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

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Content

Introduction

- This guideline is concerned with organizing the rules and procedures for registration of human Pharmaceutical products in different cases in the Egyptian Drug Authority in accordance with the law of establishing the Authority promulgated by Law No. (151) of 2019.This guide applies to Human Pharmaceutical Products manufactured locally in factories inside theArab Republic of Egypt for the purpose of local marketing, tender and export or for export only or for imported finished products or imported bulk products and Under license products.
- 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 dossier.

Scope

- This guide applies to EDA Chairman Decree No (450) of 2023, as well as EDA Chairman memorandum issued on 13/8/2025 which includes the implementation of the "One submission" pathway for local human pharmaceutical products (CTD) under registration, in accordance with all ministerial decrees regarding the registration of human pharmaceutical products.
- 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 pre-qualified products.
  2. Generics having a reference similar product approved by stringent regulatory authority (SRAs) included in a list of the reference countries approved by the Technical Committee for Drug Control or WHO pre-qualified products.
  3. Generics that differ from the reference product in the dosage form, concentration or method of administration after presentation to the scientific committees.

- This decree shall not apply to the registration of products containing new active chemical entities that have not previously been registered in any of the reference countries, or biological/herbal/veterinary products.

Terms and Definitions

- **Box:** The number of similars in the box consisting of a group of pharmaceutical dosage forms shall be determined starting from the innovator product of the active ingredient as indicated in Appendix No. (1) and in accordance with the rules specified in details in the regulatory guideline issued for implementation of this decree's provisions and after being presented to EDA Chairman, provided that the pharmaceutical dosage forms in the box indicated in the Appendix No. (2) shall be updated in the event of the emergence of a new pharmaceutical dosage form and after being presented to the Technical Committee for Drug Control.
- **Line extension:** is the addition of another concentration for the same company with the same pharmaceutical dosage form or in different pharmaceutical dosage forms within the same box of the same active ingredient for the registered products that have a valid marketing authorization license or for the under-registration products whose registration procedures are in progress. **OR** addition of the same concentration and dosage form with new indication differ in dose, supported by a scientific reference. The approval of the registration request for the line extension shall follow the same track and case as the original registration, with full compliance to the corresponding service consideration and procedures.
- **Reliance:** Relying on the decisions of Stringent Regulatory Authorities regarding registration and analysis, in accordance with the rules and regulations outlined in Appendix No. (3).
- **Routine Registration:** The company submits a registration request for human pharmaceutical products in adherence to the procedures set out in Appendix No. (4). in accordance with the following cases:

  First case: In this case, the company shall submit a registration request for human pharmaceutical products as per the number allowed in the box, provided that the complete Common Technical Document (CTD) is submitted as a condition for completing the final registration dossier.

  Second case: The company shall submit a registration request for human pharmaceutical products as per the number allowed in the box and with Fast Track registration. provided that the complete Common Technical Document (CTD) is submitted as a condition for completing the final registration dossier. This case includes the following tracks:

  Track (A): The imported 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 (1) month from the date of receiving the complete registration dossier.

  Track (B): The imported 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 (2) 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 (3) 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 (6) 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 (6) months from the date of receiving the complete registration dossier.

Third case: The company shall submit for the registration of human pharmaceutical products, and their registration requests shall be accepted exceeding the allowed number of the box, provided that the complete Common Technical Document (CTD) is submitted as a condition for completing the final registration dossier. This case includes the following tracks:

Track (A): Human pharmaceutical products listed in any of the approved shortage lists for human pharmaceutical products in effect at the time, based on market needs as determined by the EDA, provided that such lists shall be published every three (3) months. **These lists shall be determined in accordance with the following procedures:**

1. Central Administration of Drug Policies and Market Access shall conduct the necessary studies to determine the products (as per the active ingredient, concentration, and pharmaceutical form) that meet the aforementioned standards and shall submit reports thereon every (3) months at most to the Technical Committee for Drug Control.
2. These lists shall be presented to the Technical Committee for Drug Control to be studied for their approval.
3. 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 consider its approval.
4. The approved lists shall then be announced on EDA's website to allow companies to submit requests for registering the products incorporated therein.

Track (B): Human pharmaceutical products that are manufactured locally on rare production lines specified by EDA in accordance with proposals submitted by Central Administration of Inspection on Pharmaceutical Institutions and approved by the Chairman of the Egyptian Drug Authority. The list of rare production lines in effect at that time shall be announced once annually.

Track (C): Human pharmaceutical products applied for by the owners of the factories licensed since 10 August 2023, toll manufacturing contracts shall not be permitted.

Track (D): Human pharmaceutical products applied for by the owners of the under-construction factories & the beginning of construction from 10 August 2025.

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

**The registration procedures for human pharmaceutical products submitted under the different tracks stipulated in this case shall be completed in accordance with the procedures and conditions of the first or second case, as per the company's preference.

**It is permitted to transfer from one track to another within the same case in the event that the status of the company or the product has changed and it becomes eligible for more than one track under the same case based on approval from the EDA chairman and upon a report submitted by the Head of the Central Administration for Pharmaceutical Products provided that the company is committed to pay the required service consideration before receiving approval.

- **Non-routine registration:** The company submits a registration request for human pharmaceutical products and includes the following tracks:

(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 allowed 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 authorization license.
- The box shall be opened exceeding the allowed 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 guidance, Appendix No. (5).
- 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 for Human Pharmaceuticals 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 regulating procedure 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:

- 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 allowed number of the box. The registration procedures For Human Pharmaceutical Products submitted shall be completed on the First Case or Second Case up on company preference, fulfillments of the requirements, completion of the required technical studies and getting the approvals required for registration in accordance with the procedures mentioned in the regulatory guideline of this decree.
- The box shall be opened exceeding the allowed 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 the classifications listed in Appendix No. (6).
- Only imported human pharmaceutical products that are marketed in one of the reference countries approved by the Technical Committee for Drug Control shall be accepted, in accordance with the rules and procedures outlined in the regulatory guideline.
- For imported human pharmaceutical products submitted for registration under the Non- Routine pathway: companies are granted a maximum period of (6) months from the date of issuing the first pricing approval or the date of approval by the General Administration of Pharmacovigilance, whichever is later, to submit the complete registration dossier (CTD) to the Regulatory Affairs Administration of Human Pharmaceuticals .The pricing approval and issuance of the pricing certificate shall be completed within (6) months from the date of submission to the Pricing.
- 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 registration requests specified monthly.

Company Commitments

The company is committed, under this decisionto the following clauses:

-Clause (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.

-Clause (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 Pharmaceuticals Registration. Any change on the product shall be prohibited except after getting an approval from the Egyptian Drug Authority.

-Clause (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 Inspection on Pharmaceutical Institutions shall follow up this commitment.

-Clause (4): Manufacturing the product from the same source of the active pharmaceutical ingredient from which the pilot batches were manufactured in accordance with the different registration cases and on which all the required studies have been conducted. This applies to locally manufactured products 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 Pharmaceuticals Registration to determine the required studies.

-Clause (5): A declaration that any change shall not be made except after the approval of Central Administration of Pharmaceutical Products, otherwise the marketing authorization license shall be canceled based on a report issued by the Central Administration of Inspection on Pharmaceutical Institutions

-Clause (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)

- Clause(7): Adherence of the company to the clauses mentioned in Article (12) in the Egyptian Drug Authority Chairman's decree.

-Clause (8): The products registered for export only or for tender and export are not subjected to the grace periods of production and importation.

-Clause (9): In case of registering the innovator product (whether it was imported or Under-License Product), 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.

-Clause (10): Adherence of the company to submit a report on the safety, quality and efficacy of the registered product during the last 3 months of the fifth year from the date of the 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.

Chapter One: Procedures and requirements for submitting a registration request for human pharmaceutical product

This chapter includes three main steps:

- ✓ **Step 1: Obtaining registration request approval for human pharmaceutical product.**
- ✓ **Step 2: Obtaining naming and mock-ups, pricing, and pharmacovigilance approvals.**
- ✓ **Step 3: Importation of Active Pharmaceutical Ingredient (API) then ,proceed with production and conduction of technical studies.**

Step1: Obtaining registration request approval for human pharmaceutical products

Steps for submitting a registration request for human pharmaceutical products locally manufactured **Products and imported products**

- The company is committed to submit the registration request in accordance with the regulations approved by the General Administration of Human Pharmaceuticals Registration and the published on the website of the Egyptian Drug Authority, according to Appendix No. (7). The registration request shall be registered according to the date and time of its correct and complete submission. The company shall be notified of confirmation of the initial acceptance of the registration request and the status of the product in accordance with the rules regulating this in accordance with Appendix No. (8).
- If any additional requirements are needed, the company is obliged to complete them within a period not exceeding (3) months from the date of notification . Registration request approval will be issued asof the date on which all requested requirements are accepted,in accordance with Appendix No. (8). The company is also committed to paying the service consideration required to register the product before receiving approval for the registration request, provided that the approval is received within (30) working days from the date of its issuance, otherwise the registration request will be cancelled.
- The approval of the registration request shall state whether the product has a scientific reference or not, based on what the company provides and under its full responsibility. If a scientific reference is present, the company shall comply with the active ingredient, dosage form, and concentration specified in the submitted scientific reference.
- **In the event that there is no availability in the box in accordance with case 1 and case 2:**
  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 event 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 event 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.

- **In the case of imported human pharmaceutical products from non-reference countries and not marketed in any of the reference countries**

The human pharmaceutical product is presented to the specialized scientific committees and then presented to the technical committee for drug control to take the appropriate decision and the company is committed to the decision of the technical committee for drug control by submitting (Module 3) to Administration of Technical Affairs for Human Pharmaceuticals and Site Master File to the Central Administration of Inspection on Pharmaceutical Institutions . An inspection of the manufacturing site abroad shall then be conducted. In the event that the Technical Committee for Drug Control requests some documents from the company, the company is obligated to submit the required documents within a maximum of (30) working days from the date of notifying the company, otherwise the registration request will be cancelled.

In the event of the Technical Committee's approval: The approval for the registration request will be issued upon receipt of the Technical Committee's decision in accordance with Appendix No. (8). The company is obligated to pay the service consideration for registering the product before receiving approval for the registration request, provided that the company receives approval for the registration request within (30) working days of its issuance, otherwise the registration request will be cancelled.

In the event of the technical committee refuses to exempt the product from the requirement for marketing in the reference countries, The company may appeal the decision of the Technical Committee for Drug Control, provided that it submits a new registration request to the General Administration of Human Pharmaceuticals Registration and pays the required service consideration.

Note: The factory is inspected abroad by the General Administration of Factories Inspection at the Central Administration of Inspection on Pharmaceutical Institutions, and the re-inspection is carried out according to the Risk-based inspection planning issued by the General Administration of Factories Inspection .

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

- If the human pharmaceutical product does not have a scientific reference in the same dosage form, concentration and method of administration, the company is obligated to submit the scientific files for the product to the specialized scientific committees within (30) working days from the date of issuance of registration request approval, otherwise the registration request will be cancelled , and presented to the specialized scientific committees within (60) working days from the date of receiving the complete 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 product shall be re-presented to the specialized scientific evaluation committee within 30 working days from the date of accepting the fulfilled required documents, otherwise the registration request will be cancelled.
  - **In the event of the non-approval on a scientific basis:** The General Administration of Human Pharmaceuticals Registration shall present the product 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 evaluation committee. 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 wants to rely. The decisions of the specialized scientific evaluation committee shall be used as guidance in the study of the registration requests to be submitted later.

Note: In the case of products provided submitted according to the second case

- The company shall address the specialized scientific evaluation committee within (15) working days from the date of issuance of the registration request approval to submit the scientific file, otherwise the registration request shall be cancelled and presented to the specialized scientific committees within (30) working days from the date of receiving of the complete 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 product shall be re-presented to the specialized scientific evaluation committee within 20 working days from the date of accepting the fulfilled required documents, otherwise the registration request will be cancelled.
- **In the event of the non-approval on a scientific basis:** The General Administration of Human Pharmaceuticals Registration shall present the product 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 evaluation committee. 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 wants to rely. The decisions of the specialized scientific evaluation committee shall be used as guidance in the study of the registration requests to be submitted later.

- In the event that a scientific reference for the product arises 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 arises 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.

Step 2 : Obtaining Approvals for names and mockups, pricing and pharmacovigilance

The company is committed to applying in parallel to the following administrations to obtain the required approvals:

Administrations and Units	Steps to obtain approvals
Names and Mockup **Evaluation Unit for Trade names and Mockup for Human Pharmaceuticals** **(Central Administration for Pharmaceutical Products)**	▪ The company shall submit a list including a maximum of (15) proposed trade names for the product within the timelines in accordance with Appendix .No 8 from the date of issuance of the registration request approval or from the date of issuance of approval of the specialized Scientific Committe, otherwise the registration request shall be cancelled. ▪ The list of trade names submitted by the company is reviewed within the timeframes in accordance with Appendix .No 8 from the date of receiving the list of names from the company, a letter will be issued to the company approving the name of the product or the rejection of the first list of names that were previously submitted. ▪ In case of rejection, the company shall submit another list within the timelines, in accordance with Appendix .No 8 from the date of issuing the rejection letter of the first list of names that were previously submitted, otherwise the registration request will be cancelled. ▪ The company is allowed to submit (4) Lists of proposed names including the first list ,to be evaluated and approved as mentioned above. If all four submitted lists are rejected, an approval will be

Administrations and Units	Steps to obtain approvals
	issued with the scientific name alongside the company name as the Trade name. **Note: In the case of Products submitted for registration under the export only or export and tender, and the company does not submit or complete the step of obtaining approval for the trade name within the timelines in accordancewith Appendix .No 8 The approval is issued with the scientific name next to the company name as the trade name of the product.
Pricing **(General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration)** **(Central Administration of Drug Policies and Market Access)**	▪ The documents required for pricing local and imported products shall be submitted in accordance with Appendix No. (9) within the timelines in Appendix No. (8) from the date of issuance of the registration request approval or from the date of issuance of the approval of the Scientific Committee, otherwise the registration request shall be cancelled based on a report submitted by the relevant central administration provided that the product is priced within the timelines in accordance with Appendix No. (8) from the date of receipt of the complete pricing file **Note:** Locally manufactured products for export only or for export & tender are exempted from pricing
Pharmacovigilance **(General Administration of Pharmaceutical vigilance)** **(Central Administration of Pharmaceutical Care)**	▪ The documents necessary to fulfill the Pharmacovigilance requirements as per the regulatory rules of the General Administration of Pharmaceutical vigilance in accordance with Appendix No. (10), This shall be within the timeline in accordance with Appendix No. (8) from the date of issuance of registration request approval or from the date of approval of the Scientific Committee. Otherwise, the registration request shall be cancelled by the General Administration for Registration of Human pharmaceutical products after referring to the relevant central administrations. ▪ The documents submitted by the company shall be evaluated within the timelines in accordance with Appendix No. (8) from the date of receiving the complete vigilance documents (provided that the document describing the Pharmacovigilance system of the company shall be completed upon evaluation). **In case of approval:** The company will be notified and the procedures for registering the product will be completed. In the event that the company requests fulfillments, the company will be granted a grace period in accordance with the timelines in accordance with Appendix

Administrations and Units	Steps to obtain approvals
	No. (8), The evaluation shall be completed within the timelines in accordance with Appendix No. (8) of receiving the requirements **In case of non-approval or non fulfillment of-documents:** The registration request will be presented to the Technical Committee for Drug Control by the General Administration of Pharmacovigilance to take the appropriate decision, stating the reasons for rejection of the registration request.

Step 3: Importion of active ingredients, then production and conduction of technical studies:

(A) For locally manufactured human pharmaceutical products for local Marketing , Tender and export and export only
Importation Approvals
The company applies to the General Administration of Importation and Customs Release to import active ingredient s/packaging supplies, based on the registration request approval. This is in accordance with the regulatory guide issued by the General Administration of Importation and Customs Release at the Central Administration for Drug Policies and Market Accessand its ongoing updates .
Production and Conduction of Technical Studies
Pilot batch specifications: The size of the pilot batch is determined to be a minimum of 10% of the production batch size and exceed the minimum capacity of the production line. At least two of the three batches may be the same size as the pilot batches, with the third batch permitted to be produced in a smaller size. Pilot batches must be manufactured with the same composition, specifications, primary pack & manufacturing process that will be used to produce the production batches of the final product that will be marketed. 1. Before production, the company shall apply to the Central Administration of Inspection on Pharmaceutical Institutions as per the regulatory guidelines of the relevant Central Administration in order to manufacture three pilot/ production batches (Appendix No. 11) in the presence of an inspector from the Central Administration of Inspection on Pharmaceutical Institutions, provided that pilot batches 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 Inspection on Pharmaceutical Institutions to ensure that the pilot/production batches are produced on the same production lines located in the factory. 2. The inspector shall attach the composition of the product on which production was conducted, signed by the factory manager stamped and signed by the inspector, with a report detailing the source of the active ingredient and shall take samples to conduct the necessary technical studies. 3. It is not permitted to produce both pilot and production batches together, only pilot batches or production batches.

If the company wants to manufacture production batches

1. The company applies to the General Administration of Human Pharmaceuticals Registration for permission to manufacture production batches instead of pilot batches , Conduct all studies required to get a marketing authorization license for these production batches, stating the reasons. The request must be submitted in a detailed report to the head of the Central Administration for Pharmaceutical products explaining the reasons provided that the required service consideration is paid. Accordingly an approval will be issued to the company to produce production batches.
2. The company is committed to analyze the first three production batches at the Central Administration for Drug Control before issuing the marketing authorization license in accordance with the regulatory guideline for analysis files at the Central Administration for Drug Control in accordance with Appendix .No 12 provided that the analysis is carried out as follows:
   - ✓ The first production batch should be analyzed at the Administration of Evaluation and Approval in Central Administration for Drug Control.
   - ✓ The second and third batches should be analyzed at the Administration of Post Approval Control at the Central Administration for Drug Control.
3. Approving leaflet according to guidelines of the Central Administration of Pharmaceutical Care in accordance with Appendix No (13), The internal and external mockup of the product is checked by the relevant central administrations before submitting the final registration dossier to the Administration of Regulatory Affairs for Human Pharmaceuticals.

Note: Regarding the API borrowing status, the company applying for the borrowing must provide a legalized "Letter of Access" issued by the supplier, which includes their approval to allow the company to use the active ingredient.

Technical studies conducted after production of batches

1. An accelerated stability study is conducted for a period of (6) months on the three pilot/ production batches accompanied by the composition on which the product was produced, signed and stamped by the inspector of the Central Administration for Inspection of Pharmaceutical institutions. Inaddition to (1) year long-term stability study at least on the same pilot/ production batches and the product is given an initial shelf life of (2) years and stability study is conducted after opening in cases where this is required and it is printed on batches until the final expiry date of the registration dossier is determined with the commitment to notify the Central Administration for Inspection of Pharmaceutical institutions where and when the stability study will be conducted before starting it. The source of the active ingredient, batch number, batch type, factory name, product name and data must be mentioned in the approval.
2. It is allowed for Companies to submit 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 three pilot/production batches to be submitted to the Administration of Regulatory Affairs for Human Pharmaceuticals upon completion within the complete CTD dossier , with the company's commitment to pay the specified service consideration.

- The S-Part of the active ingredient will not be re-evaluated if evidence is provided that it was previously submitted and approved with the same version number to the same supplier in the following cases:
  - ✓ Optional pre-assessment of the quality file of the active pharmaceutical ingredient.
  - ✓ Optional listing of active ingredient for pharmaceutical products
  - ✓ Use of active ingredients included in the Egyptian Drug Authority's list of active ingredients for pharmaceutical products

  In all cases, the company is obligated to submit letter of access for the active ingredient file in the name of the applicant.

3. The company is committed to submit a request to the Evaluation unit of bioavailability and bioequivalence studies for human pharmaceuticals attached with proposed composition signed and stamped from company representative **or** composition on which the production is made and signed and stamped by the inspector of the Central Administration for Inspection of Pharmaceutical institutions in order to determine the status of the product in terms of the type of the study required, and Evaluation unit of bioavailability and bioequivalence studies for human pharmaceuticals will notify the company with the type of the study required.

- In the cases that require conducting a study of bioavailability, bioequivalence, or comparative dissolution in accordance with the issued letter from Evaluation unit of bioavailability and bioequivalence studies for human pharmaceuticals with the study required , samples shall be taken by the Central Administration for Inspection of Pharmaceutical Institutions 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 for Inspection of Pharmaceutical Institutions. These samples shall be sent to the bioavailability and bioequivalence centers that are licensed by the Egyptian Drug Authority.
- In case of registration of 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.

(B) For Imported Human Pharmaceutical Products

Regarding Imported human pharmaceutical products submitted for registration and imported from reference countries or from non- reference country and marketed in one of the reference countries

– The company is committed to submit the analysis file to the Central Administration for Drug Control including all documents and attachments required for the analysis file for the first incoming shipment after the issuance of the marketing authorization license. The first shipment will not be released until the analysis results are received from the Central Administration for Drug Control.

– The company may ,if it wishes ,submit the analysis file to the Central Administration for Drug Control , including the required documents and attachments, before the issuance of the final marketing authorization license .In this case, it may apply to the General Administration for Importation and

Customs Release to request the import of the necessary samples with the registration-request approval , in accordance with what is stated in the regulatory guide issued by the General Administration for Import and Customs Release affiliated with the Central Administration for Drug Policies and Market Access taking into account its continuous updates .

Regarding Imported human pharmaceutical products submitted for registration and imported from non- reference country & not marketed in any of the reference countries

The company is obligated to submit the analysis file to the Central Administration for Drug Control including all required documents and attachments, before the issuance of the marketing authorization license. The company is committed to applying to the General Administration of Import and Customs Release to import samples based on the registration request approval in accordance with the regulatory guide issued by the General Administration of Import and Customs Release at the Central Administration for Drug Policies and Market Access and its approved updates.

Chapter Two : Procedures for receiving the complete CTD registration Dossier and issuing the Marketing Authorization license

First: Submitting and evaluating the complete CTD registration Dossier

1. The company is committed to submit the complete CTD registration Dossier within the timelines in accordance with Appendix No. (4), including the required documents announced on the Authority's official website and related to the Administration of Regulatory Affairs for Human Pharmaceuticals at the General Administration of Human Pharmaceuticals Registration.
2. The Administration of Regulatory Affairs for Human Pharmaceuticals and its affiliated units shall conduct the initial screening of the Dossier within the timeframes in accordance with Appendix No. (8) and shall notify the company of the product's status, whether the Dossier is accepted or rejected.

**For imported products submitted under the Second Case: The Dossier may be received, including evidence of its submission to the Pricing and Pharmacovigilance administrations.

3. If the Dossier is initially accepted, the Administration of Regulatory Affairs for Human Pharmaceuticals and its affiliated units will distribute the complete Registration Dossier to the relevant administrations and units, in order to begin the technical evaluation procedures within the timelines in accordance with Appendix No. (8), and the company will be notified of the product's status after the technical evaluation process is completed.
   - ✓ **In the event that additional requirements are required /requested from the company,** the company will be notified of the requirements and will be obligated to submit within the timelines in accordance with Appendix No. (8) from the date of submitting the requirements. In the event that the total deadline for the required fulfillments is exceeded, the company is obligated to pay the service consideration for extending the deadline for fulfilling the requirements to the General Administration of Human Pharmaceuticals Registration. In the event that an additional deadline is granted, the fulfillments submitted within the timelines will be reviewed in accordance with Appendix No. (8).

- ✓ **If all requirements are fulfilled,** the company will be notified of the completion of the technical evaluation of the dossier, in preparation for the final review of the dossier and the preparation of the final report of the dossier by the Administration of Regulatory Affairs for Human Pharmaceuticals.

4. The final review of the dossier and the preparation of the final report for the dossier shall be carried out by the Administration of Regulatory Affairs for Human Pharmaceuticals and its affiliated units within the timelines in accordance with Appendix No. (8), and the company shall be notified of the dossier's status:
   - ✓ **In the event that additional requirements are required /requested from the company,** the company will be notified of the requirements and will be obligated to submit within the timelines in accordance with Appendix No. (8) from the date of sending the requirements. In the event that the total deadline for the required requirements is exceeded, the company will be obligated to pay the service consideration for extending the deadline for completing the requirements to the General Administration of Human Pharmaceuticals Registration. If an additional period is granted, the submitted fulfillments will be reviewed within the timelines in accordance with Appendix No. (8).
   - ✓ **If the final report for the Dossier is completed,** the company will be notified to submit the originals of the marketing authorization license attachments in preparation for presentation to the Technical Committee for Drug Control.

Second: Presentation to the technical committee and issuance of Marketing Authorization License

The Dossier shall be submitted to the Technical Committee for Drug Control within the timelines in accordance with Appendix No. (8). from the date of receiving the originals, and the company shall be notified of the Technical Committee's decision immediately upon its issuance.

In case of Technical Committee for Drug Control approval: A marketing authorization license for the product will be issued, provided the company complies with the requirements contained in the license. The Central Administration of Inspection on Pharmaceutical Institutions will monitor the implementation of these requirements

In case of rejection of the Technical Committee for Drug Control: The company may submit an appeal to the General Administration of Human Pharmaceuticals Registration against the final decision issued by the Technical Committee for Drug Control within (60) days from the date of issuing the decision, pursuant to a reasoned request submitted to the Technical Committee for Drug Control supported by the documents and information that the company wishes to rely on when considering the appeal and it is presented to the Technical Committee within (60) working days from the date of its submission.

Third: The necessary procedures after issuing the Marketing authorization license

1. The company is committed to the terms mentioned in **Article Twelve** of the decision of the Chairman of the Drug Authority.

2. For locally manufactured human products that have been produced pilot batched prior to the issuance of the marketing authorization license,
   - The company is obligated to conduct an analysis of the first three production batches at the Central Administration for Drug Control after the issuance of the final license, in accordance with the approved complete CTD registration dossier upon which the registration was based. The analysis is performed as follows:
     - ✓ The analysis of the first production batch is conducted by the Administration of Evaluation and approval in central Administration for Drug Control
     - ✓ The analysis of the second and third batches is conducted by the Administration of Post Approval Control at the Central Administration for Drug Control.

     No production batch may be released by the Central Administration of Inspection on Pharmaceutical Institutions until the conformity result has been received from the Central Administration for Drug Control.
   - The company is obligated to submit Process Validation study to the Central Administration of Inspectionon Pharmaceutical Institutions immediately after conducting it on the three production batches.

3. For imported products submitted according to the second case Track (A) or Track (B), and in the event that the pricing certificate is not issued before the end of the registration procedures, a marketing authorization license may be issued provided that the product is not marketed in the local market until the pricing certificate is issued. Provided that the company has completed the submission procedures to the pricing committee and the price of the product has been determined. The pricing certificate must be issued within a period not exceeding (1)month from the date of issuance of the product 's marketing authorization.

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 reasoned request for a 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 the Third Case Track (A), the product shall be granted an additional grace period of a maximum of (12) months. The grace period may be divided into (4) cycles, 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 of (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) cycles, each of them shall be (3) months depending on the company's 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, and if the company wants to convert the product, in accordance with the stipulated regulatory rules, where the differentials of the specified service consideration and the service consideration shall be paid for each phase as per the registration service consideration approved in accordance with this case. The provisions in accordance with Appendix No. (14) 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.

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, and if the company wants to convert the product, in accordance with the stipulated regulatory rules, where the differentials of the specified service consideration and the service consideration shall be paid for each phase as per the registration service consideration approved in accordance with this case. The provisions indicated in accordance to Appendix No. (15) 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.

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 or addition of the same concentration and dosage form with new indication differ in dose, supported by a scientific reference.
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 Inspection on Pharmaceutical Institutions:** 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 of 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 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									
			Sprinkle 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-	Solutions	Syrup	Oral drops	Elixirs	Drinking ampoules	Powders /oral (Solution)	Powders/ (Emulsion / Susp)	Emulsion	Suspension	Oral Gels	Oral Jelly

		Powder/ Granules for Reconstitution)	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 Preparation	Topical Cream		
			Topical gels/Emulgel		
			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) Reliance

Egyptian Drug Authority adopts Good Reliance Practises in the evaluation of safety, efficacy and quality data of human pharmaceutical products registered in stringent regulatory authorities (SRAs) included in the list of 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, based on registration or authorization by Stringent Regulatory Authority or WHO prequalification.	- Product that has been approved by at least two stringent regulatory authorities or one reference and WHO prequalification -Full Sameness of product (where EDA ensures that the product for local marketing is equal or similar to that approved by the stringent regulatory authority or WHO prequalified including CMC).	1. Valid Certificate of Pharmaceutical Product 2. Complete CTD dossier 3. Verification of Full 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 6. Good Manufacturing Practise Certificate (GMP)
Abridged (A limited assessment -assessing specific parts of the Common Technical Document (CTD) - of suitability of use under local 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)

Evaluation Route	Eligibility Criteria	Requirements
and regulatory requirements, while relying on prior assessment from Stringent regulatory authorities or WHO prequalification.		5. Proof of approval from least one stringent regulatory authority or WHO prequalification 6. Good Manufacturing Practise Certificate (GMP)

***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).

Appendix No. (4) Regulatory guides and procedures for registering Human Pharmaceutical Products according to different Cases

Table (1): Regulatory guides and procedures for registering human pharmaceutical products according to first and second cases

<table>
<tr><th colspan="5">First / Second Case</th></tr>
<tr><th>Type of Applicant</th><th>Licensed Human Pharmaceutical Factories</th><th>Human Pharmaceutical Factories Under Construction</th><th>Toll Manufacturing Companies</th><th>Scientific Offices & Company Authorized for importation</th></tr>
<tr><td rowspan="3">Number of registration requests available to be submitted per month</td><td colspan="2">2 registration requests for local marketing</td><td>1 Registration Request for local marketing</td><td rowspan="3">1 Registration Request for local marketing</td></tr>
<tr><td colspan="2">In the case of locally manufactured human pharmaceutical products intended for tender and export:
2 registration requests.
Companies are allowed to submit additional requests upon payment of service consideration for additional requests.</td><td>In the case of locally manufactured human pharmaceutical products intended for tender and export:
1 registration requests.
Companies are allowed to submit additional requests upon payment of service consideration for additional requests.</td></tr>
<tr><td colspan="3">In the case of locally manufactured human pharmaceutical products intended for export only:
not restricted by a monthly limit</td></tr>
<tr><td>Permission of additional requests</td><td colspan="4">1- For Line Extension: In the event that the company wants to submit a registration request for a Line Extension of a product, which was applied for 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 (10) 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.</td></tr>
<tr><td colspan="4">2- For Non-Routine Registration (B) : 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 the company wants 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</td></tr>
</table>

First / Second Case				
Type of Applicant	**Licensed Human Pharmaceutical Factories**	**Human Pharmaceutical Factories Under Construction**	**Toll Manufacturing Companies**	**Scientific Offices & Company Authorized for importation**
Total Number of Products Allowed to be Registered	Not restricted	Total of (20) Local Products Total of (20) F-Toll Products	Total of (20) Active Ingredients	Not restricted
Submission of Full Registration Dossier	**First Case**: • For locally manufactured human pharmaceutical products: Submission within a maximum of (33) months from the date of issuance of the first pricing approval or from the date of approval by the General Administration of Pharmacovigilance, whichever is later. • For locally manufactured products intended for tender and export: Submission within (33) months from the date of approval by the General Administration of Pharmacovigilance. • For locally manufactured products intended for export only: Submission within (33) months from either the registration request approval date or the date of approval by the Scientific Committee. • For imported human pharmaceutical products: Submission within a maximum of (6) months from the date of the first pricing approval or from the date of approval by the General Administration of Pharmacovigilance, whichever is later.		**Second Case**: • Track (A): Submission within (30) working days from the naming approval. • Track (B): Submission within (30) working days from the naming approval. • Track (C) I: Submission within (2) months from the naming approval. • Track (C) II: Submission within (2) months from the naming approval. • Track (C) III: Submission within (33) months from the date of issuance of the first pricing approval or from the date of approval by the General Administration of Pharmacovigilance, whichever is later.	
Production and Marketing	Production / Importation and marketing shall take place within (18) months from the issue date of final marketing authorization license.			

Table (2): Regulatory guides and procedures for registering human pharmaceutical products according to the third case & its tracks:

Third Case						
	Track (A)		Track (B)	Track (C)	Track (D)	Track (E)
Type of Applicant	Scientific Offices & Company Authorized for importation	- Licensed Human Pharmaceutical Factories - Human Pharmaceutical Factories Under Construction - Toll Manufacturing Companies -Scientific offices	- Licensed Human Pharmaceutical Factories - Human Pharmaceutical Factories Under Construction - Toll Manufacturing Companies	Licensed Human Pharmaceutical Factories as of August 10, 2023	Human Pharmaceutical Factories Under Construction as of August 10, 2025	- Licensed Human Pharmaceutical Factories - Human Pharmaceutical Factories Under Construction - Toll Manufacturing Companies
Number of registration requests available to be submitted per month	(4) Registration requests	(4) Registration requests for Local Factories and Factories under construction (2) registration requests for Toll companies	(2) Registration requests for Local Factories and Factories under construction (1) registration request for Toll companies	(1) registration request. in the event that the company wants 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	(1) registration request in the event that the company wants 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	(1) registration request in the event that the company wants 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

Third Case						
	Track (A)		Track (B)	Track (C)	Track (D)	Track (E)
				be submitted per month.		
Line Extension	For Line Extension: In the event that the company wants to submit a registration request for a Line Extension of a product, which was applied for 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 (10) 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.					
Total Number of Products Allowed to be Registered	The number of submitted products must not exceed (2) per active ingredient, concentration, and dosage form mentioned in the shortage lists	Not restricted	Not restricted	(20) 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.	(20) 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.	(2) product registration requests per year
Submission of Full Registration Dossier	For locally manufactured human pharmaceutical products: submission must occur within a maximum of (21) months from the date of the first pricing approval or the date of approval from the General Administration of Pharmacovigilance, whichever is later. For imported human pharmaceutical products: submission must occur within a maximum of (6) months from the date of	The company must apply to the Administration of Human Pharmaceuticals Regulatory Affairs within a maximum of (33) months from the date of issuing the first pricing approval or the date of approval by the General Administration of Pharmacovigilance, whichever is later.				

Third Case					
	Track (A)	**Track (B)**	**Track (C)**	**Track (D)**	**Track (E)**
	the first pricing approval or from the date of approval from the General Administration of Pharmacovigilance, whichever is later. Note: If the above deadlines are exceeded, an additional grace period of (3) months is granted to submit the Full Registration Dossier only for products that have already undergone experimental/ production batches.				
Production and Marketing	For locally manufactured human pharmaceutical products: production and Marketing must occur within (6) months from the issue date of final marketing authorization license. For imported human pharmaceutical products: importation must occur within (3) months from the issue date of final marketing authorization license.	Production and Marketing must occur within (1) year from the issue date of final marketing authorization license.		Production and Marketing must occur within (2) years from the issue date of final marketing authorization license.	Production must occur within (9) months, and export must occur within (30) months from the issue date of final marketing authorization license.

Appendix No. (5) 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 Egyptian Drug Authority to support the availability of some important products and with reference to approving the emergency use authorization by EDA Chairman on April 16th and May 14th, 2020, 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 the 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 registration request approval 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 approval to follow up the rest of the procedures.
4. It is permitted to produce a production batch on the responsibility of the License Holder. The production process shall be carried out in the presence of an inspector to follow up the critical production steps as submitted by the company 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 in conducting 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. The analysis 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 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 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.

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

Procedures	Central Administration	The relevant division concerned with reviewing, evaluation and follow-up
Submitting a registration request	Central Administration of Pharmaceutical Products	Evaluation Unit of Registration Request for Human Pharmaceuticals General Administration of Human Pharmaceuticals Registration
Approving the trade name	Central Administration of Pharmaceutical Products	Evaluation unit of Trade Names and mockup of Human pharmaceuticals General Administration of Human Pharmaceuticals Registration
Pricing certificate	Central Administration of Drug Policies and Market Access	Pricing Policies and Pharmacoeconomics
Submitting a pharmacovigilance file	Central Administration for pharmaceutical care	General Administration for pharmaceutical vigilance
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"	Central Administration of Pharmaceutical Products	Unit of Evaluation Human Product Specifications Administration of Technical Affairs for Human Pharmaceuticals General Administration of Human Pharmaceuticals Registration
Approving the product leaflet according to the reference product	Central Administration for pharmaceutical care	General Administration of Pharmaceutical References and Inserts

"After approving the composition and specifications"		
Approving the outer and inner packaging of the product **"After approving the composition and specifications"**	Central Administration of Pharmaceutical Products	Evaluation unit of Trade Names and mockup of Human pharmaceuticals General Administration of Human Pharmaceuticals Registration
Follow up the full steps of manufacturing the production batch of the product and the initiation of the required studies	Central Administration of pharmaceutical institutions	General Administration of Factories Inspection
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	Central Administration for Drug Control
Approving storage conditions and initial shelf life	Central Administration of Pharmaceutical Products	General Administration for stability
Conduct a study of the Comparative Invitro dissolution compared to the reference product "Innovator Product"	Central Administration for Drug Control	Central Administration for Drug Control
Evaluating and approving the Comparative Invitro dissolution and bioequivalence study	Central Administration of Pharmaceutical Products	The Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals General Administration of Human Pharmaceuticals Registration
Submitting the registration dossier to get an Emergency Use Authorization License for Human pharmaceutical Product	Central Administration of Pharmaceutical Products	Administration of Regulatory Affairs for Human Pharmaceuticals General Administration of Human Pharmaceuticals Registration

Appendix No. (6): Products that undergo to Non-Routine Registration – (B)

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:

1. **Vitamins, minerals, amino acids, distilled water and water for injection where the product does not contain any other active ingredients.**
2. **Solutions, including: (glucose with its concentrations - saline with its concentrations - glucose saline with its concentrations - Ringer - Ringer lactate - Ringer acetate - Mannitol with its concentrations).**
3. **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.**
4. **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.**
5. **Synthetic Peptides Human Pharmaceutical Products that refer to a Reference Peptide Product of rDNA Origin**

Appendix No. (7) The required documents for a registration request of human products

Table (1): Required Documents for Registration Request of Locally Manufactured Human Pharmaceutical Products, Locally Manufactured Under License from a Foreign Company, and Imported Products for Local Marketing

Items	خطوات التقديم	Soft copy	Hard copy	Original to review
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.	يجب على الشركة التقدم لإدارة النظم والمعلومات الدوائية لانشاء حساب خاص بالشركة حتى تتمكن من التقدم بطلبات التسجيل على برنامج الميكنة.	√		
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 "	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".	√		
Link of the approved scientific Reference and copy of the leaflet (if found)	رابط المرجع العلمي المعتمد و صوره منه.(ان وجد)	√		
Submit paid Receipt of the registration request service	إرفاق إيصال الدفع لمقابل خدمة طلب التسجيل	√		

Items	خطوات التقديم	Soft copy	Hard copy	Original to review
In case of imported products / Under license				
Valid & legalized CPP for the product OR Valid Electronic Certificate of Pharmaceutical Product (eCPP)	شهادة تداول مستحضر صيدلي CPP (سارية وموثقة) للمستحضر أو شهادة الكترونية لتداول مستحضر صيدلي سارية للمستحضر	√	√	√
Valid GMP for the manufacturing site (will be requested later on after reviewing the request to be fulfilled before the due date specified)	شهادة GMP سارية للمصنع (سيتم طلبها بعد دراسة طلب التسجيل ويجب استيفائها في المعاد المحدد)	√	√	√
Valid & legalized Agency agreement or 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)	عقد وكالة أو خطاب تفويض من الشركة الأجنبية الى الشركة المستوردة بالموافقة على تسجيل المستحضر (في حالة المستحضرات المستوردة والمصنعة بالخارج أو معبأة بمصر) (ساري و موثق) (سيتم طلبها بعد دراسة طلب التسجيل ويجب استيفائها في المعاد المحدد)	√	√	√
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)	عقد التصنيع مع الشركة الأجنبية (في حالة المستحضرات المصنعة محلياً بترخيص من شركة أجنبية) (ساري و موثق) (سيتم طلبها بعد دراسة طلب التسجيل ويجب استيفائها في المعاد المحدد)	√	√	√
Legalized Innovator letter (in case of Innovator) (will be requested later on after reviewing the request to be fulfilled before the due date specified)	خطاب من الشركة صاحبة المستحضر يفيد أن المستحضر المقدم هو المستحضر الأصيل (موثق) (سيتم طلبها بعد دراسة طلب التسجيل ويجب استيفائها في المعاد المحدد)	√	√	√
List of countries in which the product 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)	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 استيفائها في المعاد المحدد)	√		

Items	خطوات التقديم	Soft copy	Hard copy	Original to review
In case of Line Extension				
Documents showing that the company's product is still valid: **In case of Under Registration products:** **Naming Approval or Submission** **Pricing Approval or Submission** **Pharmacovigilance Approval or Submission (if found)** **In case of Registered products:** ▪ **Valid final marketing authorization license/ valid re-registration license / valid preliminary approval.**	مايفيد أن المستحضر الخاص بالشركة مازال سارياً في إجراءات التسجيل: في حالة المستحضرات تحت التسجيل السارية في إجراءات التسجيل موافقة الإسم التجاري للمستحضر أو مايفيد التقدم في المهلة المحددة موافقة التسعيرة للمستحضر أو مايفيد التقدم في المهلة المحددة موافقة اليقظة للمستحضر أو مايفيد التقدم في المهلة المحددة(ان وجد). في حالة المستحضرات المسجلة إخطار تسجيل مبدئي أو نهائي/ اخطار اعادة تسجيل ساري /موافقة سير في إجراءات اعادة تسجيل سارية 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.	√		
In case the company requests the fast-track registration pathway				
A cover letter specifying the case and confirming that the submitted product is to follow the fast-track registration process must be provided.				

Table (2): Required Documents for Registration Request of Locally Manufactured Human Pharmaceutical Products for Tender and Export or Export only

Items	الأوراق المطلوبة	Soft Copy	Hard copy	Original to review
Registration request form stamped by company stamp (according to the form attached in the submission link)	نموذج طلب التسجيل طبقاً للاليات الخاصة بالإدارة العامة لتسجيل المستحضرات البشرية المعلنة علي موقع هيئة الدواء المصرية ويراعى أن يكون على ورق الشركة ومختوما بختم الشركة	√		
Submit paid Receipt of registration request service	ارفاق ايصال الدفع لمقابل خدمة طلب التسجيل	√		
Link of the approved scientific Reference and copy of the leaflet (if found)	رابط المرجع العلمي المعتمد و صوره منه. (ان وجد)	√		
In case the company requests the fast-track registration pathway				
A cover letter specifying the case and confirming that the submitted product is to follow the fast-track registration process must be provided.				

Appendix No. (8) Time frames for Reviewing and Evaluation

Table (1): Time Frame for Registration Request Evaluation for Human Pharmaceutical Products

Time frame for evaluating registration request	Case 1	Case 2					Case 3
		Track (A)	Track (B)	Track (C) / I	Track (C) / II	Track (C) / III	
Initial Screening for registration request	Within (3) working days from the date of receiving the fulfilled request in accordance with the regulating rules						
Evaluation and Notifying the company with 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	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	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				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
Release registration request approval	Within (10) working days from acceptance of the fulfilled required documents /from the date of receiving Technical Committee decision	Within (2) working days from receiving the fulfilled required documents	Within (3) working days from receiving the fulfilled required documents	Within (5) working days from the date of receiving Technical Committee decision with exception of product from marketing reference countries	Within (3) working days from acceptance the fulfilled required documents		Within (10) working days from acceptance of the fulfilled required documents/ from the date of receiving Technical Committee decision

Table (2): Time Frame for getting approval for names and layouts, pricing and pharmacovigilance

Administration		Case					
		Case 1 / 3	Case 2				
		Locally manufactured products	Imported products	Track (A)	Track (B)	Track (C) II / I	Track (C) III
Naming and layout	Submission within:	(30) working days from the date of releasing registration request approval or from the date of releasing Scientific approval committees	(15) working days from the date of releasing registration request approval or from the date of releasing approval Scientific committees				
	Evaluation within:	(15) working days from the date of receiving list of names from the company	(2) working days from the date of receiving list of names from the company		(4) working days from the date of receiving list of names from the company	(5) working days from the date of receiving list of names from the company	(10) working days from the date of receiving list of names from the company
	Incase of rejection, submit new list within (20) working days from the issue date of the rejection letter. A maximum of (4) lists are allowed to be submitted including the first list		Incase of rejection, submit new list within (15) working days from the issue date of the rejection letter. A maximum of (4) lists are allowed to be submitted including the first list				
Pricing	Submission within:	(30) working days from the date of releasing registration request approval or from the date of releasing Scientific approval committees	(15) working days from the date of releasing registration request approval				
	Presentation to pricing committee & price approval within:	(90) working days from the date of receiving complete pricing file	(30) working days from the date of receiving complete pricing file				
Pharmacovigilance	Submission within:	(30) working days from the date of releasing registration request approval or from the date of releasing Scientific approval committees	(15) working days from the date of releasing registration request approval or from the date of releasing approval Scientific committees				

	Evaluation within:	(60) working days from the date of receiving the fulfilled pharmacovigilance documents	(5) working days from the date of receiving the fulfilled pharmacovigilance documents	(10) working days from the date of receiving the fulfilled pharmacovigilance documents	(15) working days from the date of receiving the fulfilled pharmacovigilance documents
	Submission of the supplementary documents within:	(30) working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance	(60) working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance	(60) working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance	(60) working days (this period may be renewed once, when necessary, based on the evaluation of the Administration of Pharmaceutical vigilance
	Evaluation of the supplementary documents within:	(30) working days from the date of receiving the supplementary documents	(5) working days from the date of receiving the supplementary documents	(10) working days from the date of receiving the supplementary documents	(15) working days from the date of receiving the supplementary documents
Note: in case exceeding grace period required of submission for trade name lists or pricing or PV, Company can appeal for extending grease period with rational in this issue for relevant Central Administration within 60 days from expiration of these timeline, and in case of approval, company has not exceeding 30 days from issuing date of approval after paying service consideration for each grease period.					

Table (3): Time frames for reviewing and evaluating locally manufactured products:

Serial	Screening steps of dossier	First & Third case (Normal track)	Second case (Fast Track)
1	**Screening** [1]	(30) working days	(15) working days
2	**Distribution and Technical Evaluation** [2]	Technical Evaluation and sending letter of comments (60) working days Review of 1st Supplementary Documents (20) working days Review of 2nd Supplementary Documents (20) working days Review of 3rd Supplementary Documents (20) working days	Technical Evaluation and sending letter of comments (40) working days Review of 1st Supplementary Documents (10) working days Review of 2nd Supplementary Documents (10) working days Review of 3rd Supplementary Documents (10) working days
3	**Review and Final report preparation for presentation to the Technical Committee**	Technical Evaluation and sending letter of comments (15) working days Review of 1st Supplementary Documents (10) working days Review of 2nd Supplementary Documents (10) working days	Technical Evaluation and sending letter of comments (10) working days Review of 1st Supplementary Documents (5) working days Review of 2nd Supplementary Documents (5) working days
4	**Presentation to Technical Committee and MA License release**	(25) working days	(20) working days

[1] **Screening:** An initial review of the registration dossier is conducted by Administration of Regulatory Affairs for Human Pharmaceuticals to ensure the presence of all required technical studies and approvals, ensuring completeness before proceeding with the technical evaluation.

[2] **Technical Evaluation:** A detailed technical review is being conducted by the relevant administrations and units.

Table (4): Time frames for reviewing and evaluating imported products

	Procedure/Time Frame for Dossiers submitted according to	First & Third case (Normal Track)		Second case (Fast Track)			
		Imported from Reference Country or imported from non-reference country & marketed in reference country	Imported from Non- Reference Country and Not marketed in Reference Country	Track A	Track B	Track C Imported from Reference Country or imported from non-reference country & marketed in reference country	Track C Imported from non-reference country & not marketed in reference country
1	**Screening**	(20) WDs	(30) WDs	(3) WDs	(6) WDs	(9) WDs	(15) WDs
2	**Distribution and Technical Evaluation**	1st Evaluation and sending letter of comments. = (25) WDs Review of 1st Suppl. Doc. = (10) WDs Review of 2nd Suppl. Doc. = (10) WDs Review of 3rd Suppl. Doc. = (10) WDs	1st Evaluation and sending letter of comments. = (60) WDs Review of 1st Suppl. Doc. = (20) WDs Review of 2nd Suppl. Doc. = (20) WDs Review of 3rd Suppl. Doc. = (20) WDs	1st Evaluation and sending letter of comments. = (7) WDs Review of 1st Suppl. Doc. = (3) WDs Review of 2nd Suppl. Doc. = (3) WDs Review of 3rd Suppl. Doc. = (2) WDs	1st Evaluation and sending letter of comments. = (14) WDs Review of 1st Suppl. Doc. = (6) WDs Review of 2nd Suppl. Doc. = (6) WDs Review of 3rd Suppl. Doc. = (4) WDs	1st Evaluation and sending letter of comments. = (20) WDs Review of 1st Suppl. Doc. = (8) WDs Review of 2nd Suppl. Doc. = (8) WDs Review of 3rd Suppl. Doc. = (5) WDs	1st Evaluation and sending letter of comments. = (40) WDs Review of 1st Suppl. Doc. = (10) WDs Review of 2nd Suppl. Doc. = (10) WDs Review of 3rd Suppl. Doc. = (10) WDs
3	**Review and Final report preparation for presentation to the Technical Committee**	Technical Evaluation and sending letter of comments = (15) WDs Review of 1st Suppl. Doc = (10) WDs Review of 2nd Suppl. Doc = (10) WDs	Technical Evaluation and sending letter of comments = (15) WDs Review of 1st Suppl. Doc= (10) WDs Review of 2nd Suppl. Doc= (10) WDs	(7) WDs	(14) WDs	(25) WDs	1st Evaluation and sending letter of comments. = (10) WDs Review of 1st Suppl. Doc. = (5) WDs Review of 2nd Suppl. Doc. = (5) WDs
4	**Presentation to Technical Committee and MA License release**	(30) WDs	(25) WDs				(20) WDs

Table (5): Time frames of company required supplementary:

	Administration	First & Third case (Normal Track)	Second case (Fast Track)
1	**All administrations and units concerned with technical evaluation**	The company is committed to submitting the completions within (90) days from the date of sending the supplementary, may be divided into (3) cycles	The company is committed to submitting the completions within (90) days from the date of sending the supplementary, divided into (3) cycles
2	**Administration of Regulatory affairs of human pharmaceuticals**	The company is committed to submitting the completions within (60) days from the date of sending the supplementary, divided into (2) cycles	

Appendix No. (9) 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, 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 (factory & public price).

Appendix No. (10) The regulatory guide of the General Administration of Pharmaceutical vigilance regarding EDA Chairman Decree No. (450) of 2023 on unifying the regulating rules and procedures of registration of Human Pharmaceutical Products.

The company shall be committed to submitting 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 submitting the pharmacovigilance file to General Administration of Pharmaceutical vigilance within (30) working days from the date of registration request approval or from the date of 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, either a letter of approval of the submitted files or a letter for fulfilling the required documents. In the latter 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 documents required.

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 scientific committee approval. 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 Scientific Committee approval.

For the Second Case

The company shall be committed to submitting 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 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 Dossier

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 or a copy of the latest evaluation letter for the Pharmacovigilance System description document previously submitted by the General Administration of Pharmacovigilance, provided that the period is still valid, or submit a copy of the email proving that an updated copy has been submitted under evaluation to the administration.

In the case of registration, the imported products / locally manufactured products under license from a foreign entity (Under-License Products):

- (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. Or a copy of the latest evaluation letter for the Pharmacovigilance System description document previously submitted by the General Administration of Pharmacovigilance, provided that the period is still valid, or submit a copy of the email proving that an updated copy has been submitted under evaluation to the administration.
- Pharmacovigilance Sub-System System File (PSSF) of the company or local agent in Egypt along with its summary. Or a copy of the latest evaluation letter for the Pharmacovigilance System description document previously submitted by the General Administration of Pharmacovigilance, provided that the period is still valid, or submit a copy of the email proving that an updated copy has been submitted under evaluation to the administration.
- 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 submission 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.

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 submit an appeal to the Central Administration for Pharmaceutical Care / the General Administration of Pharmaceutical vigilance to request acceptance of the product file after the expiry of the grace period specified for the file submission, 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 date of issuance of the approval after paying the determined service consideration 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.

Note: A statement from the Central Administration of Pharmaceutical Products to approve the progression of the registration 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 submission of the Pharmaceutical Vigilance System (PV system), using the published link on the Egyptian Drug Authority web site.

- The company shall be committed to fulfilling the pharmacovigilance system permanently and not to breaching any of the pharmacovigilance requirements after registration according to the principles of Good Practice of Pharmacovigilance and the organizing rules and regulations.
- 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 Inspection on Pharmaceutical Institutions shall be addressed to take the necessary measures regarding the registered products.

Appendix No. (11) The regulatory guide of General Administration of Factories inspection – Central Administration of Inspection on Pharmaceutical Institutions

First: Procedure for submitting a request to attend the manufacturing of pilot/production batches of pharmaceutical products

- The licence holder shall submit a request on the approved template to the General Administration of Factories Inspection to attend the manufacturing process of the three pilot/production batches and shall apply to pay for the service consideration. The request shall be uploaded on the electronic link designated for receiving the requests of the pilot batches.
- The approval shall be issued after paying the service consideration and completing the required documents stipulated in the registration requestform and it shall be sent to the company via the official e-mail within (3) working days, provided that the production shall take place within 3 working days 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 Normal Track, the company shall be allowed to manufacture the pilot/production batches after (10) days from the date of fulfilling the request submitted by the company to get the approval of the manufacturing request.
- In the case of Fast Track, the company shall be allowed to manufacture the pilot/production batches within (3) days from the date of fulfilling the request submitted by the company for getting the approval of the manufacturing request.
- The pilot/production batches shall be produced in the presence of the inspector(s) of the Central Administration of Inspection on Pharmaceutical Institutions for following up the batches record and approving the composition on which the manufacturing was carried out.
- The inspector shall approve 2 original copies of the composition (an original copy shall be attached to the inspector's report and another original copy shall be delivered to the company).
- The required studies shall be conducted on the pilot/production batches produced in compliance with the registration protocols, while adhering to the good manufacturing practice for the pilot/production batches. Additionally, the company must provide a commitment that the pilot batches will not be marketed.

Second: The travelling procedure to inspect manufacturers overseas regarding 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 to inspect the manufacturer and re-inspection is conducted in accordance with the Risk-based Inspection Plan issued by the General Administration for Factories Inspection in accordance with EDA Chairman Decree No. (157) of 2021 and No. (150) of 2022. The letter of request shall include the following:

1. A letter containing the proposed travelling 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 service 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 manufacturer within (45) days.
4. The manufacturer shall be committed to sending the Corrective and Preventative Actions (CAPA) within (30) days.
5. The report shall be presented to the relevant committees to decide whether to approve the manufacturer or not.

Appendix No. (12) The regulatory guide for the analysis files at the Central Administration of Drug Control

Executive procedures for regulating the registration procedures of the pharmaceutical products in accordance with the consolidated legal provision:

- The company submits a request to submit the analysis file at the link designated for that in order to specify the required service consideration for analysis
- The company must upload receipt of the analysis service consideration at the link designated in order to know the analysis requirements in accordance with the approved specifications and methods of analysis mentioned in the approved registration dossier, which has been registered by the Central Administration of Pharmaceutical Products.
- The approved number of samples for each pharmaceutical dosage form is adhered to in accordance with the regulating rules followed by the Central Administration for Drug Control.
- The Central Administration for Drug Control has the right to request requirements for analysis that are not present in the laboratories during the analysis of the product file if needed. The Central Administration for Drug Control also has the right to request additional samples if needed.
- The company is committed to submitting a request to reserve an appointment to deliver the samples and their attached documents and analysis requirements on the link designated for that within a period not exceeding (3) months from the mail sent to the company with the analysis requirements.
- If the company delayed for (3) months to submit the file with samples for analysis after the Central Administration for Drug Control responds with the necessary requirements for analysis, 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 delivery of the samples to the Central Administration for Drug Control if the analysis request was submitted according to Normal Track.
- The analysis shall be carried out within (30) working days from the date of delivering the samples to the Central Administration for Drug Control if the analysis request is submitted according to Fast Track.

- If a letter is issued to the company during the analysis, the company is obligated to respond to it within a period not exceeding (3) months.
- If the company delayed in responding to the letter for more than (3) 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 along with the composition on which the analysis was carried out.

Appendix No. (13) 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 dossier. This step shall follow the approval of Module 3 according to the requirements of each case as previously mentioned in this regulatory guide 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 products under registration

- A receipt (according to 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) in word document.

** 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 composition submitted by the company on its responsibility.

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 country of origin 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 in the country of origin. The leaflet shall be translated into Arabic as a patient information leaflet.

The Summary of Product Characteristics leaflet (SMPc) shall be submitted to be uploaded on Egyptian Drug Authority 's website.

In case of using a reference in a language other than English language: The company shall submit authorized letter from the company of origin & stamped from Egyptian embassy including company commitment for translation on its responsibility with attached the original & the translated copy

In the case of non-reference products:

- The cover letter shall state that the product is not a reference 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 proposed 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 (3) months prior to any deadlines.
- It shall be allowed to send the required amendments / corrections to the leaflets within (1) month for the local products from the date of sending the required amendments by Administration of Inserts and (3) months for the imported and licensed products from the date of sending the required amendments by 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 ingredients of the product presented in the relevant clause.

Appendix No. (14) 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 registration request approval:

1. The applicant shall send a request to 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 Chief Executive Officer 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 change the case on which the registration request was 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 requirements by the company, the registration request approval 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 registration request approval:

1. Submitting a request to convert the registration of the product according to the Second Case:

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

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

2. **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 in accordance with the first Case and the service consideration/service consideration that have been paid shall be reviewed.

3. **Issuance of the conversion approval:**

In the event of fulfilling the requirements 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.

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 service consideration / service consideration according to the regulatory guide of Second Case.

Attachment No. (15): Mechanisms for Converting the Registration System of Human Pharmaceutical Products Registered or Under Registration for Export Only, or for Export and Tenders, to Local Market Distribution in accordance with Case (3).

	Stage	Requirements for Registered products	Requirements for under registered products
	Registration request	• Submission of a registration request for the product in accordance with **Case (3)** and its corresponding implementation procedure. The approval of the registration requests shall be **conditional upon the cancellation** of the product previously registered for *export only* or for *export and tenders* once the registration MA is issued for the product submitted under **Case (3)**. The product status shall then be updated in the human drug database. • It is required that the Marketing Authorization license of the product be **valid**—whether it is a **preliminary**, **final**, or **renewal** marketing Authorization license — at the time of submitting the new registration request. **Note:** Products registered for **export** or for **export and tenders** are permitted to continue circulation **in accordance with their registration type** until the completion of the registration procedures for the product submitted under **Case (3)** and the issuance of its new MA license	• Submission of a registration request for the product in accordance with **Case (3)** and its respective implementation procedure. The approval of the registration request shall be conditioned by the cancellation of the previous MA for export *only* or *export and tenders* once the registration MA is issued for the product submitted under **Case (3)**. The product status shall then be updated in the **human drug database**. • The **marketing authorization** must be **valid** at the time of submitting the new registration request. **Note:** The **marketing authorization** for registration procedures under *export only* or *export and tenders* shall be **cancelled immediately upon obtaining the registration request approval** for the locally marketed product.

	Scientific committee	In the absence of an available scientific reference, scientific dossiers shall be submitted to the scientific committees for evaluation within the prescribed timelines, and the decisions issued by these committees shall be considered final and enforceable.
	Naming	Registration request for obtaining a trade name shall be submitted **within the specified timeframes**, and it is permitted to **use the same trade name previously issued for the product registered for export and tenders only**.
	Pricing	Submission shall be made to the (**General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration)** for pricing purposes, **within the specified timeframes (30) working days from scientific committee approval**.
	Pharmacovigilance	Submission shall be made to the **General Administration of Pharmacovigilance** at the **Central Administration for Pharmaceutical Care** to fulfill the **pharmacovigilance requirements** within the specified timeframes. The submitted file must be **updated according to the most recent information available at the time of submission**. Previously submitted documents **shall not be considered**, and **any prior approvals issued for the export and tender product shall not be valid**.
	Technical studies	The company shall comply with conducting the **technical studies** and obtaining their **approval from the relevant administrations**, as stipulated in the above-mentioned regulatory guidelines. Technical studies conducted **prior to the conversion** may be utilized, **provided that they comply with the requirements** of the ministerial decree and the regulatory guideline.
	Leaflet	Registration request for **updating the package insert** shall be submitted **within the specified timeframes**.
	Internal & external mockups	Registration request for the **approval of new outer and inner package labels** shall be submitted **within the specified timeframes**.
	Final registration Dossier	The **registration Dossier**, containing the aforementioned documents, shall be submitted **within the specified timeframes** to the regulatory affairs administration of human pharmaceuticals.

References

1- Annex 6 (Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products) WHO Technical Report Series, No. 1019, 2019
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs1019-annex6.pdf?sfvrsn=f839be63_2&download=true

2- Annex 10 (Stability testing of active pharmaceutical ingredients and finished pharmaceutical products). WHO Technical Report Series, No. 1010, 2018
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs1010-annex10-who-stability-testing-of-active-pharmaceutical-ingredients.pdf?sfvrsn=7cb7a4c9_4&download=true

3- Guideline on process validation for finished products - information and data to be provided in regulatory submissions. (21 November 2016)
https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-process-validation-finished-products-information-and-data-be-provided-regulatory-submissions-revision-1_en.pdf

4- CADC guidelines (Guidelines for File Assessment for Pharmaceutical Products for Human Use).(version 2)
https://www.edaegypt.gov.eg/media/zpidyytc/guidelines-for-file-assessment-for-human-pharmaceutical-product.pdf

Document History

Version	Issue Date	Reasons
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 dossier 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 registration request 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 the issuance of the marketing authorization license.
Version No. (3)	March 31, 2024	▪ Clarifying the criteria of full sameness. ▪ Clarifying the criteria for selection of batches.
Version No. (4)	December 25, 2024	▪ Amending and clarifying the steps for evaluating and submitting registration dossiers for locally manufactured products in all relevant divisions. ▪ Clarifying the time frames for evaluation and the time frames for fulfilling the completions and adding appendix (13) and (14). ▪ Amending Appendix No. (8) regarding the regulatory mechanism for analysis files in the Central Administration for Drug Control.
Version No. (5)	November 1,2025	▪ Update and clarification of the registration procedures for locally manufactured human pharmaceutical products under registration, in accordance with all ministerial decrees and

		pursuant to the directive of the Chairman of the Egyptian Drug Authority dated August 13, 2025, which stipulates the implementation of the **"One Submission" complete registration Dossier system** for locally manufactured human pharmaceutical products under registration starting from **November 1, 2025**, to align them with the registration procedures applied to imported human pharmaceutical products. Accordingly, the appendices and timelines have been updated.