administration for Drug Control.

- The analysis file including the required documents and attachments may be submitted to the Central Administration for Drug Control before the issuance of the marketing authorization license. Accordingly, the Importation and Custom Release General Administration shall be addressed to apply for importing samples as per the registration request approval, pursuant to the regulatory guideline along with its continuous updated versions issued by the Importation and Custom Release General Administration at the Central Administration of Drug Policies and Market Access.

❖ **Required procedures to be implemented after the issuance of the marketing authorization license:**

Importation of the imported products that have a marketing authorization license in the Egyptian markets shall take place within eighteen months from the issuance date of the marketing authorization license; otherwise, the marketing authorization license shall be cancelled based on a report issued by the Central Administration of Operations.

❖ **For human pharmaceutical products that are imported from non-reference countries and that are not marketed in any of the reference countries:**

First: The procedures of getting a registration request approval

1. The company shall submit a registration request of the product in accordance with the regulating rules of the General Administration of Human Pharmaceuticals Registration published on the Egyptian Drug Authority website, the same appendix No. (3). The company shall receive a confirmation of the initial acceptance of the registration request within 3 working days from the date of receiving the fulfilled request in accordance with the regulating rules.
2. The company shall be notified of the status of the product within a maximum of 18 working days from the date of confirming the initial acceptance of the fulfilled registration request in accordance with the regulating rules.
3. The product shall be presented to the Technical Committee for Drug Control to take the decision that it deems appropriate. The company shall adhere to the decision of the Technical Committee for Drug Control regarding submitting the (Site Master File) to General Administration for Factories Inspection and conducting inspection on the factory abroad. In the event that the Technical Committee for Drug Control requests some documents from the company, the company shall be obligated to submit the required documents within a maximum of **30 working days** from the date of notifying the company, otherwise the registration request shall be cancelled.

- **In the event of the approval by the Technical Committee**: The registration request approval shall be issued within 10 working days from the date of receiving the decision of the Technical Committee. The company shall be obligated to pay the product registration fees/service consideration before heading for receiving the registration request approval, provided that the company shall receive the registration request approval within 30 working days from the date of its issuance, otherwise the

registration request shall be cancelled.

- **In the event that the Technical Committee refuses to exclude the product from the condition of being marketed in the reference countries**: The company may submit an appeal against the decision of the Technical Committee for Drug Control, provided that a new registration request shall be submitted to the General Administration of Human Pharmaceuticals Registration after paying the specified service consideration.
- **In the event that there is availability in the box**: The company shall be granted a grace period of a maximum of 3 months to submit the required documents in accordance with to the stipulated regulating rules of the General Administration of Human Pharmaceuticals Registration published on the website of the Egyptian Drug Authority, (the same appendix No. 3) and to have the registration request approval issued, provided that it shall be issued within 10 working days from the date of receiving the fulfilled required documents. The company shall be obligated to pay the service consideration of product registration before heading for receiving the registration request approval, provided that the company shall receive the registration request approval within 30 working days from the date of its issuance, otherwise the registration request shall be cancelled.
- **In the event that there is no availability in the box**:

  The registration request which is fulfilled as per the regulating rules shall be registered in the waiting list record in accordance with the date and time of its submission until it has availability in the box for whatever reason. A grace period shall be granted to the company whose turn comes in the waiting list to submit the fulfilled required documents within 3 months from the date of being notified that there is availability in the box. In the event that company does not adhere to the specified deadline, the request of this company shall be considered cancelled and the company that has the next turn shall be addressed.

Second: Applying to the Evaluation unit for Trade Names and Mockup for Human Pharmaceuticals for getting an approval for the name:

The company shall be obligated to apply to the Evaluation unit for Trade Names and Mockup for Human Pharmaceuticals within 30 working days from the date of the registration request approval for getting approval for the product name, provided that name approval shall be issued within 15 working days from the date when the company applies to the Evaluation unit for Trade Names and Mockup for Human Pharmaceuticals.

Third: Applying to Central Administration of drug Policies and Market Access / General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration:

Applying to the Pricing Policies and Pharmacoeconomics Administration within a maximum of 30 working days from the issuance date of the registration request approval

otherwise the registration request shall be cancelled based on a report submitted by the relevant central administration, provided that the products shall be priced within a maximum period of 90 working days from the date of receiving the complete pricing file.

Fourth: Applying to the Central Administration for Pharmaceutical Care/General Administration of Pharmaceutical vigilance:

The documents necessary to fulfill the Pharmacovigilance requirements as per the regulatory rules of the General Administration of Pharmaceutical vigilance (Appendix No. 6), shall be submitted within 30 working days from the issuance date of the registration request approval, otherwise the registration request shall be canceled based on a report submitted by the relevant central administration. The documents submitted by the company shall be evaluated within a maximum of 60 working days from the date of receiving of the fulfilled pharmacovigilance documents (provided that the document describing the Pharmacovigilance system of the company shall be completed upon evaluation).

- **In the event of the approval of the General Administration of Pharmaceutical vigilance**: The company shall be notified of the approval and the product registration procedures shall be completed. In the event that the company is required to fulfill other documents, the company shall be given a period of a maximum of 30 working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance). The evaluation shall be finished by the General Administration of Pharmaceutical vigilance within 30 working days from the date of receiving the required documents.
- **In the event of non-approval or non-fulfillment of the documents**: The registration request shall be presented to the Technical Committee for Drug Control by the General Administration of Pharmaceutical vigilance to take the decision it deems appropriate and to state the reasons in the case of rejecting the registration request.

Fifth: procedures for receiving and reviewing the complete registration dossier and issuing the marketing authorization license:

1. The company shall submit the complete registration dossier containing the required documents after the following:
   a. Getting the registration request approval and the name approval.
   b. Applying to the pricing and pharmaceutical vigilance Administrations.

   This complete registration dossier shall be initially reviewed by representatives of the Administration of the Regulatory Affairs along with its affiliated units, within 30 working days. In case of documents were required to be submitted by the company, the company shall be granted a grace period of 30 working days as a maximum.

2. The Administration of the Regulatory Affairs along with its affiliated units shall send the complete registration dossier to the different divisions to initiate the technical evaluation within 80 working days and notify the company with the dossier status. In

case of documents were required to be submitted by the company, the company shall be granted a grace period of three months as a maximum.

3. Upon fulfilling all the requirements, the time set for the product registration shall be resumed and all the approvals shall be issued within a maximum of 10 working days.
4. **Module 1** shall be updated after getting the approvals, pricing certificate and pharmacovigilance approval within six months from the date of issuance of the first pricing certificate of the product or from the issuance date of the approval of the General Administration of Pharmaceutical vigilance whichever is later. The final review of the dossier shall be carried out by the Administration of the Regulatory Affairs and its affiliated units and the company shall be notified of the status of the dossier within 45 working days from the date of receiving the complete registration dossier. In case of documents were required to be submitted by the company, the company shall be granted a grace period of 60 days as a maximum from the date of notifying the company, provided that the required submitted documents shall be evaluated within 15 working days from the date of submission of the required documents. The matter shall be presented to the Technical Committee for Drug Control within 30 working days from the date when the company fulfills the complete dossier, so that the Technical Committee shall take the appropriate decision whether to register the product or not.

** In case of exceeding the grace period of fulfilling required documents, the company may submit a request to the General Administration of Human Pharmaceuticals Registration to extend the grace period after paying the service consideration.

Note:

The company shall be obligated to submit the analysis file including the required documents and attachments to the Central Administration for Drug Control and to issue the analysis result at Administration of Evaluation and Approval as per the regulatory rules for analysis the files before the marketing authorization license is issued. Accordingly, Importation and custom release General Administration shall be addressed to apply for importing samples as per the registration request approval, pursuant to the regulatory guideline along with its continuous updated versions issued by the Importation and custom release General Administration at the Central Administration of Drug Policies and Market Access.

❖ **Required procedures to be implemented after the issuance of the registration notification:**

Importation of the imported products that have a marketing authorization license in the Egyptian markets shall take place within eighteen months from the issuance date of the marketing authorization license; otherwise, the marketing authorization license shall be cancelled based on a report issued by the Central Administration of Operations.

Exceeding the specified grace periods of submitting the registration dossier

- In the event of exceeding the stipulated previous grace periods, the company may apply to the General Administration of Human Pharmaceuticals Registration with a request for a reasoned grace period, provided that the request shall be presented to EDA Chairman and shall be accompanied with a detailed report indicating the reasons for exceeding the grace periods and the importance of the product in addition to the evidences proving the seriousness of the company to take necessary measures regarding the product that serve the public interest. In the event of approval, the company shall be granted an additional grace period, after paying the specified service consideration. The grace periods shall be as follows:
- In the case of locally manufactured products for the purpose of local marketing or tender and export that are under registration Except the Second Case and Track (A) of the Third Case, the product shall be granted an additional grace period of a maximum 12 months. The grace period may be divided into 4 periods, provided that the specified service consideration shall be paid.
- In the case of imported products under-registration, the product shall be granted an additional grace period of a maximum 6 months from the expiry date of the grace period of submitting the final registration dossier of the product. The grace period may be divided into 2 periods each of them shall be 3 months depending on the company desire, provided that the specified service consideration shall be paid.

Converting to the registration system of the Second Case

- The company may apply for converting any product under registration from a previous registration system or another case of this decree to the registration system of the Second Case if the product conforms with any of the articles specified in this decree for this case. In the event that the company is desirous to convert the product in accordance with the stipulated regulatory rules, the differentials of the specified fees and the service consideration shall be paid for each phase as per the registration fees approved in accordance with this case. The provisions indicated in Appendix No. (10) shall be adhered to.
- The product shall not exceed any of the grace periods stipulated in the ministerial decree and the cases for which the registration was previously applied.
- The grace period required to apply for the next step of the registration shall be calculated from the issuance date of the converting approval.

Converting to the registration system of the Third Case

- The company may apply for converting any product registered or under registration for the purpose of export or tender and export from a previous registration system or another case of this decree to the registration system of the Third Case if the product conforms with any of the articles specified in this decree for this case. In the event that the company is desirous to convert the product in accordance with the stipulated regulatory rules, the differentials of the specified fees and the service consideration shall be paid for each phase as per the registration fees approved in accordance with this case. The provisions indicated in Appendix No. (11) shall be adhered to.
- It shall be permitted to convert a product from one Track to another within the same case in the event that the company status or the product status have changed so that more than one Track can be applied thereto within the same case by virtue of an approval by EDA chairman based on a report submitted by the Head of the Central Administration of Pharmaceutical Products, provided that the company shall be committed to pay the service consideration before receiving the approval.
- The products submitted in accordance with the previous ministerial decrees or the other cases of this decree which are on the waiting list shall not be eligible to convert under this decree and new registration requests shall be submitted for these products to benefit from the case.
- The product shall not exceed any of the grace periods stipulated in the ministerial decree and the cases for which the registration was previously applied.
- The grace period required to apply for the next step of the registration shall be calculated from the issuance date of the converting approval.

The Second Case

The company shall apply for registering human pharmaceutical products as per the number allowed in the box and with Fast Track registration. The Complete registration dossier shall be submitted. This case includes the following tracks:

Track (A): The human pharmaceutical products that have an approval of the two international bodies "US-FDA" and "EU-EMA" in addition to one of the stringent regulatory authorities (SRAs) included in a list of the reference countries approved by the Technical Committee for Drug Control or WHO prequalified products. Such products shall be registered by EDA within a period of one month from the date of receiving the complete registration dossier

Track (B): The human pharmaceutical products that have an approval of any of the two international bodies "US-FDA" OR "EU-EMA" in addition to one of the stringent regulatory authorities (SRAs) included in a list of the reference countries approved by the Technical Committee for Drug Control or WHO prequalified products. Such products shall be registered by EDA within a period of two months from the date of receiving the complete registration dossier.

Track (C) i: The imported human pharmaceutical products from one of the stringent regulatory authorities (SRAs) included in a list of the reference countries approved by the Technical Committee for Drug Control or the products imported from a non-reference country and marketed in one of the reference countries approved by the Technical Committee for Drug Control. Such products shall be registered by the EDA within a period of three months from the date of receiving the complete registration dossier

Track (C) ii: The human pharmaceutical products imported from non-reference country and not marketed in any of the reference countries approved by the Technical Committee for Drug Control. Such products shall be registered by the EDA within a period of six months from the date of receiving the complete registration dossier

Track (C) iii: The locally manufactured human pharmaceutical products. Such products shall be registered by EDA within a period of six months from the date of receiving the complete registration dossier.

- For the new imported human pharmaceutical products submitted for registration in accordance with the Tracks A, B, and C, 1 registration request is received (with its concentrations, if any) for each company or scientific office per month. (In the case of applying of more than one concentration of the product, the service consideration specified for each concentration shall be paid).
- For the new locally manufactured human pharmaceutical products submitted for registration in accordance the Track C, 2 registration requests are received for each manufacturer and 1 registration request for each Toll company per month. (In the case of applying of more than one concentration of the product, the service consideration specified for each concentration shall be paid).

Track (A): The human pharmaceutical products that have an approval of the two international bodies "US-FDA" and "EU-EMA" in addition to one of the stringent regulatory authorities (SRAs) included in a list of the reference countries approved by the Technical Committee for Drug Control or WHO prequalified products.

First: Procedures for getting the registration request approval:

1. The company shall be obligated to submit a registration request of the product in accordance with the regulating rules of the General Administration of Human Pharmaceuticals Registration published on the Egyptian Drug Authority website, the same appendix No. (3). The company shall receive a confirmation of the initial acceptance of the registration request within 3 working days from the date of receiving the fulfilled request in accordance with the regulating rules.
2. The company shall be notified of the status of the product within a maximum of 7 working days from the date of confirming the initial acceptance of the fulfilled registration request in accordance with the regulating rules:

- **In the event that there is availability in the box**: The company shall be granted a grace period of a maximum of 3 months to submit the required documents in accordance with to the stipulated regulating rules of the General Administration of Human Pharmaceuticals Registration published on the website of the Egyptian Drug Authority, (the same appendix No. 3) and to have the registration request approval issued, provided that it shall be issued within 2 working days from the date of receiving the fulfilled required documents. The company shall be obligated to pay the service consideration of product registration before heading for receiving the registration request approval, provided that the company shall receive the registration request approval within 30 working days from the date of its issuance, otherwise the registration request shall be cancelled.
- **In the event that there is no availability in the box**:
  The registration request which is fulfilled as per the regulating rules shall be registered in the waiting list record in accordance with the date and time of its submission until it has an availability in the box for whatever reason. A grace period shall be granted to the company whose turn comes in the waiting list to submit the fulfilled required documents within 3 months from the date of being notified that there is availability in the box. In the event that company does not adhere to the specified deadline, the request of this company shall be considered cancelled and the company that has the next turn shall be addressed.

Second: Applying to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals for getting an approval for the name:

The company shall be obligated to apply to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals within a maximum period of 15 working days from the date of the registration request approval for get the approval for the product name, provided that the name approval shall be issued within 2 working days from the date when the company applied to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals.

Third: Applying to Central Administration of drug Policies and Market Access / General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration:

Applying to the Pricing Policies and Pharmacoeconomics Administration within a maximum of 15 working days from the issuance date of the registration request approval, provided that the products shall be priced within a maximum period of 30 working days from the date of receiving the complete pricing file.

Fourth: Applying to the Central Administration for Pharmaceutical Care/General Administration of Pharmaceutical vigilance:

The documents necessary to fulfill the Pharmacovigilance requirements as per the regulatory rules of the General Administration of Pharmaceutical vigilance (Appendix No. 6), shall be submitted within 15 working days from the issuance date of the registration request approval, otherwise the registration request shall be canceled based on a report submitted by the relevant

central administration. The documents submitted by the company shall be evaluated within a maximum of 5 working days from the date of receiving of the fulfilled pharmacovigilance documents (provided that the document describing the Pharmacovigilance system of the company shall be completed upon evaluation).

- **In the event of the approval of the General Administration of Pharmaceutical vigilance**: The company shall be notified of the approval and the product registration procedures shall be completed. In the event that the company is required to fulfill other documents, the company shall be given a period of a maximum of 60 working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance). The evaluation shall be finished by the General Administration of Pharmaceutical vigilance within 5 working days from the date of receiving the required documents.
- **In the event of non-approval or non-fulfillment of the documents**: The registration request shall be presented to the Technical Committee for Drug Control by the General Administration of Pharmaceutical vigilance to take the decision it deems appropriate and to state the reasons in the case of rejecting the registration request.

Fifth: procedures for receiving and reviewing the complete registration dossier and issuing the marketing authorization license:

1. The company shall submit the complete registration dossier containing the required documents after the following:
   a. Getting the registration request approval and the name approval.
   b. Applying to the pricing and pharmaceutical vigilance Administrations.

   Within 30 working days from the date in which the registration request was approved. This complete registration dossier shall be initially reviewed by representatives of the Administration of the Regulatory Affairs along with its affiliated units, within 3 working days. In case of documents were required to be submitted by the company, the company shall be granted a grace period of 3 months as a maximum.
2. The stipulated month shall start at receiving the complete registration dossier.
3. The Administration of Regulatory Affairs along with its affiliated units shall send the complete registration dossier to the different divisions to initiate the technical evaluation within 10 working days and notify the company with the dossier status. In case of documents were required to be submitted by the company, the company shall be granted a grace period of three months as a maximum.
4. Upon fulfilling all the requirements, the time set for the product registration shall be resumed and all the approvals shall be issued within a maximum of 5 working days.
5. **Module 1** shall be updated after get the approvals, pricing certificate and Pharmacovigilance approval. The final review of the registration dossier shall be carried out by the Administration of human pharmaceuticals Regulatory affairs and its affiliated units in

preparation to be presented to the Technical Committee for Drug Control within 7 working days, to adjudicate whether to issue or not the marketing authorization license and in case of approval a marketing authorization license shall be issued.

Track (B): The human pharmaceutical products that have an approval of any of the two international bodies "US-FDA" OR "EU-EMA" in addition to one of the stringent regulatory authorities (SRAs) included in a list of the reference countries approved by the Technical Committee for Drug Control or WHO prequalified products.

First: Procedures for getting the registration Request approval:

1. The company shall be obligated to submit a registration request of the product in accordance with the regulating rules of the General Administration of Human Pharmaceuticals Registration published on the Egyptian Drug Authority website, the same appendix No. (3). The company shall receive a confirmation of the initial acceptance of the registration request within 3 working days from the date of receiving the fulfilled request in accordance with the regulating rules.
2. The company shall be notified of the status of the product within a maximum of 7 working days from the date of confirming the initial acceptance of the fulfilled registration request in accordance with the regulating rules:

- **In the event that there is availability in the box**: The company shall be granted a grace period of a maximum of 3 months to submit the required documents in accordance with to the stipulated regulating rules of the General Administration of Human Pharmaceuticals Registration published on the website of the Egyptian Drug Authority, (the same appendix No. 3) and to have the registration request approval issued, provided that it shall be issued within 2 working days from the date of receiving the fulfilled required documents. The company shall be obligated to pay the service consideration of product registration before heading for receiving the registration request approval, provided that the company shall receive the registration request approval within 30 working days from the date of its issuance, otherwise the registration request shall be cancelled.
- **In the event that there is no availability in the box**:
  The registration request which is fulfilled as per the regulating rules shall be registered in the waiting list record in accordance with the date and time of its submission until it has availability in the box for whatever reason. A grace period shall be granted to the company whose turn comes in the waiting list to submit the fulfilled required documents within 3 months from the date of being notified that there is availability in the box. In the event that company does not adhere to the specified deadline, the request of this company shall be considered cancelled and the company that has the next turn shall be addressed.

Second: Applying to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals for getting an approval for the name:

The company shall be obligated to apply to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals within a maximum period of 15 working days from the date of the registration request approval for get the approval for the product name, provided that the name approval shall be issued within 4 working days from the date when the company applied to Evaluation Unit of Trade Names and mockup of Human pharmaceuticals.

Third: Applying to Central Administration of drug Policies and Market Access / General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration:

Applying to the Pricing Policies and Pharmacoeconomics Administration within a maximum of 15 working days from the issuance date of the registration request approval, provided that the products shall be priced within a maximum period of 30 working days from the date of receiving the complete pricing file.

Fourth: Applying to the Central Administration for Pharmaceutical Care/General Administration of Pharmaceutical vigilance:

The documents necessary to fulfill the Pharmacovigilance requirements as per the regulatory rules of the General Administration of Pharmaceutical vigilance (Appendix No. 6), shall be submitted within 15 working days from the issuance date of the registration request approval, otherwise the registration request shall be cancelled based on a report submitted by the relevant central administration. The documents submitted by the company shall be evaluated within a maximum of 10 working days from the date of receiving of the fulfilled pharmacovigilance documents (provided that the document describing the Pharmacovigilance system of the company shall be completed upon evaluation).

- **In the event of the approval of the General Administration of Pharmaceutical vigilance**: The company shall be notified of the approval and the product registration procedures shall be completed. In the event that the company is required to fulfill other documents, the company shall be given a period of a maximum of 60 working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance). The evaluation shall be finished by the General Administration of Pharmaceutical vigilance within 10 working days from the date of receiving the required documents.
- **In the event of non-approval or non-fulfillment of the documents**: The registration request shall be presented to the Technical Committee for Drug Control by the General Administration of Pharmaceutical vigilance to take the decision it deems appropriate and to state the reasons in the case of rejecting the registration request.

Fifth: procedures for receiving and reviewing the complete registration dossier and issuing the marketing authorization license:

1. The company shall submit the complete registration dossier containing the required documents after the following:

a. Getting the registration request approval and the name approval.
b. Applying to the pricing and pharmaceutical vigilance Administration.

Within 30 working days from the date in which the registration request was approved. This complete registration dossier shall be initially reviewed by representatives of the Administration of the Regulatory Affairs along with its affiliated units, within 6 working days. In case of documents were required to be submitted by the company, the company shall be granted a grace period of 3 months as a maximum.

2. The stipulated two months shall start at receiving the complete registration dossier.
3. The Administration of Regulatory Affairs along with its affiliated units shall send the complete registration dossier to the different divisions to initiate the technical evaluation within 20 working days and notify the company with the dossier status. In case of documents were required to be submitted by the company, the company shall be granted a grace period of three months as a maximum.
4. Upon fulfilling all the requirements, the time set for the product registration shall be resumed and all the approvals shall be issued within a maximum of 10 working days.
5. **Module 1** shall be updated after get the approvals, pricing certificate and Pharmacovigilance approval. The final review of the registration dossier shall be carried out by the Administration of Regulatory affairs and its affiliated units in preparation to be presented to the Technical Committee for Drug Control within 14 working days, to adjudicate whether to issue or not the marketing authorization license and in case of approval a marketing authorization license shall be issued.

Track (C) I: The imported human pharmaceutical products from one of the stringent regulatory authorities (SRAs) included in a list of the reference countries approved by the Technical Committee for Drug Control or the products imported from a non-reference country and marketed in one of the reference countries approved by the Technical Committee for Drug Control.

First: Procedures for getting the registration request approval:

1. The company shall be obligated to submit a registration request of the product, as per the same Appendix No. (3). The company shall receive a confirmation of the initial acceptance of the registration request within 3 working days from the date of receiving the fulfilled request in accordance with the regulating rules.
2. The company shall be notified of the status of the product within a maximum of 7 working days from the date of confirming the initial acceptance of the fulfilled registration request in accordance with the regulating rules:

- **In the event that there is availability in the box:**
  - The company shall receive a confirmation of the initial acceptance of the registration request within 12 working days from the date of receiving the completed request in

accordance with the regulating rules. The company is given a maximum period of three months to submit the required documents, same as Annex No. (3) and to have the registration request approval issued, provided that it shall be issued within 3 working days as a maximum from the date of submitting the complete required documents. The company is obligated to pay the specified service consideration required to register the product before proceeding to receive approval for the request, provided that the company shall receive the registration request approval within 30 working days from its issuance date, otherwise the registration request shall be cancelled.

- For the products imported from a non-reference country and marketed in any of the reference countries, a Certificate of Pharmaceutical Product from country of origin and documents proving marketing of the product in a reference country shall be submitted as well.

- **In the event that there is no availability in the box**:

  The registration request which is fulfilled as per the regulating rules shall be registered in the waiting list record in accordance with the date and time of its submission until it has availability in the box for whatever reason. A grace period shall be granted to the company whose turn comes in the waiting list to submit the fulfilled required documents within 3 months from the date of being notified that there is availability in the box. In the event that company does not adhere to the specified deadline, the request of this company shall be considered cancelled and the company that has the next turn shall be addressed.

Second: Applying to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals for get an approval for the name:

The company shall be obligated to apply to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals within a maximum period of 15 working days from the date of the registration request approval for get the approval for the product name, provided that the name approval shall be issued within 5 working days from the date when the company applied to Evaluation Unit of Trade Names and mockup of Human pharmaceuticals.

Third: Applying to Central Administration of drug Policies and Market Access / General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration:

Applying to the Pricing Policies and Pharmacoeconomics Administration within a maximum of 15 working days from the issuance date of the registration request approval, provided that the products shall be priced within a maximum period of 30 working days from the date of receiving the complete pricing file.

Fourth: Applying to the Central Administration for Pharmaceutical Care/General Administration of Pharmaceutical vigilance:

The documents necessary to fulfill the Pharmacovigilance requirements as per the regulatory

rules of the General Administration of Pharmaceutical vigilance (Appendix No. 6), shall be submitted within 15 working days from the issuance date of the registration request approval, otherwise the registration request shall be canceled based on a report submitted by the relevant central administration. The documents submitted by the company shall be evaluated within a maximum of 15 working days from the date of receiving of the fulfilled pharmacovigilance documents (provided that the document describing the Pharmacovigilance system of the company shall be completed upon evaluation).

- **In the event of the approval of the General Administration of Pharmaceutical vigilance**: The company shall be notified of the approval and the product registration procedures shall be completed. In the event that the company is required to fulfill other documents, the company shall be given a period of a maximum of 60 working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance). The evaluation shall be finished by the General Administration of Pharmaceutical vigilance within 15 working days from the date of receiving the required documents.
- **In the event of non-approval or non-fulfillment of the documents**: The registration request shall be presented to the Technical Committee for Drug Control by the General Administration of Pharmaceutical vigilance to take the decision it deems appropriate and to state the reasons in the case of rejecting the registration request.

Fifth: procedures for receiving and reviewing the complete registration dossier and issuing the marketing authorization license:

1. The company shall submit the complete registration dossier containing the required documents after the following:
   a. Getting the registration request approval and the name approval.
   b. Applying to the pricing and pharmaceutical vigilance Administration.

   Within two months from the date in which the registration request was approved. This complete registration dossier shall be initially reviewed by representatives of the Administration of the Regulatory Affairs along with its affiliated units, within 9 working days. In case of documents were required to be submitted by the company, the company shall be granted a grace period of 3 months as a maximum.
2. The stipulated three months shall start at receiving the complete registration dossier.
3. The Administration of the Regulatory Affairs along with its affiliated units shall send the complete registration dossier to the different divisions to initiate the technical evaluation within 30 working days and notify the company with the dossier status. In case of documents were required to be submitted by the company, the company shall be granted a grace period of three months as a maximum.
4. Upon fulfilling all the requirements, the time set for the product registration shall be resumed and all the approvals shall be issued within a maximum of 10 working days.

5. **Module 1** shall be updated after getting the approvals, pricing certificate and Pharmacovigilance approval. The final review of the registration dossier shall be carried out by the Administration of Regulatory affairs and its affiliated units in preparation to be presented to the Technical Committee for Drug Control within 25 working days, to adjudicate whether to issue or not the marketing authorization license and in case of approval a marketing authorization license shall be issued.

Track (C) II: The human pharmaceutical products imported from non-reference country and not marketed in any of the reference countries approved by the Technical Committee for Drug Control.

First: Procedures for getting the registration request approval:

1. The company shall be obligated to submit a registration request of the product in accordance with the regulating rules of the General Administration of Human Pharmaceuticals Registration published on the Egyptian Drug Authority website, the same appendix No. (3). The company shall receive a confirmation of the initial acceptance of the registration request within 3 working days from the date of receiving the fulfilled request in accordance with the regulating rules.
2. The company shall be notified of the status of the product within a maximum of 12 working days from the date of confirming the initial acceptance of the fulfilled registration request in accordance with the regulating rules:
3. The company shall be granted a period of no more than three months to submit the required documents (as per the same Appendix No. 3), in order to present the Product to the Technical Committee for Drug Control to exclude the product from the condition of being marketed in the reference countries. The company shall adhere to the decision of the Technical Committee for Drug Control regarding submitting the (Site Master File) to General Administration for Factories Inspection and conducting inspection on the manufacturer abroad.
    - The product shall be presented to the Technical Committee for Drug Control within 15 working days from the date of submitting the required documents so that the Committee can take its appropriate decision. In the case that certain documents are required by the Technical Committee for Drug Control, the company shall be committed to submit them within a maximum of two months from the date of notifying the company.
    - The registration request approval shall be issued within 5 working days from the date of receiving the Technical Committee decision to exclude the product from the condition of being marketed in the reference countries. The company shall be obligated to pay the specified service consideration for product registration before heading for receiving the registration request approval. The company shall be obligated to receive the registration request approval within 30 working days as of its issuance, otherwise the registration request approval shall be cancelled.
    - In the case that the Technical Committee for Drug Control refuses to exclude the product

from the condition of being marketed in the reference countries, the company may submit an appeal against the decision of the Committee, provided that a new registration request shall be submitted to the General Administration of Human Pharmaceuticals Registration along with the payment of the specified service consideration for submitting a new registration request

- **In the event that there is no availability in the box**:

  The registration request which is fulfilled as per the regulating rules shall be registered in the waiting list record in accordance with the date and time of its submission until it has availability in the box for whatever reason. A grace period shall be granted to the company whose turn comes in the waiting list to submit the fulfilled required documents within 3 months from the date of being notified that there is availability in the box. In the event that company does not adhere to the specified deadline, the request of this company shall be considered cancelled and the company that has the next turn shall be addressed.

  The registration request approval shall state whether the product has a scientific reference or not in accordance with the documents submitted by the company and on its own responsibility taking into consideration that the company shall adhere to the active ingredient, the pharmaceutical form, and the concentration mentioned in the scientific reference which it has sent.

Second: Applying to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals for getting an approval for the name:

The company shall be obligated to apply to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals within a maximum period of 15 working days from the date of the registration request approval for getting the approval for the product name, provided that the name approval shall be issued within 5 working days from the date when the company applied to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals

Third: Applying to the Central Administration of drug Policies and Market Access / General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration:

Applying to the Pricing Policies and Pharmacoeconomics Administration within a maximum of 15 working days from the issuance date of the registration request approval, provided that the product shall be priced within a maximum 30 working days from the date in which the fulfilled pricing file was received.

Fourth: Applying to General Administration of Pharmaceutical vigilance at the Central Administration for Pharmaceutical Care:

- The documents necessary to fulfill the Pharmacovigilance requirements as per the regulatory rules of the General Administration of Pharmaceutical vigilance (Appendix No. 6), shall be submitted within 15 working days from the issuance date of the registration request approval,

otherwise the registration request shall be canceled based on a report submitted by the relevant central administration. The documents submitted by the company shall be evaluated within a maximum of 15 working days from the date of receiving of the fulfilled pharmacovigilance documents (provided that the document describing the Pharmacovigilance system of the company shall be completed upon evaluation).

- **In the event of the approval of the General Administration of Pharmaceutical vigilance**: The company shall be notified of the approval and the product registration procedures shall be completed. In the event that the company is required to fulfill other documents, the company shall be given a period of a maximum of 60 working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance). The evaluation shall be finished by the General Administration of Pharmaceutical vigilance within 10 working days from the date of receiving the required documents.
- **In the event of non-approval or non-fulfillment of the documents**: The registration request shall be presented to the Technical Committee for Drug Control by the General Administration of Pharmaceutical vigilance to take the decision it deems appropriate and to state the reasons in the case of rejecting the registration request.

Fifth: procedures for receiving and reviewing the complete registration dossier and issuing the marketing authorization license:

1. The company shall submit the complete registration dossier containing the required documents after the following:
   a. Getting the registration request approval and the name approval.
   b. Applying to the pricing and pharmaceutical vigilance Administration.

   Within two months from the date in which the registration request was approved. This complete registration dossier shall be initially reviewed by representatives of the Administration of the Regulatory Affairs along with its affiliated units, within 15 working days. In case of documents were required to be submitted by the company, the company shall be granted a grace period of 3 months as a maximum.
2. The stipulated six months shall start at receiving the complete registration dossier.
3. The Administration of the Regulatory Affairs along with its affiliated units shall send the complete registration dossier to the different divisions to initiate the technical evaluation within 60 working days and notify the company with the dossier status. In case of documents were required to be submitted by the company, the company shall be granted a grace period of three months as a maximum.
4. Upon fulfilling all the requirements, the time set for the product registration shall be resumed and all the approvals shall be issued within a maximum of 10 working days.

5. **Module 1** shall be updated after getting the approvals, pricing certificate and Pharmacovigilance approval. The final review of the registration dossier shall be carried out by the Administration of Regulatory affairs and its affiliated units in preparation to be presented to the Technical Committee for Drug Control within 60 working days, to adjudicate whether to issue or not the marketing authorization license and in case of approval a marketing authorization license shall be issued.

Notes on new imported human pharmaceutical products submitted for registration in accordance with Tracks A, B, or C

- For the products which have a Certificate of Pharmaceutical Product (CPP) from one of the reference countries approved by the Technical Committee for Drug Control or the products which are marketed in one of the reference countries, the analysis file shall be submitted to the Central Administration for Drug Control, which includes the documents and attachments required for the analysis file of the first received shipment after the issuance of the marketing authorization license. The first received shipment shall not be released until the analysis result is received from the Central Administration for Drug Control.
- The analysis file including the required documents and attachments may be submitted to the Central Administration for Drug Control before the marketing authorization license is issued. Accordingly, Importation and custom release general administration shall be addressed to apply for importing samples as per the registration request approval, pursuant to the regulatory guideline along with its continuous updated versions issued by the Importation and custom release general administration at the Central Administration of drug Policies and Market Access
- For imported human medical products submitted for registration and which are imported from non-reference countries and are not marketed in any of the reference countries, the company shall be obligated to submit the analysis file including the required documents and attachments to the Central Administration for Drug Control before the marketing authorization license is issued. Accordingly, the Importation and custom release general administration shall be addressed to apply for importing samples as per the registration request approval, pursuant to the regulatory guideline along with its continuous updated versions issued by the Importation and custom release general administration at the Central Administration of drug Policies and Market Access.
- The company may address the Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals to determine the type of study required, if any, before submitting the complete registration dossier if it so desires.
- **For products submitted in accordance with Track A or Track B:**

  In the event that a pricing certificate is not issued before completing the registration procedures, it is permitted to issue a marketing authorization license on condition that no marketing in the local market is gone into until the pricing certificate is issued, provided that presentation to the pricing committee has been completed, a price has been determined, and

the pricing certificate shall be issued within a maximum of one month from the issuance of the product marketing authorization license

Track (C) III: Locally manufactured human pharmaceutical products

First: Procedures for get the registration request approval:

The company shall be obligated to submit a registration request of the product in accordance with the regulatory rules of the General Administration of Human Pharmaceuticals Registration published on the Egyptian Drug Authority website. The company shall receive a confirmation of the initial acceptance of the registration request within 3 working days from the date of receiving the completed request in accordance with the regulating rules.

(A) In the event that there is availability in the box in the box:	(B) In the event that there is no availability in the box:
▪ The company shall be notified of the status of the product within a maximum of 12 working days from the date of confirming the initial acceptance reception of the fulfilled registration request in accordance with the regulating rules. In the case there are documents required to be fulfilled, the company shall be obligated to complete any required documents within a maximum of 3 months from the date of being notified. The registration request approval shall be issued within 3 working days from the date of receiving the fulfilled required documents. ▪ As for locally manufactured products under license from a foreign company, the company shall be granted a period of no more than three months to submit the required documents which are necessary for issuing the registration request approval. The approval shall be issued within a maximum of 3 working days from the date of receiving all the required documents. ▪ The company shall be obligated to pay the specified service consideration for product registration before heading for receiving the registration request approval. The company shall be obligated to receive the registration request approval within 30 working days as of its issuance, otherwise the registration request shall be cancelled.	The registration request which is fulfilled as per the regulating rules shall be registered in the waiting list record in accordance with the date and time of its submission until it has availability in the box for whatever reason. A grace period shall be granted to the company whose turn comes in the waiting list to submit the fulfilled required documents within 3 months from the date of being notified that there is availability in the box. In the event that company does not adhere to the specified deadline, the request of this company shall be considered cancelled and the company that has the next turn shall be addressed.

The registration request approval shall state whether the product has a scientific reference or not in accordance with the documents submitted by the company and on its own responsibility

taking into consideration that the company shall adhere to the active ingredient, the pharmaceutical form, and the concentration mentioned in the scientific reference which it has sent.

Second: Applying to the specialized scientific committees in the event that the registration request approval states that the product is non-referenced

- The company shall address the specialized scientific committees within 15 working days from the date of issuance of the registration request approval to submit the scientific file, otherwise the registration request will be cancelled.
- The scientific file shall be presented to the specialized scientific committees within a month and a half from the date of receiving the complete scientific file. In the event of the approval on a scientific basis, the company shall be notified by a letter issued by the specialized scientific committee and the registration procedures of the product shall be fulfilled.
- In the event that some submitted studies are required to be fulfilled by the company, another grace period of one month and a half shall be granted to the companies and the file shall be represented to the specialized scientific committees within a period of one month and a half from the date of completing the requirements.
- **In the event of non-approval by the specialized scientific committees,** the product shall be presented to the Technical Committee for Drug Control to take the decision that it deems appropriate and a letter shall be issued to the company by the specialized scientific committees stating the reasons for refusal in the case of rejecting the registration request. In case of rejection, the company is permitted to file an appeal against the final decision issued by the Technical Committee for Drug Control, based on a reasoned request supported by the documents and information on which the company desires to rely. The decisions of the specialized scientific committees shall be used as a guidance in the study of the registration request to be submitted later.
- In the event that a scientific reference for the product emerges before applying for the scientific committees or before presenting the issue there to or in the event that the company submits a different scientific reference that matches the product submitted in the registration request approval, a study of this reference shall be conducted and a statement shall be issued by the Evaluation unit of Scientific data and drug Development for human pharmaceuticals without being presented to the scientific committees. Accordingly, the Evaluation unit of the Registration Request for human pharmaceuticals shall be addressed to amend the registration Request approval with the scientific reference.
- In the event that a scientific reference for the product emerges after the product is rejected by the scientific committees and the Technical Committee for Drug Control, the Evaluation unit of the registration request for human pharmaceuticals shall be addressed to get a new registration request approval.

Third: Applying to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals for getting an approval for the name:

The company shall be obligated to apply to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals within a maximum period of 15 working days from the date of the registration request approval for get the approval for the product name, provided that the name approval shall be issued within 10 working days from the date when the company applied to the Evaluation Unit of Trade Names and mockup of Human pharmaceuticals

Fourth: Applying to the Central Administration of drug Policies and Market Access / General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration:

Applying to the Pricing Policies and Pharmacoeconomics Administration within a maximum of 15 working days from the issuance date of the registration request approval, provided that the product shall be priced within a maximum 30 working days from the date in which the fulfilled pricing file was received.

Fifth: Applying to General Administration of Pharmaceutical vigilance at the Central Administration for Pharmaceutical Care:

- The documents necessary to fulfill the Pharmacovigilance requirements as per the regulatory rules of the General Administration of Pharmaceutical vigilance (Appendix No. 6), shall be submitted within 15 working days from the issuance date of the registration request approval, otherwise the registration request shall be canceled based on a report submitted by the relevant central administration. The documents submitted by the company shall be evaluated within a maximum of 15 working days from the date of receiving of the fulfilled pharmacovigilance documents (provided that the document describing the Pharmacovigilance system of the company shall be completed upon evaluation).
- **In the event of the approval of the General Administration of Pharmaceutical vigilance**: The company shall be notified of the approval and the product registration procedures shall be completed. In the event that the company is required to fulfill other documents, the company shall be given a period of a maximum of 60 working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance). The evaluation shall be finished by the General Administration of Pharmaceutical vigilance within 15 working days from the date of receiving the required documents.
- **In the event of non-approval or non-fulfillment of the documents**: The registration request shall be presented to the Technical Committee for Drug Control by the General Administration of Pharmaceutical vigilance to take the decision it deems appropriate and to state the reasons in the case of rejecting the registration request.

Sixth: Studies and approvals required in the registration procedures:

a. Commencement of manufacturing the pilot/production batches:

- The Importation and custom release general administration shall be addressed to apply

for importing the active ingredient / packaging-material as per the registration request approval, pursuant to the regulatory guideline along with its continuous updated versions issued by the Importation and custom release general administration at the Central Administration of Drug Policies and Market Access.

- Before production, the company shall apply to the Central Administration of Operations as per the regulatory guideline of the relevant central administration for producing the three pilot/production batches, in the presence of an inspector from the Central Administration of Operations, provided that these batches shall never be marketed in the local market. The company shall be permitted to produce according to the approval concerning the active ingredient used in the product, which approval is issued by the relevant central administration in the presence of an inspector from the Central Administration of Operations to ensure that the pilot/production batches are produced on the same production lines located in the factory.

Specifications of pilot/production batches:

- At least two of the three batches shall be produced in the same size of the pilot batches, while the third batch is allowed to be produced in a smaller size. (The pilot batch size shall correspond to at least 10% of the production batch, exceeding the minimum production capacity of the manufacturing line).
- The pilot/production batches shall be manufactured in accordance with the same composition, primary pack and manufacturing method that shall be used in the manufacturing of the production batches of the final product that will be marketed.
- The same quality and specifications of the final product shall be committed to.

b. The inspector shall attach the composition according to which the production is made and this composition shall be signed by the manufacturer representative and shall be sealed and signed by the inspector in an inspection report indicating the source of the active ingredient, provided that the procedures shall be fulfilled as follows:

1. Samples shall be taken through the Central Administration of Operations from one pilot/production batch for analysis at the Central Administration for Drug Control in accordance with the regulating rules and deadlines as per the regulatory guideline of the Central Administration of Operations. The Central Administration for Drug Control shall issue the analysis result stating the active ingredient source, the batch number, the batch type, the manufacturer name, and the product name and its data.

2. The company shall address the Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals to which it shall submit the request with the attached composition on which the production is made, and signed and sealed by the inspector of the Central Administration of Operations in order to know the position of the product in terms of the type of the study required in accordance with the applicable rules. The company shall be obligated to send a commitment stating the presence or absence of any other concentrations of the same active ingredient in the same pharmaceutical form (be under registration or registered). The company shall submit the compositions approved

by the Authority for these concentrations so that the company's request can be adjudicated. When the company receives the decision of the specialized scientific committee of evaluating the Bioavailability and bioequivalence studies regarding the type of study required, the following shall be done:

3. The inspector of the General Administration of Inspection shall take samples of the same pilot batch to conduct the studies of bioavailability, bioequivalence or comparative dissolution in the cases requiring these studies and shall state them in an inspection report dated and signed by the manufacturer representative and the inspector of the General Administration of Inspection, provided that the General Administration of Inspection is notified of the place and time of conducting the bioequivalence study before starting it.

4. The accelerated stability study shall be conducted for a period of six months on the three pilot/production batches and shall be accompanied with the composition according to which the production was made, signed and sealed by the inspector of the Central Administration of Operations. This study shall be conjoined with a long-term stability study for a period of at least one year that shall be conducted on the same pilot/production batches so that the product is entitled to be granted a validity period of two years, provided that the General Administration of Operations shall be notified of the place and time of conducting the stability study before starting it.

   Companies may apply for submitting an accelerated and long-term stability study on the first three pilot/production batches for a period of 6 months only, with a commitment to complete the long-term stability study for a period of 12 months on the same first three pilot/production batches and to submit it to the General Administration of Stability immediately after its completion, provided that the company shall be obligated to pay the specified service consideration.

Note:

The company may apply to the General Administration of Human Pharmaceuticals Registration with a reasoned request to permit the manufacture of a production batch(s) instead of a pilot batch(s) and conduct all the studies required to get the marketing authorization license on these production batches, provided that this request shall be presented to the Head of the Central Administration of Pharmaceutical Products with a detailed report stating the reasons and provided that the specified service consideration shall be paid.

Seventh: Procedures for receiving and reviewing the complete registration dossier and issuing the marketing authorization license

1. The complete registration dossier containing the required documents shall be submitted by the company after getting the registration request approval, name approval, pricing certificate and pharmacovigilance approval, provided that this procedure shall be done within 33

months of the pricing certificate. The dossier shall be initially reviewed by representatives of the Administration of Regulatory Affairs and its affiliated units within 15 working days. In the event that the company is required to fulfil some required documents, the company shall be granted a grace period of 3 months as a maximum.

2. The stipulated six months shall start at receiving the complete registration dossier.
3. The Administration of the Regulatory Affairs along with its affiliated units shall send the complete registration dossier to the different divisions to initiate the technical evaluation within 60 working days. In case of documents were required to be submitted by the company, the company shall be granted a grace period of three months as a maximum.
4. Upon fulfilling all the requirements, the time set for the product registration shall be resumed and all the approvals shall be issued within a maximum of 10 working days.
5. **Module 1** shall be updated after get the approvals, pricing certificate and Pharmacovigilance approval. The final review of the registration dossier shall be carried out by the Administration of Regulatory affairs and its affiliated units in preparation to be presented to the Technical Committee for Drug Control within 60 working days, to adjudicate whether to issue or not the marketing authorization license and in case of approval a marketing authorization license shall be issued.

Required procedures to be implemented after the issuance of the marketing authorization license

- The production of the locally manufactured products that are intended for local marketing as well as the importation of the imported products that have a final marketing authorization license in the Egyptian markets shall take place within eighteen months from the issuance date of the marketing authorization license otherwise, the marketing authorization license shall be canceled based on a report from the Central Administration of Operations.
- The company shall be obligated to submit accelerated and long-term stability studies on the first three production batches for the locally manufactured products within five years from the date of issuing the marketing authorization license in accordance with the report submitted by the Central Administration of Operations; otherwise, the marketing authorization license shall be canceled.
- Or the company shall complete the long-term stability study that was previously conducted on the three production batches, provided that the registration request shall apply to the Administration of Stability with the study after completion (in the event that manufacturing had been carried out on production batches before the marketing authorization license was issued).

Third case

The company shall apply for the registration of human pharmaceutical products, and their registration requests shall be accepted exceeding the specified number of the box, which is provided in the regulatory guideline of this decree and referred to in Article 3 thereof, provided

that the registration procedures shall be completed in accordance with the first case, pursuant to the articles provided for in this regulatory guideline on a case-by-case basis.

General rules

- Locally manufactured and imported products shall complete the registration procedures for this case in accordance with the first case of this decree, and the company shall submit the complete dossier to the Administration of Regulatory affairs.
- The number of registration requests available to be submitted per month by any of the beneficiaries of this decree shall not be counted within any the specific number of submissions of registration request in accordance with other registration cases or decisions of the Technical Committee for Drug Control.
- It shall be permitted to convert a product from one track to another within the same case in the event that the company status or the product status has changed so that more than one track can be applied there to within the same case by virtue of an approval by the EDA chairman based on a report submitted by the Head of the Central Administration of Pharmaceutical Products, provided that the company shall be committed to paying the service consideration before receiving the approval.
- The human pharmaceutical products enrolled in the third case of the decree shall be priced in accordance with the regulatory pricing guidelines.

Track (A): Human pharmaceutical products included in any of the human pharmaceutical product's shortage lists which are approved in conformity with Track (A) and in force at that time, as per the market needs determined by EDA, provided that these lists shall be announced once every three months.

1. The box shall be opened after reviewing each individual request separately and determining whether the product is incorporated in any of the human pharmaceutical product's shortage lists which are approved in conformity with Track (A) and in force at that time, as per the market needs determined by EDA, provided that these lists shall be announced once every three months.

These lists shall be determined in accordance with the following procedures:

a. **Central Administration of Drug Policies and Market Access** shall conduct the necessary studies to determine the products (as per the active ingredient, the concentration, and the pharmaceutical form) that meet the aforementioned standards, and shall submit reports thereon every three months at most to the Technical Committee for Drug Control.
b. These lists shall be presented to the Technical Committee for Drug Control to be studied for their approval.
c. The Head of the Central Administration of Pharmaceutical Products and the Head of Central administration of Drug policies and Market access shall submit a report to EDA chairman to reconsider its approval.
d. The approved lists shall then be announced on EDA's website to allow companies to submit

requests for registering the products incorporated therein.

2. This track shall be applied to human pharmaceutical products that are locally manufactured and to human pharmaceutical products that are imported from reference countries.

A. Locally manufactured human pharmaceutical products shall be permitted to be applied for by:

- Owners of human pharmaceutical products factories that are licensed or under construction (four registration requests per month).
- Toll companies (two registration requests per month)

- The company shall apply to Administration of Regulatory Affairs within a maximum of 21 months from the issuance date of the first pricing certificate of the product or from the approval date of the General Administration of Pharmaceutical vigilance, whichever is later, to submit the complete registration dossier. In the event that the previous deadlines are exceeded, the product shall be granted an additional period of 3 months to submit the complete registration dossier for the products for which pilot batches/ production batches have already been produced.
- The marketing authorization license requires that production and marketing shall take place within six months from the issuance date of the marketing authorization license.

B. Human pharmaceutical products imported from reference countries shall be permitted to be applied for by:

Companies and scientific offices (four registration requests per month) (provided that the number of submitted products shall not exceed two products for each active ingredient, concentration and pharmaceutical form mentioned in the shortage lists of the imported human pharmaceutical products).

- The company shall apply to Administration of Regulatory Affairs within a maximum of 6 months from the issuance date of the first pricing certificate or from the approval date of the General Administration of Pharmaceutical vigilance, whichever is later, to submit the complete registration dossier.
- The product shall be imported within three months from the issuance date of the marketing authorization license will be a condition in marketing authorization license.

Track (B): Human pharmaceutical products that are manufactured locally on rare production lines and specified by EDA.

1. The box shall be opened for all requests submitted for manufacturing on those lines that are determined according to what was presented by the Central Administration of Operations and approved by the EDA Chairman. The list of rare lines that are in effect at that time and that are determined by EDA shall be announced, provided that such lists are announced once a year.
2. This track shall be applied to human pharmaceutical products that are locally manufactured only and they shall be permitted to b applied for by.

- Human pharmaceutical products factories that are licensed or under construction (two registration requests per month).
- Toll companies (one registration request per month).

3. The company shall apply to Administration of Regulatory Affairs within a maximum of 33 months from the issuance date of the first pricing certificate of the product or from the approval date of the General Administration of Pharmaceutical vigilance, whichever is later, to submit the complete registration dossier.
4. The production and marketing shall take place within one year from the from the issuance date of the marketing authorization license will be a condition in marketing authorization license.

Track (C): Human pharmaceutical products applied for by the owners of the licensed factories during the last ten years

1. This track shall be applied to human pharmaceutical products applied for by the owners of licensed factories during the last ten years of the issuance of the decree, and the licensing date shall be calculated from the issuance date of the first factory license; toll manufacturing contracts shall not be permitted; and working to this track shall end within two years from the issuance of the decree.
2. The applicant shall have the right to register twenty human pharmaceutical products only, and the active ingredient with different concentrations and pharmaceutical forms of the same box (Line Extension) shall be considered one product when calculating the twenty products.
3. The company shall be permitted to submit one registration request per month, and in the event that the company is desirous to submit other registration requests in the same month, the company shall be obligated to pay the service consideration specified for additional requests other than the number permitted to be submitted per month.
4. The company shall apply to the Administration of Regulatory Affairs within a maximum of 33 months from the issuance date of the first pricing certificate of the product or from the approval date of the General Administration of Pharmaceutical vigilance, whichever is later, to submit the complete registration dossier.
5. The production and marketing shall take place within one year from the issuance date of the marketing authorization license will be a condition in marketing authorization license, provided that the marketing date shall be the date of the final release of the produced batch.

Track (D): Human pharmaceutical products applied for by the owners of the under-construction factories

1. This track shall be applied to human pharmaceutical products applied for by the owners of under-construction factories; toll manufacturing contracts shall be permitted but with the obligation to produce in the factory within two years from the issuance date of the marketing authorization license ; under-construction production lines in factories that are already licensed shall not be considered within this track; and working to this track shall end within two years from the issuance of the decree.

2. The applicant shall have the right to register twenty human pharmaceutical products only, and the active ingredient with different concentrations and pharmaceutical forms of the same box (line extension) shall be considered one product when calculating the twenty products.
3. The company shall be permitted to submit one registration request per month, and in the event that the company is desirous to submit other registration requests in the same month, the company shall be obligated to pay the service consideration specified for additional requests other than the number permitted to be submitted per month.
4. The company shall apply to the Administration of human pharmaceutical regulatory affairs within a maximum of 33 months from the issuance date of the first pricing certificate of the product or from the approval date of the General Administration of Pharmaceutical vigilance, whichever is later, to submit the complete registration dossier.
5. The production and marketing shall take place within two years from the issuance date of marketing authorization license will be a condition in marketing authorization license, provided that the marketing date shall be the date of the final release of the produced batch.

Track (E): Locally manufactured human pharmaceutical products produced for the purpose of local marketing and exporting with no less than (25%) of the production.

1. This track shall be applied to locally manufactured human pharmaceutical products produced for the purpose of local marketing and for export with no less than (25%) of local production, as per information disclosed by the company, and follow-up made by the Central Administration of Operations. Requests shall be permitted for the owners of the licensed or under-construction factories of human pharmaceutical products and toll companies (two product registration requests per year), taking in consideration that the number of registration requests available for submission per month is one registration requests. In the event that the company is desirous to submit other registration requests in the same month, the company shall be obligated to pay the service consideration specified for additional requests other than the number permitted to be submitted per month.
2. The company shall apply to the Administration of Regulatory Affairs within a maximum of 33 months from the issuance date of the first pricing certificate of the product or from the approval date of the General Administration of Pharmaceutical vigilance, whichever is later, to submit the complete registration dossier.
3. The production shall take place within nine months from the issuance date of the marketing authorization license and that exportation shall take place within thirty months from the issuance date of the marketing authorization license will be a condition in marketing authorization license.

Studies and approvals required in the registration steps

a. **Commencement of manufacturing the three pilot/production batches for locally manufactured human pharmaceutical products:**
   - Importation and custom release General Administration shall be addressed to apply for

importing the active ingredient / packaging material as per the registration request approval, pursuant to the regulatory guideline along with its continuous updated versions issued by the Importation and custom release General Administration at the Central Administration of Drug Policies and Market Access.

- Before production, the company shall apply to the Central Administration of Operations as per the regulatory guideline of the relevant Central in order to manufacture the three pilot/production batches in the presence of an inspector from the Central Administration of Operations, provided that this batch shall never be marketed in the local market. The company shall be permitted to produce according to the approval issued by the relevant central administration concerning the active ingredient used in the product in the presence of an inspector from the Central Administration of Operations to ensure that the pilot/production batches is produced on the same production lines located in the factory.

b. <u>The inspector shall attach the composition according to which the production is made and this composition shall be signed by the manufacturer representative and shall be sealed and signed by the inspector in an inspection report indicating the source of the active ingredient, provided that the registration procedures shall be fulfilled as in the following steps:</u>

1. Samples shall be taken through the Central Administration of Operations from one pilot/production batch for analysis at the Central Administration for Drug Control in accordance with the regulating rules and deadlines as per the regulatory guideline of the Central Administration of Operations. The Central Administration for Drug Control shall issue the analysis result stating the active ingredient source, the batch number, the batch type, the manufacturer name, and the product name and its data.
2. The accelerated stability study shall be conducted for a period of six months on the three pilot/production batches and shall be accompanied with the composition according to which the production was made, signed and sealed by the inspector of the Central Administration of Operations. This study shall be conjoined with a long-term stability study for a period of at least one year that shall be conducted on the same pilot/production batches so that the product is entitled to be granted a validity period of two years, provided that the General Administration of Operations shall be notified of the place and time of conducting the stability study before starting it.
    - Companies may apply for submitting an accelerated and long-term stability study on the first three pilot/production batches for a period of 6 months, with a commitment to complete the long-term stability study for a period of 12 months on the same first three pilot/production batches and to submit it to the General Administration of Stability immediately after its completion, provided that the company shall be obligated to pay the specified service consideration.
3. The company shall address the Evaluation unit of bioavailability and bioequivalence studies for human pharmaceutical to which it shall submit the request with the attached composition on which the production is made, and which is signed and sealed by the

inspector of the Central Administration of Operations, in order to determine the status of the product in terms of the type of the study required. The company shall be obligated to send a commitment stating the presence or absence of any other concentrations of the same active ingredient in the same pharmaceutical form (under registration or registered).

- In the event that there are other concentrations, the company shall submit the composition of the concentrations approved by EDA so that the company's request can be adjudicated. The Evaluation unit of bioavailability and bioequivalence studies for human pharmaceutical shall notify the company of the type of the required study. In the cases that require conducting a study of bioavailability, bioequivalence, or comparative dissolution in accordance with the rules and procedures regulating the conduction of studies of bioavailability, bioequivalence, or comparative dissolution, samples shall be taken by the Central Administration of Operations and stated in an inspection record dated and signed by the manufacturer representative and the inspector of the Central Administration of Operations. These samples shall be sent to the bioavailability and bioequivalence centers that are licensed by the Egyptian Drug Authority. The study shall be submitted to the Evaluation unit of bioavailability and bioequivalence studies for human pharmaceuticals to be evaluated within 60 working days from the date of submitting the fulfilled study in accordance with the rules and procedures applied in this regard.

Note:

The company may apply to the General Administration of Human Pharmaceuticals Registration with a reasoned request to permit the manufacture of a production batch(s) instead of a pilot batch(s) and to conduct all the studies required to get the marketing authorization license on these production batches and be presented to the Head of the Central Administration of Pharmaceutical Products with a detailed report stating the reasons, provided that the specified service consideration shall be paid.

c. Required documents to be submitted to all concerned administrations:

1. **General Administration of Stability:**

   The company shall address the General Administration of Stability to which it shall submit the stability study on the pilot/production batches accompanied with the composition which the production was made thereon and which shall be signed and sealed by the inspector of the Central Administration of Operations. The General Administration of Stability shall evaluate the stability study in addition to the stability of the active ingredient.

2. **General Administration of Pharmaceutical References and Leaflets at the Central Administration for Pharmaceutical Care:**

   The company shall submit application to approve the internal leaflet of the product after the stability approval is issued.

3. **Evaluation unit of trade names and mock up for human pharmaceuticals:**
   The company shall apply for approving the internal and external mock up after the stability approval is issued.
4. **Evaluation unit of bioavailability and bioequivalence studies for human pharmaceuticals:**
   The study required from the Evaluation unit of bioavailability and bioequivalence studies for human pharmaceuticals shall be submitted in the case of products that require this study.
5. **Administration of Technical Affairs:**
   The file shall be submitted for evaluation.

Note:

Companies shall be permitted to approve the medical leaflet as well as the internal and external mockup of the product by the relevant central administrations before approving the stability study in the event that the production is carried out on a production batch.

Submission of a complete registration dossier for locally manufactured human pharmaceutical products

- The company shall submit the complete registration dossier including the required documents through the submission links announced on EDA's website to the Administration of human Regulatory Affairs at the General Administration of Human Pharmaceuticals Registration in accordance with the aforementioned deadlines.
- The final review of the file shall be carried out by Administration of human Regulatory Affairs and its affiliated units and the company shall be notified of the status of the file within 45 working days from the date of receiving the complete registration dossier. In the event that the company is required to fulfill documents, the company shall be granted a grace period of a maximum 60 days from the date of notifying the company, provided that the fulfilled required documents submitted by the company shall be evaluated within a maximum of 15 working days from the date of submitting the fulfill documents. In the event that the deadline for completing the fulfilled required documents is exceeded, the company may apply to the General Administration of Human Pharmaceuticals Registration for extending the deadline of completing the fulfilled required documents after paying the service consideration.
- The products shall be presented to the Technical Committee for Drug Control within 30 working days from the date when the company fulfills the complete file, so that the Technical Committee shall take the appropriate decision whether to register the product or not.

In the event of the approval by the Technical Committee for Drug Control	In the event of the rejection by the Technical Committee for Drug Control
A final marketing authorization license shall be issued, provided that the company shall comply with the requirements mentioned in the marketing authorization license and the Central Administration of Operations shall follow up the company compliance.	The company shall be notified of the rejection by virtue of a letter containing the decision of the Technical Committee for Drug Control. The reasons of rejection shall be indicated. The company may submit a grievance to the General Administration of Human Pharmaceuticals Registration against the final decision issued by the Technical Committee for Drug Control within 60 working days from the issuance date of the decision, by virtue of a reasoned request to be submitted to the Technical Committee for Drug Control, which request shall be supported by the documents and information that the company is desirous to rely on when its grievance is being considered. The matter shall be presented to the Technical Committee within 60 working days from the date when the grievance is submitted.

Required procedures to be implemented after the issuance of the marketing authorization license

- The company shall be obligated to submit accelerated and long-term stability studies on the first three production batches for the locally manufactured products within five years from the date of issuing the marketing authorization license in accordance with the report submitted by the Central Administration of Operations; otherwise, the marketing authorization license shall be canceled.
- Or the company shall complete the long-term stability study that was previously conducted on the three production batches, provided that applicant shall apply to the General Administration of Stability with the study after completion (in the event that manufacturing had been carried out on production batches before the marketing authorization license was issued).

Non-routine registration

A. Emergency Use Authorization License guideline of Human pharmaceutical products to get Emergency Use Authorization License for Human pharmaceutical Product:

- In the cases of emergency circumstances, any product may be marketed with the exception of some conditions required for registration mentioned in this decree, and exceeding the specified number of the box, based on detailed technical memorandum prepared by the Central Administration of Pharmaceutical Products and approved by the EDA Chairman, provided that the concerned applicant shall submit the registration dossier upon its completion, pursuant to the applicable procedures for granting an emergency use license.
- The box shall be opened exceeding the specified number of the box - unless a cancellation decision is issued by EDA Chairman regarding it - after studying each request separately and indicating whether the product contains one of the active ingredients whose registration is required by urgent need and which shall be announced on the website of the Egyptian Drug Authority.
- This track shall be applied to human pharmaceutical products that are locally manufactured as well as human pharmaceutical products that are imported from reference countries.
- Registration procedures shall be completed in accordance with the Emergency Use Authorization guideline, Appendix No. (12).
- The number of registration requests available to be submitted per month by any of the beneficiaries of this decree shall not be counted within any specific submission numbers of the registration requests submitted according to other registration cases or decisions of the Technical Committee for Drug Control.
- The company shall apply to the Administration of Regulatory Affairs within a maximum period of 3 months from the date of the registration request approval and this period is renewed for an additional period of 3 months only. In the event of non-compliance with this deadline, the registration procedures shall be completed in accordance with the normal procedure of the ministerial decree on which the registration request approval is issued.

B. Human pharmaceutical products for which decisions are issued by the EDA chairman due to their scientific, technical or market needs or due to emergency circumstances:

- This track shall be applied to human pharmaceutical products for which decisions are issued by the EDA chairman due to their scientific, technical or market needs or due to emergency circumstances and exceeding the specified number of the box. For Human Pharmaceutical Products submitted on the First Case, the registration procedures shall be completed, the requirements shall be fulfilled, the required technical studies shall be completed; and the approvals required for registration shall be get in accordance with the procedures mentioned in the regulatory guideline of this decree.

- The box shall be opened exceeding the specified number of the box - unless a cancellation decision is issued by EDA Chairman regarding it - after studying each request separately and indicating whether the product conforms with one of the following classifications or not:
  - Vitamins, minerals, amino acids, distilled water and water for injection in the cases where the product does not contain any other active ingredients.
  - Solutions, including: (glucose with its concentrations - saline with its concentrations - glucose saline with its concentrations - Ringer - Ringer lactate - Ringer acetate - Mannitol with its concentrations).
  - Lidocaine: (Companies shall be permitted to register Lidocaine solvent for intramuscular injection only in volumes (1-2 - 3.5 - 3.6 - 4 - 5 ml) with a concentration of 1% and 2%, while it is not allowed to be sold except as a solvent only.
  - Oncology and immunosuppressants, provided that they are classified in accordance with the reference product / scientific references that include but are not limited to (BNF), pursuant to the decision of the Technical Committee for Drug Control, in its session on 27/2/2020, regarding the submission of the complete registration dossier.
- The number of registration requests available to be submitted per month shall be counted within the specific number of submissions of registration requests, and in case that the company desires to submit other registration requests in the same month, the company shall be obligated to pay the specific service consideration for additional requests other than the specific number to be submitted per month.
- For products which Article 4, paragraph (b) is applied to, and which are listed in waiting lists in accordance with previous ministerial decrees, a new registration request shall be submitted with the implementation of the same rules for calculating the specified monthly registration requests.

Appendix No. (1) Boxes

The number of similar within each box including a set of pharmaceutical forms shall be determined as follows:

1. **The number of products for each concentration of the pharmaceutical form with the same active ingredient shall not exceed 12 products, divided as follows:**
   - One (1) original product (Brand or Innovator).
   - One (1) imported product (Imported Generic).
   - Ten (10) local products, including a maximum of two (2) products for toll companies, in accordance with the priority of submission and the fulfillment of the requirements.
2. **In the event of completing the number of permitted products for any pharmaceutical form within the same box for each registration type with the same concentration:** Registration requests for the rest of the concentrations shall not be accepted, except for the following:
   - The Line Extension cases (Adding of another concentration for the same company with the same pharmaceutical form or in different pharmaceutical forms within the same box of the same active ingredients for the registered products that have a valid marketing authorization license or for the under-registration products whose registration procedures are in progress).
3. **For the products whose manufacturing requires high technology which is unavailable in the Egyptian manufacturers. Such products are determined in accordance with the decision of the Central Administration of Operations:**

   The number of products for each active ingredient shall be twelve (12) products, including the following:
   - One (1) original product (Brand or Innovator).
   - Five (5) imported products (Imported Generic).
   - Six (6) locally manufactured products, including a maximum 1 for Toll Companies, in accordance with the priority of submission.
4. **In the case of the original product (Brand or Innovator):**

   The company shall submit a legalized commitment printed on the papers of License Holder mentioned in the certificate of pharmaceutical product to declare its responsibility as regards whether its product is the innovator or not.

Appendix No. (2) Table of the merge and dividing of pharmaceutical forms in the box

1	**Box I**	Solid unit dosage form (traditional (Conventional) immediate release)	Tablets (Sugar - Film Coated)	Hard Gelatin capsules	Dragees (Tablet in French)	Caplets	Lactabs	Pilules (Pills / Capsule)	Spansules (Sugar coated Pills /Capsule)
			Lozenges						
			Gums						
			Soft Gelatin capsules						
2	**Box II**	Solid Unit Dosage Form (Fast Immediate Release)	Quick Tablets	Flash Tablets (DISSOLVE IN MOUTH only)	Oro-disintegrating	Melt tablets			Oro-Dispersible Tablets
			Chewable Tablets						
			sublingual Tablets						
			Buccal Mucoadhesive Tablets (Buccal Mucoadhesive Tablets (prolonged only in mouth for local effect or systemic effect)						
			effervescent Tablets		Disintegrating Tablets	Dispersible Tablets			
			Effervescent Granules/Powders		Powder in Bottle (each dose will be reconstituted at time of use				Powder / Sachets
3	**Box III**	Solid unit Dosage Form (Modified release)	SR, CR, MR, XR Capsules / Tablet		Depotabs		Retard Capsules / Tablet		Enteric Coated tablets
			Modified Release Powder/Granules in Sachets				Modified Release Powder/Granules in Bottle (each dose will be reconstituted at time of use		

4	**Box IV**	Oral Preparation (Liquid-semisolid-Powder/ Granules for Reconstitution)	Solutions	Syrups	Oral drops	Elixirs	Drinking ampoules	Powders /oral (Solution)	Powders/ (Emulsion / Susp)	Emulsion	Suspension	Oral Gels	Oral Jelly
			Modified Release Oral Preparations										
5	**Box V**	Buccal Preparation	Oral Paste										
			Oromucosal Gels										
			Oromucosal Sprays										
			Gargles					Mouth washes					
6	**Box VI**	Sterile Preparation (injections)	Solutions					Suspensions			Emulsions		
			Irrigation Solutions (LVP)										
			Modified release Injections					oily injections					
7	**Box VII**	Implants											
8	**Box VIII**	Sterile Preparation (sterile Prefilled Injections)	Prefilled Syringes										
			Pen Filled Preparations										
			Cartridges										
9	**Box IX**	Traditional topical	Topical Cream										
			Topical gels/Emulgel										

		Preparation	Topical ointments		
			Topical solutions	Topical lotions (if solution)	
			Topical Emulsions	Topical lotions (if Emulsion)	
			Topical Pastes	Poultices (Cataplasm)	
			Topical Nail Preparation		
			Topical Paints		
			Topical Shampoos		
			Topical Plaster		
			Topical Liniments		
			Roll on (Pack)		
10	**Box X**	Non-Traditional Topical Preparations	Topical Sprays (Pressurized)		
			Topical Foams		
			Bag on valve (BOV)		
11	**Box XI**	Transdermal Systems	Transdermal Patches (Transdermal Plaster)		
			Medicated dressings		
			Transdermal Semisolids		
12	**Box XII**	Vaginal & IUD Preparations	Vaginal Creams		
			Vaginal ointments		
			Vaginal Foams		
			Vaginal Ovules/Pessaries	Vaginal Capsules	Vaginal Tablet
			Medicated IUD		
			Vaginal Rings (Diaphragm)		
			Vaginal Sponges		

			Vaginal Douches				
13	**Box XIII**	Rectal Preparations	Rectal suppositories	Rectal Tablets	Rectal Capsules		
			Rectal Creams				
			Rectal ointments				
			Enemas				
			Rectal Foam				
14	**Box XIV**	Eye/ear Preparations	Solutions	Viscous Liquids (Soln)	Drops	Suspensions	Viscous Liquids (Susp)
			Gels				
			Ointments				
			Ocular Injections				
			Ocuserts				
			Creams				
			Sprays				
15	**Box XV**	Nasal Preparations	Nasal Drops	Nasal Solutions			
			Nasal Sprays				
			Nasal Viscous Liquids	Nasal Gels			
			Nasal Ointments				
			Nasal Creams				
			Nasal Powder				
16	**Box XVI**	Inhaler	Rota Tabs				
			Capsules				
			Solutions				
			Powders				

			Aerosols		
17	**Box XVII**	Nebules	Respules		
18	**Box XVIII**	Oral Soluble Films	Thin Film	Wafer	Sublingual Wafer

Appendix No. (3) Documents required for a registration request of imported human products, manufactured abroad and packaged locally products or locally manufactured under license from a foreign company

Items	خطوات التقديم	Soft copy	Hard copy	Original to review
A- Registration request inquiries submitted for Imported, Bulk & Under License products (في حالة المستحضرات المستوردة أو مصنعة بالخارج ومعبأه محليا أو المصنعة محلياً بترخيص من شركة أجنبية)				
1. The company must apply to Pharmaceutical Information Systems (PIS) administration for creating a company profile to be able to submit registration requests on the box inquiry program.	**1. يجب على الشركة التقدم لإدارة النظم والمعلومات الدوائية لإنشاء حساب خاص بالشركة حتى تتمكن من التقدم بطلبات التسجيل على برنامج الميكنة.**	√		
2. Submit registration requests on the box inquiry program " http://eservices.edaegypt.gov.eg/WebMedicalSheets/login.aspx?ReturnUrl=../WebMedicalSheets/MedSheet.aspx?dk=8000%26sk=33249%26ui=616%26pi=-1%26ek=-1%26st=0%26bv=0 "	**2. التقدم بطلبات التسجيل على برنامج الميكنة" http://eservices.edaegypt.gov.eg/WebMedicalSheets/login.aspx?ReturnUrl=../WebMedicalSheets/MedSheet.aspx?dk=8000%26sk=33249%26ui=616%26pi=-1%26ek=-1%26st=0%26bv=0".**	√		
3. Link of the approved scientific Reference and copy of the leaflet (if found)	**3. رابط المرجع العلمي المعتمد وصورة منه. (إن وجد)**	√		
4. Submit paid Receipt of the registration request service stamped from Financial department; General Administration of Drug Policy & Planning & Central Administration of Pharmaceutical Products written on it all generic details & purpose (Registration Request Inquiry)	**4. إرفاق ايصال الدفع لمقابل خدمة طلب التسجيل مختوم من الإدارة المالية ومركز التخطيط و السياسات الدوائية والادارة المركزية للمستحضرات الصيدلية ومدون عليه كافة بيانات المستحضر والغرض من السداد (طلب تسجيل).**	√		
5. Valid & legalized CPP for the product OR Valid Electronic Certificate of Pharmaceutical Product (eCPP)	**5. شهادة تداول مستحضر صيدلي CPP (سارية وموثقة) للمستحضر أو شهادة إلكترونية لتداول مستحضر صيدلي سارية للمستحضر**	√	√	√

Items	خطوات التقديم	Soft copy	Hard copy	Original to review
6. Valid GMP for the manufacturing site (will be requested later on after reviewing the request to be fulfilled before the due date specified)	6. شهادة GMP سارية للمصنع (سيتم طلبها بعد دراسة طلب التسجيل ويجب استيفاؤها في الميعاد المحدد)	√	√	√
7. Valid & legalized Agency agreement / Authorization letter between License holder and Applicant Company (in case of imported products or bulk) (will be requested later on after reviewing the request to be fulfilled before the due date specified)	7. عقد وكالة أو خطاب تفويض من الشركة الأجنبية إلى الشركة المستوردة بالموافقة على تسجيل المستحضر (في حالة المستحضرات المستوردة والمصنعة بالخارج أو معبأة بمصر) (ساري وموثق) (سيتم طلبها بعد دراسة طلب التسجيل ويجب استيفاؤها في الميعاد المحدد)	√	√	√
8. Valid & legalized manufacturing agreement (in case of under license) (will be requested later on after reviewing the request to be fulfilled before the due date specified)	8. عقد التصنيع مع الشركة الأجنبية (في حالة المستحضرات المصنعة محلياً بترخيص من شركة أجنبية) (ساري وموثق) (سيتم طلبها بعد دراسة طلب التسجيل ويجب استيفاؤها في الميعاد المحدد)	√	√	√
9. Legalized Innovator letter (in case of Innovator) (will be requested later on after reviewing the request to be fulfilled before the due date specified)	9. خطاب من الشركة صاحبة المستحضر يفيد أن المستحضر المقدم هو المستحضر الأصيل (موثق) (سيتم طلبها بعد دراسة طلب التسجيل ويجب استيفاؤها في الميعاد المحدد)	√	√	√
10. List of countries in which the produ is marketed (in case of CPP is from non-reference country) (will be requested later on after reviewing the request to be fulfilled before the due date specified)	10. خطاب من الشركة مالكة المستحضر يوضح قائمة بالدول المتداول بها المستحضر (في حالة المستحضرات الواردة من دول غير مرجعية) (سيتم طلبها بعد دراسة طلب التسجيل ويجب استيفاؤها في الميعاد المحدد)	√		
B- Registration request inquiries submitted as Line Extension				
11. Documents showing that the company's product is still valid: **In case of Under Registration products:**	11. ما يفيد أن المستحضر الخاص بالشركة ما زال سارياً في إجراءات التسجيل: **في حالة المستحضرات تحت التسجيل السارية في إجراءات التسجيل**			
▪ Naming Approval or Submission	▪ موافقة الاسم التجاري للمستحضر أو ما يفيد التقدم في المهلة المحددة	√		
▪ Pricing Approval or Submission	▪ موافقة التسعيرة للمستحضر أو ما يفيد التقدم في المهلة المحددة	√		
▪ Pharmacovigilance Approval or Submission (if found) **In case of Registered products:**	▪ موافقة اليقظة للمستحضر أو ما يفيد التقدم في المهلة المحددة (ان وجد). **في حالة المستحضرات المسجلة**	√		

Items	خطوات التقديم	Soft copy	Hard copy	Original to review
▪ Valid final registration license. ▪ Any other documents…	▪ إخطار تسجيل مبدئي أو نهائي ▪ أي مستندات أخرى… يشترط أن يكون طلب التسجيل من نفس مجموعة الأشكال الصيدلية داخل نفس صندوق المثائل من نفس المادة الفعالة للمستحضرات المسجلة او المستحضرات تحت التسجيل السارية في إجراءات التسجيل.	√		

Appendix No. (4) The documents required for a registration request of human products submitted for tender and export or export only

Items	الأوراق المطلوبة	Soft Copy	Hard copy	Original to review
1.Registration request form stamped by company stamp (according to the form attached in the submission link)	1. نموذج طلب التسجيل طبقاً للآليات الخاصة بالإدارة العامة لتسجيل المستحضرات البشرية المعلنة علي موقع هيئة الدواء المصرية ويراعى أن يكون على ورق الشركة ومختوما بختم الشركة.	√		
2.Submit paid Receipt of registration request service stamped from financial department written on it: (product generic name, concentration & dosage form withtype of marketing tender & export or export only)	2. إرفاق إيصال الدفع لمقابل خدمة طلب التسجيل مختوما من الإدارة المالية ومركز التخطيط والسياسات الدوائية والادارة المركزية للمستحضرات الصيدلية ومدون عليه كافة بيانات المستحضر والغرض من السداد (طلب تسجيل) ونوع التداول تصدير ومناقصات أم تصدير فقط	√		
3. Link of the approved scientific Reference and copy of the leaflet (if found)	3. رابط المرجع العلمي المعتمد وصوره منه. (إن وجد)	√		

Appendix No. (5) The documents required for pricing the local and imported products

- **Documents required for the pricing file of local products:**

1. A pricing request form stating the price, showing the proposed package, and printed on company paper and stamped with its seal.
2. Registration request approval.
3. The receipt of payment for pricing services.
4. Cost sheet (bills for active, inactive ingredients, packaging and packing materials (if any).

- **Documents required for the pricing file of imported products:**

1. A pricing request form stating the price, showing the proposed package, printed on company paper and stamped with its seal.
2. Registration request approval.
3. The receipt of payment for pricing services.
4. A copy of the certificate of free sale in the country of origin.
5. Cost sheet, import price and the price in the country of origin.
6. A list of the countries in which the product is registered and their marketing prices.

Appendix No. (6) The regulatory guide of the General Administration of Pharmaceutical vigilance regarding EDA Chairman Decree No. (450) of 2023 on unifying the regulating of the rules and procedures of registration of human pharmaceutical products.

The company shall be committed to submit the pharmacovigilance file, including all requirements, in accordance with the principles of Good Pharmacovigilance Practice and in accordance with the organizing rules and regulations as follows:

❖ For the First and Third Cases (For all Tracks)

The company shall be committed to submit the pharmacovigilance file to General Administration of Pharmaceutical vigilance within 30 working days from the date of registration request approval or from the date Scientific Committee approval.

In the event that the submitted files are received, these files shall be evaluated within 60 working days from the date in which they were received (provided that the Pharmacovigilance System File (PSMF) shall be submitted at evaluation). Then, a letter shall be issued to the company, which letter may be either a letter of approval of the submitted files or a letter for fulfilling the required documents. In this case, the company shall be given a grace period of 30 working days to fulfill the required documents (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance). the evaluation of the Administration of Pharmaceutical vigilance shall be completed within 30 working days from the date of receiving of the fulfilled require documents.

In the event of not fulfilling the submitted documents, the Administration of Pharmaceutical vigilance shall present the matter to the Technical Committee for Drug Control to take the decision it deems appropriate.

In the case of non-reference products:

The company shall submit the pharmacovigilance file to the General Administration of Pharmaceutical vigilance within 30 working days from the date of approval by the scientific committee. The deadlines for evaluation, issuance of letters, the grace periods granted to the company, and the procedures mentioned above shall apply to it.

In addition, the company shall be obligated to submit the approval of the Scientific Committee.

❖ For the Second Case

The company shall be committed to submit the pharmacovigilance file to General Administration of Pharmaceutical vigilance within 15 working days from the date of registration request approval.

In the event of receiving of the submitted files, the evaluation shall be carried out according to the grace periods stipulated for each Track as follows:

- **Track (A)**: The files shall be evaluated within 5 working days and a letter shall be issued to the company, either a letter of approval of the submitted files or a letter for fulfilling documents. In the latter case, the company shall be given a grace period for fulfilling the required documents, the grace period shall be determined according to the nature of the documents required to be fulfilled (up to 60 working days as a maximum). (Renewed if required based on the evaluation of the Administration of Pharmaceutical vigilance); The Administration of Pharmaceutical vigilance shall complete the evaluation within 5 working days from the date of receiving the required documents.
- **Track (B)**: The files shall be evaluated within 10 working days and a letter shall be issued to the company, either a letter of approval of the submitted files or a letter for fulfilling documents. In the latter case, the company shall be given a grace period for fulfilling the required documents, the grace period shall be determined according to the nature of the documents required to be fulfilled (up to 60 working days as a maximum). (Renewed if required based on the evaluation of the Administration of Pharmaceutical vigilance); The Administration of Pharmaceutical vigilance shall complete the evaluation within 10 working days from the date of receiving the required documents.
- **Track (C)**: The files shall be evaluated within 15 working days and a letter shall be issued to the company, either a letter of approval of the submitted files or a letter for fulfilling documents. In the latter case, the company shall be given a grace period for fulfilling the required documents, the grace period shall be determined according to the nature of the documents required to be fulfilled (up to 60 working days as a maximum). (Renewed if required based on the evaluation of the Administration of Pharmaceutical vigilance); The Administration of Pharmaceutical vigilance shall complete the evaluation within 15 working days from the date of receiving the required documents.

❖ Documents required for the pharmacovigilance file in the registration file

In the case of registering the local products (products of local companies):

- The Risk Management Plan (RMP).
- Pharmacovigilance System File (PSMF) in the company along with its summary

In the case of registration, the imported products / locally manufactured products under license from a foreign company / the local products of the international companies:

- (EU/Global Risk Management Plan of the product (RMP).
- Egyptian Display of Risk Management Plan.
- Pharmacovigilance System Master File (PSMF) of the company abroad along with its summary.
- Pharmacovigilance Sub-System System File (PSSF) of the company or local agent in Egypt

along with its summary.

- The Periodic Benefit and Risk Evaluation Report (PBRER) of the product.

❖ Apply to the Administration of Pharmaceutical vigilance

The Administration of Pharmaceutical vigilance shall be applied to through the electronic reception window of the registration files as well as to know all the documents and requirements required for all the different cases through the link published on the Egyptian Drug Authority website.

The services consideration stipulated in the EDA Chairman Decree, No. (6) of 2021 and No. (99) of 2022, shall be paid, considering the updates of the services consideration to which the companies are notified on the link mentioned above.

In the event of exceeding the grace periods set for submission, whether at applying for the first time or at submitting the required documents specified by the letters issued by the Administration of Pharmaceutical vigilance, the company may apply to the Central Administration for Pharmaceutical Care / the General Administration of Pharmaceutical vigilance with an appeal for the purpose of accepting the file of the product after the expiry of the grace period specified for the file submission within 60 days from the date of expiration of these grace periods. In the event of approval, a grace period not exceeding 30 days from the date of issuance of the approval after paying of the service consideration determined for that for each grace period separately. The appeal includes the following:

- The root causes that led to exceed the grace period (Root cause analysis).
- Corrective and preventive measures taken to avoid exceeding the grace periods in the future, along with submitting the full evidence of their implementation.
- Registration request approval to proceed in the registration process.
- Request a statement from the Central Administration of Pharmaceutical Products to approve the for the progression of registering process of the product according to the case on which the product is registered (if required)

The appeal shall be submitted to the Administration of Pharmaceutical Vigilance through the electronic reception window of the Pharmaceutical Vigilance System (PV system), using the published link on the Egyptian Drug Authority web site.

- The company shall be committed to fulfill the pharmacovigilance system permanently and not to breach any of the pharmacovigilance requirements after registration according to the principles of Good Practice of Pharmacovigilance and the organizing regulations and rules.
- In the event of non-compliance with all the rules of the pharmacovigilance system by the company, the necessary measures shall be taken by the Administration of Pharmaceutical Vigilance and the Central Administration of Pharmaceutical Products and the Central Administration of Operations shall be addressed to take the necessary measures regarding the registered products.

Appendix No. (7) The Regulatory Guide of the General Administration of Factories Inspection – Central Administration of Operations

First: Procedure for submitting a request to attend the manufacturing of pilot batch of pharmaceutical products:

- The company owning the product shall submit a request to the General Administration of Factories Inspection to attend the manufacturing process of the pilot batch / exceptional batch. The request shall be submitted on the approved template and it shall be uploaded on the electronic link designated for receiving the requests of the pilot batches.
- The approval shall be issued after completing the required documents stipulated in the application form and it shall be sent to the company via the official e-mail within three working days, provided that the production shall take place within 3 months of the issuance date of the approval, provided that the grace period specified in the registration request approval issued for the product shall be committed.
- In the case of the Normal Track, the company shall be allowed to manufacture the pilot batch within ten days from the date of fulfilling the request submitted by the company for getting the approval of the manufacturing request.
- In the case of the Fast Track, the company shall be allowed to manufacture the pilot batch within three days from the date of fulfilling the request submitted by the company for getting the approval of the manufacturing request.
- The pilot batch shall be produced in the presence of the inspector(s) of the Central Administration of Operations for following up the batch record and approving the composition on which the manufacturing was carried out.
- The inspector shall approve 2 original copies of the composition ~~form~~ (an original copy shall be attached to the inspector's report and another original copy shall be delivered to the company).
- The inspectors of the Central Administration of Operations shall take samples from the pilot batch to be analyzed at the Central Administration for Drug Control.
- The required studies shall be conducted on the pilot batches produced in compliance with the registration protocols, while adhering to the manufacturing guidelines for the pilot batches. Additionally, the company must provide a commitment that the pilot batches will not be marketed.

Second: The travel procedure to inspect factories outside the Arab Republic of Egypt with regard to products imported from non-reference countries and not marketed in reference countries, whether they are finished or bulk products and packaged in Egypt

A request letter for travelling shall be submitted on the electronic link of the General Administration of Factories Inspection to travel abroad in accordance with EDA Chairman Decree No. (157) of 2021 and No. (150) of 2022. The request letter shall include the following:

1. A letter containing the proposed travel dates (three dates shall be specified during the month in which the travel is proposed).

2. A commitment submitted by the company that it shall pay the financial consideration for the inspection services, as indicated in the statement attached to the EDA Chairman Decree No. (157) of 2021, and another commitment from the company that it shall bear all travel and transportation expenses of the committee.
3. The final report shall be sent by the Egyptian Drug Authority Committee to the factory within 45 days.
4. The factory shall be committed to send the Corrective and Preventative Actions (CAPA) within 30 days.
5. The report shall be presented to the relevant committees to decide whether approve or not the factory.

Appendix No. (8) The regulatory guide for reviewing the analysis files at the Central Administration of Drug Control

Products submitted to the Evaluation and Approval Administration:

- The company shall submit a request to review the analysis file through the link of the Evaluation and Approval Administration after paying the approved service consideration in accordance with the cases stipulated in the EDA Chairman Decree 450/2023.
- The fulfilling of the file contents shall be confirmed in accordance with the approved and published guideline of the Central Administration for Drug Control.
- The file shall be technically reviewed, and the response shall be sent electronically to the company within a period of 20 working days as a maximum in the event of applying according to the Normal Track.
- In the event of fulfilling the requirements of the registration file, the requirements shall be reviewed, and the company shall be notified within 10 working days.
- The file shall be reviewed, and the company shall receive a response within 10 working days in the event of applying according to the Fast Track.
- In the event of fulfilling the requirements of the registration file, the requirements shall be reviewed, and the company shall be notified within 7 working days.
- The company shall be granted a period not exceeding three months to fulfill the required documents.
- In the event of exceeding the specified period to fulfill the requirements by the company, the company shall submit an appeal for timeframe extension after paying the approved service consideration.
- The company's appeal shall be considered after perusing the company's reasons for the delay.
- After fulfilling the requirements of the file, the quantity of samples approved for each pharmaceutical form should be followed in accordance with the guidelines provided by the Central Administration for Drug Control.
- The Central Administration for Drug Control may request the materials of the analysis that are not present in the laboratories during the examination / analysis of the product file if needed and the Central Administration for Drug Control has the right to request additional samples if needed.
- After fulfilling the company shall submit a request to upload the analysis file, samples and analysis requirements on the link designated for that purpose.
- In the event of the company delayed for three months to submit the file alongside the samples to be analyzed after its completion, the company has the right to submit a reasoned appeal to extend the grace period after paying the approved service consideration.
- The analysis shall be carried out within 60 working days from the date of delivering of the samples to the Central Administration for Drug Control in the event that the analysis

request was submitted according to the Normal Track system.

- The analysis shall be carried out within 30 working days from the date of delivering the samples to the Central Administration for Drug Control in the event that the analysis request was submitted according to the Fast Track.
- In case of issuing a letter to the company during the analysis, the company shall be obliged to send a response within a period not exceeding three months.
- In the event that the company delayed in responding the letter for more than three months, the company has the right to submit a reasoned appeal to extend the grace period after paying the approved service consideration.
- The final report shall be issued attached to the composition on which the analysis was carried out.

Appendix No. (9) The regulatory guide of the General Administration of Pharmaceutical References and Inserts at the Central Administration for Pharmaceutical Care to approve the medical leaflet.

The company shall be committed to apply to the Administration of Inserts on the link published on the Egyptian Drug Authority's website to approve the medical leaflets that shall be attached to the registration file. This step shall follow the approving of the stability study and fulfilling all the necessary requirements and approvals described in the Guidelines on Medical Leaflets of Medicinal Products for Human Use listed in the same submission link.

Documents required for the products under registration

- A receipt (according to the EDA Chairman Decree for paying the services consideration listed in the submission link).
- An explanatory letter by the company stating the product information and the reasons for applying.
- The proposed leaflet (in English and Arabic).

** For perusing the cases in which the inclusion of the Arabic translation of the leaflet is excluded, see the Technical Committee Decision No. 12/3/2009 and Technical Committee Decision in its session held on August 25th, 2022.

- The latest updated version of the reference leaflet in English (SmPC Summary of Product Characteristics) and the reference leaflet in Arabic (Patient Information Leaflet)
- The stability study approved by the relevant administration (except for the products submitted according to second Case, provided that it shall be submitted immediately upon its issuance by the relevant administration.
- The composition approved by the relevant administration, except for the products submitted according to second Case Track A, Track B, Track C (imported), provided that it shall be submitted immediately upon its issuance by the relevant administration).
- The Trade name approval.
- The registration request approval.
- The approval of the General Administration of Pharmaceutical Vigilance (except for the products submitted according to second Case and the products registered for the purpose of export).
- The Pricing Certificate (except for the products submitted according to according to second Case and products submitted for the purpose of tender and export).

Additional required documents:

a) **When utilizing a reference in a language other than English**, an approved medical

translation for the leaflet of the reference product shall be submitted, provided that the translation shall be attached to the original text.

b) **In the case of imported and Innovator products**, the leaflet attached to the certificate of pharmaceutical product of the product can be used as a reference (This matter will be clarified in the letter sent to the Administration of Inserts) (this step is optional if the leaflet attached to the certificate is the most recent).

If the leaflet contained in the package is in the form of patient information leaflet, a legalized letter shall be submitted by the origin country and sealed by the Egyptian embassy. The letter shall include a commitment from the company stating that the attached leaflet (patient information leaflet) with the specified trade name, scientific name, concentration, date of revision and issue number is registered and marketed information in the country of origin. The leaflet shall be translated into Arabic as a patient information leaflet.

For non-English leaflets, the following documents must be submitted:

A legalized declaration letter submitted by the License Holder. In such legalized letter, the owner shall commit to translate the leaflet into a certified medical translation on his responsibility according to the attached translation (in two languages English and non-English). The letter shall be signed and stamped by the license holder.

Or a legalized letter submitted by the head office stating that the scientific office is responsible for the translation. The medical leaflet shall be translated through their scientific office. The medical translation submitted (in two languages: English and non-English) must be signed and stamped by the scientific office.

The Summary of Product Characteristics leaflet shall be submitted to be uploaded on the electronic website of the Egyptian Drug Authority.

In the case of non-reference products:

- The cover letter shall state that the product is not a referenced product and the approvals of the relevant committees shall be attached.
- The detailed source of scientific data (references, scientific papers, books: Martindale, BNF) shall be clarified for each piece of information within the purposed leaflet according to the reference used. For example, Suggested Dosage According to the reference … "Reference Name".

Notes:

- The evaluation request of the leaflets shall be submitted at least three months prior to any deadlines.
- It shall be allowed to send the required amendments / corrections to the leaflets within one

month for the local products from the date of sending the required amendments by Administration of Inserts and three months for the imported and licensed products from the date of sending the required amendments by the Administration of Inserts, otherwise a new request shall be submitted.

- All the submitted documents shall be valid and recent (within the time frame for the approval in accordance with the ministerial decrees and decisions issued by the relevant divisions).
- The leaflet shall mention the warnings issued by the Technical Committee for Drug Control and the Pharmacology Committee regarding the active and inactive materials of the product presented in the relevant clause.

Appendix No. (10) Conversion guide the registration of the human pharmaceutical products submitted for registration from first Case to second Case

First: In the event of applying for converting before getting the approval of the registration request:

1. The applicant shall send a conversion request on the following e-mail: Hdr.regrequest@edaegypt.gov.eg to convert the registration of the product from **first Case to second Case**, provided that the request shall be approved by the Chairman of the Board of Directors of the company in this regard.
2. The Evaluation Unit of Registration Request for Human Products shall send the info required to the applicant in order to convert the case for which the request applied on the specified program, then the request shall be reviewed, and the company shall receive the respond according to the specified timeline in compliance with the second case.
3. In the event of fulfilling the requests by the company, the approval of the registration request shall be issued according to the second Case and the registration procedures shall be completed in accordance with the regulatory guide of the registration procedures for the products submitted according to this case.

Second: In the event of applying for converting after getting the approval of the registration request:

The applicant shall submit a conversion request from first Case to second Case on the link of the Follow-up Unit in the General Administration of human pharmaceuticals registration published on the EDA website, provided that the request shall include the following documents:

- An official letter approved by the Chairman of the Board of Directors of the company in this regard.
- A copy of the approval of the registration request of the product.
- A copy of all approvals issued for the product.
- A copy of the previously paid receipts.

Reviewing the status of the product regarding the registration:

The company's request, the status of the product regarding registration, the studies that have been conducted and their completion shall be reviewed according to the first Case and the fees/service consideration that have been paid.

Issuance of the conversion approval:

In the event of fulfilling the requests by the company, a conversion approval shall be issued within a maximum of 10 working days from the date of receiving the completed conversion request from the company and a copy of the conversion approval shall be issued for notifying the Pharmaceutical Information Systems to amend the type of registration of the product on the database to be on the Second Case.

General Terms:

- In order to apply for conversion to the Second Case, the product shall not have exceeded any of the grace periods stipulated in the First Case, according to which the registration request was previously applied, otherwise the request shall be cancelled.
- The applicant shall be obligated to pay the fees / service consideration according to the regulatory guide of Second Case.
- The applicant shall be obligated to complete and fulfill the registration requirements and estimate the grace period necessary to move to the next step in the registration, starting from the issuance date of the conversion approval in accordance with the regulatory guide of Second Case.

Appendix No. (11) Conversion guide for the type of registration of human pharmaceutical products registered or under registration for export only or tenders & export to be marketed in the local market according to Third Case

SN	Phase	Requirements of the registered products	Requirements of the products under registration
1	**Submitting a registration request**	– Submitting a registration request to register the product in accordance with the Third Case and its regulatory guide. – The registration request approval shall be issued provided that the product registered for export only or for tender & export will be cancelled upon issuance of the Marketing Authorization license of the product submitted according to Third Case. – The status of the product shall be changed on the database of human medicines. – The Marketing Authorization license of the product shall be valid, whether it is an initial or final marketing authorization license, or submitted for re-registration when applying for a new registration request. **Note**: Registered products shall be allowed to be marketed according to the type of registration, whether for export only or for tender & export, until completing the registration procedures for the product submitted according to Third Case and granting the marketing authorization license.	- Submitting a registration request to register the product in accordance with the Third Case and its regulatory guide. -The registration request approval shall be issued provided that the product registered for export only or for tender & export will be cancelled upon issuance of the Marketing Authorization license of the product submitted according to Third Case. -The status of the product shall be changed on the database of human medicines. – The preliminary approval shall be valid when applying for a new registration request. **Note**: It shall be allowed to complete the registration procedures for the product intended for export only or for export and tenders and to issue the marketing authorization license and marketing, until completing the registration procedures for the product submitted according to Third Case and granting the marketing authorization license.

2	**Scientific committees**	In case of the absence of a scientific reference, the scientific files shall be submitted to be presented to the scientific committees according to the specified grace periods; and the decisions issued by the scientific committees shall be valid.	
3	**Choosing trade name**	Applying to get a trade name according to the specified grace periods. Choosing the same name issued for the product intended for tender and export only, shall be allowed.	
4	**Pricing**	Apply to the Central Administration of Drug Policies and Market Access, Pricing Policies and Pharmacoeconomics for pricing the product according to the specified grace periods.	
5	**Pharmaceutical vigilance**	Apply to the Central Administration for Pharmaceutical Care and the General Administration of Pharmaceutical vigilance in order to fulfill the requirements of pharmacovigilance in accordance with the specified grace periods, provided that the file shall be updated according to the latest information at the time of submission. The documents previously submitted and any approval previously issued for the products intended for tender & export shall not be considered.	
6	**Analysis in the Central Administration for Drug Control**	Apply for analyzing at the Evaluation and approval administration of the Central Administration for Drug Control. The previously issued CADC report of the registered product on a pilot / production batch shall be considered.	Apply for analyzing at the Evaluation and approval administration of the Central Administration for Drug Control. The previously issued CADC report of the registered product on a pilot batch shall be considered.

7	**Stability studies**	An accelerated and long-term stability study, with a minimum one year, conducted on three pilot batches of the product shall be submitted. In this case all the conditions in the published regulatory guide Third Case shall be applied with regard to manufacturing of the pilot batches. The accelerated and long-term stability study on any three consecutive production batches of the registered product, shall be allowed to be submitted, provided that these batches shall be the same batches for which inspection reports have been issued.	An accelerated and long-term stability study, with a minimum one year, conducted on three pilot batches of the product shall be submitted. In this case all the conditions in the published regulatory guide Third Case shall be applied with regard to manufacturing of the pilot batches.
8	**Updating the inner leaflet**	A request shall be submitted for updating the inner leaflet according to the stipulated grace periods.	
9	**Outer and inner Mock ups**	A request shall be submitted for approving new outer and inner mock ups according to the stipulated grace periods.	
10	**Bioequivalence study**	The Evaluation Unit of bioavailability and Bioequivalence Studies of Human Pharmaceuticals may be addressed if required. The Unit may rely on the approvals issued for bioequivalence studies if they meet all the conditions for evaluating the current bioequivalence study. A statement shall be issued by the Unit in this regard.	
11	**Submitting the final registration dossier**	The registration dossier containing the previous documents shall be submitted to the Administration of Regulatory Affairs according to the specified grace periods.	

Appendix No. (12) Regulatory guides and procedures for registering human pharmaceutical products according to the Regulatory guide of the Non routine registration to get Emergency Use Authorization License for Human pharmaceutical Product

In light of the precautionary measures taken by the Egyptian Drug Authority to support the availability of some important products and with reference to approving the emergency use authorization by EDA Chairman dated April 16th and May 14th, 2020, we inform your honor that the following procedures were approved:

1. The box of the products that contain important active ingredients shall be opened according to the urgent need for their registration and they shall be published on the Egyptian Drug Authority's website.
2. The necessary procedures for registering these products under the name of Emergency Use Authorization of Pharmaceutical Products, shall be accelerated according to the accelerated registration procedure, provided that the company shall complete a number of procedures of the production within 3 months, renewed for an additional 3 months only, from the date of issuing of the registration request approval. In case of non-compliance, the registration procedures shall be completed in accordance with the normal procedures stipulated by the Ministerial Decree according to which the approval of the registration request is issued.
3. When manufacturing the product, the company shall be committed to the same pharmaceutical form, composition, specifications of the active and inactive ingredient and the initial packaging of the reference product, (Innovator Product). The company shall be granted a prior approval to follow up the rest of the procedures.
4. It shall be permitted to produce a production batch on the responsibility of the company owning the product. The production process shall be carried out in the presence of an inspector to follow up all the production procedures and in the presence of a control specialist from the Egyptian Drug Authority laboratories to attend the analysis and approve the results of the active ingredient and the final product.
5. Initiating an accelerated stability study for a period of 6 months, provided that the CADC report for the final product shall be considered the "zero time". Then the accelerated stability study shall be completed and the analyzing and following up the results shall be conducted according to the rules organizing the evaluation of stability studies.
6. Conducting a study of the dissolution rate compared to the reference product in the reference laboratory of the Egyptian Drug Authority. The study of bioequivalence compared to the reference product for cases that require this, shall be completed in accordance with the rules regulating these studies after the issuance of the Emergency Use Authorization License for Human pharmaceutical Product and before releasing the production batches intended for marketing.
7. The product shall be granted Emergency Use Authorization License for Human

pharmaceutical Product for a period of 8 months only, provided that fulfilling a number of approvals and requirements necessary for issuing the license as shown in the following table, as a minimum.

8. The production batch previously mentioned in clause (4), shall be permitted to be marketing. It shall be released gradually according to the urgent necessity and consumption rates for the purpose of local marketing through the government hospitals only. These steps shall be followed-up by the pharmacist inspection.

9. The rest of the studies, such as stability and bioequivalence, shall be completed after the issuance of Emergency Use Authorization License for Human pharmaceutical Product. The status of their completion shall be followed up by the pharmaceutical inspection.

10. Marketing and use shall be suspended when reporting any indications affecting the efficacy and safety of the product by the specialized hospitals or monitored by the General Administration of Pharmaceutical vigilance, in accordance with the regulating rules.

Procedures	The relevant division concerned with reviewing, evaluation and follow-up
Submitting a registration request**	Evaluation Unit of Registration Request for Human Pharmaceuticals General Administration of Human Pharmaceuticals Registration Central Administration of Pharmaceutical Products
Approving the trade name**	Evaluation unit of Trade Names and mockup of Human pharmaceuticals General Administration of Human Pharmaceuticals Registration Central Administration of Pharmaceutical Products
Initial pricing certificate**	Pricing Policies and Pharmacoeconomics Central Administration of drug Policies and Market Access
Submitting a pharmacovigilance file**	General Administration for pharmaceutical vigilance Central Administration for pharmaceutical care
Approving the composition, specifications of the active and inactive ingredients and the primary packaging materials for the product compared to the reference product "Innovator Product"**	Unit of Evaluation Human Product Specifications Administration of Technical Affairs General Administration of Human Pharmaceuticals Registration Central Administration of Pharmaceutical Products
Approving the product leaflet according to the reference product "Innovator Product" "After approving the composition and specifications"**	General Administration of Pharmaceutical References and Inserts Central Administration for pharmaceutical care
Approving the outer and inner packaging of the product "After approving the composition and specifications"**	Evaluation unit of Trade Names and mockup of Human pharmaceuticals General Administration of Human Pharmaceuticals Registration Central Administration of Pharmaceutical Products
Follow up the full steps of manufacturing the production batch of the product and initiate the required studies**	General Administration of Factories Inspection Central Administration of Operations
Analyzing the active ingredient, analyzing the final product and approving the results according to the composition and the approved specifications**	Central Administration for Drug Control
Approving storage conditions and initial shelf life**	General Administration for stability Central Administration of Pharmaceutical Products

**Conduct a study of the dissolution rate compared to the reference product "Innovator Product" ** ** **	Central Administration for Drug Control
Evaluating and approving of the comparative solubility rate and bioequivalence study**	The Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals General Administration of Human Pharmaceuticals Registration Central Administration of Pharmaceutical Products
Submit the registration dossier to get an Emergency Use Authorization License for Human pharmaceutical Product	Administration of Regulatory Affairs General Administration of Human Pharmaceuticals Registration Central Administration of Pharmaceutical Products

** Necessary approvals and requirements for issuing Emergency Use Authorization License for Human pharmaceutical Product.

Versions

Version	Issue Date	Places of Amendments
Version No. (1)	August 10th, 2022	---------
Version No. (2)	September 11th, 2023	▪ Clarifying Reliance Evaluation Route ▪ Updating the procedures of receiving and evaluating the registration files of the human pharmaceutical products submitted in accordance with the first case, second case, third case and their grace periods. ▪ For the human pharmaceutical products locally manufactured for the purposes of export only, the company may apply an application for exemption from conducting the studies of bioequivalence and bioavailability of the human pharmaceutical products within the Arab Republic in Egypt, provided that the company shall be committed to submit the study immediately upon conducting it abroad. These procedures shall be implemented as a condition for issuance the marketing authorization license.