The Regulatory Guideline for the Implementation of the Egyptian Drug Authority Chairman's Decree No. 388/2023 for the Registration of Innovative Products

Year 2026

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1- Introduction

The objective of issuing this regulatory guideline is to define the procedures and mechanisms for registering innovative products within the Arab Republic of Egypt, in light of the Egyptian Drug Authority (EDA) Chairman's Decree No. 388 for the year 2023.

2- Scope

This guideline applies to human pharmaceutical or biological innovative products that have not been previously registered in the Arab Republic of Egypt or abroad and for which registration is applied with the purpose of adding a new therapeutic benefit, provided that at least one manufacturing step - other than primary and secondary packaging - is performed on them in a manufacturing site within the Arab Republic of Egypt and that they are submitted for registration to the Egyptian Drug Authority (EDA) by a company registered in the Egyptian Drug Authority 's company profile database.

This guideline applies to medical products that may contain a new active substance, a new formulation with a different mechanism of action, or a novel modification, which include:

- Breakthrough innovation
- Incremental innovation

* 388/2023 decree does not apply to the registration of herbal medicinal products, dietary supplements with a therapeutic claim, or medical devices.

* In case the company wishes to obtain a patent for the invention, it shall first approach the Egyptian Intellectual Property Authority before submitting the inquiry request to the Egyptian Drug Authority (EDA). The Egyptian Intellectual

Property Authority bears the responsibility of granting or not granting a patent for the invention, based on the laws and regulations governing the protection of intellectual property rights, without any impact on the decision of the Egyptian Drug Authority (EDA) on whether to register the innovative product.

3- Abbreviations

3.1 EDA: Egyptian Drug Authority.
3.2 CTD: Common Technical Document
3.3 CMC: Chemistry, Manufacturing, and Controls.
3.4 CQAs: Critical Quality Attributes.

4- Definitions

Innovative Products: Locally manufactured medical or biological products that have not been previously registered in the Arab Republic of Egypt or abroad and which are submitted for registration with the purpose of adding a new therapeutic benefit and may include the following:

- A new substance, either alone or in combination.
- A novel modification performed on already registered products.

Therapeutic Benefit: The therapeutic or prophylactic value added by the innovative product such as the product addressing an unmet medical need, providing a new therapeutic option, being a more effective or safer product, helping to improve patient compliance with the treatment, or any other therapeutic benefit.

The Multidisciplinary Assessment Team: A team consisting of representatives from the relevant administrations based on the type of the product and the submitted application for assessment, which may include (the General Administration of Innovative Products, the General Administration of Clinical Trials, the Central Administration

of Inspection on Pharmaceutical Institutions, the Central Administration for Pharmaceutical Care, the concerned laboratories in the Central Administration of Drug Control or in the Central Administration for Biological and Innovative Products and Clinical Studies.

5- Registration Steps

1. Inquiry Request

1.1. The applicant company submits an inquiry request regarding the innovative product using the inquiry request form accompanied by the documents specified in the form to the Inquiry Requests Unit in the Innovative Products Registration Administration, via the designated email, noting that a maximum of 1 inquiry request per Toll company will be received monthly.

1.2. The Inquiry Requests Unit shall review the inquiry request within (30 working days) from the date of receipt of the complete request from the company, and the company is committed to fulfilling any requirements within (10 working days, renewable once) from the date of being notified thereof; otherwise, the inquiry request shall be considered cancelled.

1.3. The product shall be presented to the Technical Committee, when necessary, such as in case that there is a Technical Committee's decision contradicting the innovative concept of the product or in case there is a need to evaluate the concept of the product itself and whether to proceed with its registration procedures or not.

1.4. The company shall be notified of the status of the submitted request in terms of approval or rejection within (30 working days) from the date of receiving the complete request or 7 working days from the date of receiving the Technical Committee's decision.

1.5. One request shall be received per innovative concept, and in case the same concept is submitted by more than one company, subsequent requests shall

be added to a waiting list according to the order of requests. In case that the first company fails to complete the product registration procedures within the specified timeframes, the process shall move to the next company. If the registration of the product for the first company is finalized, the rest of the companies on the waiting list shall be notified of the list's cancellation.

1.6. The importation and sealed medical customs release of raw materials and packaging materials used in the manufacturing of innovative products is permitted pursuant to the approval of the inquiry request, provided that the company commits to submitting the required documents for the issuance of the import approval and the sealed medical customs release letter; in accordance with the regulatory guideline for the rules and procedures governing the importation and medical customs release process of medical products, their raw materials, and packaging materials.

2. Trade Names and Pricing

2.1. The company shall, within (30 working days, renewable once) from the date of issuance of the inquiry request approval, submit a list comprising (15) proposed trade names for the product to the Innovative Products Registration Administration, after reviewing the proposed names on the Egyptian Drug Authority (EDA) naming checker program, to ensure there is no preliminary conflict of the proposed names with the names of the products available in the EDA database.

2.2. The list of trade names submitted by the company shall be examined within (15 working days) from the date of receiving the list, and the company shall be notified by the Registration Administration of the approval of the product's trade name or the rejection of the submitted list of names.

2.3. In case the submitted list is rejected, the company must submit another list within (20 working days) from the date the company is notified of the rejection; otherwise, the registration request shall be cancelled.

2.4. The company is allowed to submit a maximum of (4) lists of proposed names, including the first list, provided that the evaluation and issuance of approval are carried out as mentioned above, and in case that the four submitted lists are rejected, an approval shall be issued with the Non-Proprietary Name alongside the company's name as the trade name of the product.

2.5. The company may approach the Pricing Policies Administration in the Central Administration of Pharmaceutical Policies and Market Access based on the inquiry request approval containing the classification of the innovative product.

3. Submission of the Designation Application

3.1. The company is committed to submitting the required innovative product documents to the Reception Unit in the Innovative Products Registration Administration in accordance with Annex No. (1) within (60 working days, renewable once) from the date of the inquiry request approval.

3.2. The Reception Unit in the Innovative Products Registration Administration shall screen the submitted application and ensure that it fulfills all requirements within (20 working days), and the company should submit any missing requirements all at once within (20 working days, renewable once) from the date of being notified thereof.

3.3. After fulfilling all requirements, the Reception Unit shall form a Multidisciplinary Assessment Team from the relevant administrations to evaluate the application and prepare a report on the product within (90 working days), and the company shall be notified with the report in preparation for presentation to the Scientific Committee.

3.4. A meeting shall be held with the company, when necessary, within 15 working days from the date the company receives the report to discuss the status of the product, and the company is committed to submitting any

requirements or amendments agreed upon within (15 working days, renewable once) from the date of the meeting, and these requirements are evaluated by the relevant administration and the report will be updated within 35 working days.

4. Presentation to the Scientific Committee

4.1. The product shall be presented to the Scientific Committee for the Evaluation of Innovative Products within (40 working days) from finalizing the report in order to express their scientific opinion regarding the product.

4.2. The Reception Unit shall update the report and notify the company thereof within a period not exceeding (20 working days) from the issuance of the Committee's recommendation.

4.3. In case that the Scientific Committee for the Evaluation of Innovative Products recommends rejecting the product, the company shall be notified of the reasons for rejection via a letter issued by the General Administration of Innovative Products within a period not exceeding (10 working days) from the issuance of the Committee's recommendation, and appeals from the company shall be received within (30 working days, renewable once) from the letter's issuance date, provided there are new developments on the company's side supporting re-presentation to the Scientific Committee for the Evaluation of Innovative Products. The appeal shall be submitted the first time to the General Administration of Innovative Products, and the second and last time to the Head of the Central Administration for Biological and Innovative Products and Clinical Studies.

5. Preparation of the Registration Dossier

5.1. The company is committed to preparing an appropriate time plan not exceeding (3 years) during which the required studies are completed and the

Common Technical Document (CTD) registration dossier is prepared. The time plan is submitted to the Innovative Products Registration Administration within (30 working days, renewable once) from the date of issuance of the report mentioned in paragraph 4.2. The company can choose to adopt the system of rolling submission and rolling review for parts of the dossier during the 3-year period.

5.2. The company is committed to updating the product status on a quarterly basis, and in case that the product status is not updated, the company shall be addressed within (10 working days, renewable once) from the date the specified period is exceeded. In the absence of a response, a memorandum shall be prepared for presentation to the Head of the Central Administration to take the necessary actions according to Article Eight of the Chairman's Decree No. 388 for the year 2023 concerning the registration of innovative products.

6. Inspection

6.1. All relevant manufacturing sites, including active substance manufacturing sites, bulk production sites, and finished product sites, are subject to inspection to ensure the application of Good Manufacturing Practice (GMP) in accordance with international standards and the regulatory mechanisms implemented by the Central Administration of Inspection on Pharmaceutical Institutions for both human pharmaceutical and biological products, and the Central Administration of Inspection on Pharmaceutical Institutions shall notify the Central Administration for Biological and Innovative Products and Clinical Studies of the inspection visit results.

6.2. Manufacturing sites approved by a reference regulatory authority or those holding World Health Organization (WHO) prequalification shall be exempted from the inspection visit.

6.3. After product registration, all local manufacturing sites shall be inspected according to the periodic risk-based inspection plan.

7. Submission of the Registration Dossier

7.1. The International Council for Harmonisation (ICH) M4 Common Technical Document (CTD) guidelines shall be followed for the preparation of the unified registration dossier, which shall be submitted in its entirety to the Reception Unit in the Innovative Products Registration Administration within (3 years) from the date of issuance of the report mentioned in paragraph 4.2.

7.2. The initial screening of the submitted registration dossier shall be conducted to ensure that the submitted dossier fulfills the technical assessment requirements within 30 working days, and the applicant shall be notified of the dossier's status regarding fulfillment or non-fulfillment.

7.3. In case the dossier is incomplete, the applicant shall fulfill the missing requirements within (30 working days, renewable once), and these submitted requirements shall be examined, and the applicant shall be notified of their status regarding fulfillment or non-fulfillment.

7.4. The technical assessment shall be conducted by the concerned administrations upon receipt of the complete dossier in accordance with the established international guidelines in addition to the International Council for Harmonisation (ICH) guidelines and their updates within 120 working days.

7.5. The company shall be notified of any requirements within 60 working days, and the company is committed to fulfilling these inquiries/requirements within (30 working days, renewable once).

7.6. In case there are unfulfilled requirements, the company shall be notified within 35 working days to fulfill them within 30 working days, renewable once.

7.7. If the applicant fails to fulfill the requested requirements/inquiries for a second time, a meeting shall be held with the applicant to identify the reasons for the delay in providing responses, and consequently, if the inquiries are still not answered, the registration application shall be considered cancelled.

7.8. The evaluation of the registration dossier shall be completed after fulfilling all requirements and clarifying the inquiries, and the Innovative Products Registration Administration shall issue the technical report for the product within 25 working days of receiving the final evaluations from all concerned administrations.

8. Analytical Testing for Registration

8.1. The pre-marketing analytical testing shall be performed at the concerned laboratories in the Central Administration of Drug Control or in the Central Administration for Biological and Innovative Products and Clinical Studies according to the type of the innovative product (human pharmaceutical product or biological product) after receiving the complete CTD dossier.

8.2. The Registration Administration shall issue a letter to determine the number of samples and the analysis requirements after receiving the technical opinion from the concerned administrations, and shall notify the Central Administration of Inspection on Pharmaceutical Institutions of the required number of samples for analysis.

8.3. The company must submit samples from a single batch of the finished product within (60 working days) from the date of issuance of the letter determining the number of samples, and this period shall be renewed only once.

8.4. *In case of biological innovative products*, samples from one commercial scale batch shall be tested prior to the issuance of the registration licence, and the product shall follow EDA's lot release policy.

8.5. In case of human pharmaceutical innovative products, samples from one batch shall be tested prior to the issuance of the registration licence, and three production batches are tested after the issuance of the registration licence and prior to marketing.

9. Presentation to the Technical Committee

9.1. The Registration Administration shall present the product to the Technical Committee for Drug Control to take the appropriate decision regarding the registration of the product within (30 working days) from the date of fulfilling all required approvals from the concerned administrations tasked with evaluating the registration dossier. In case of *approval* by the Technical Committee for Drug Control, the registration licence shall be issued, and its validity period shall be five years. In case of *rejection* by the Technical Committee for Drug Control, the company shall be notified via a justified letter.

9.2. In case of *rejection*, the applicant has the right to submit a request for the re-presentation of the product to the Technical Committee within 60 working days, and the company may submit a grievance against the final decision issued by the Technical Committee for Drug Control via a justified request submitted to the Grievances Committee formed in accordance with the Egyptian Drug Authority (EDA)'s Establishment Law, within (60 working days) from the date of the decision issuance, supported by documents and information it wishes to rely upon when the grievance is reviewed.

10. General Obligations

The Marketing Authorization Holder (MAH) is bound by the following obligations:

10.1. Submission of a declaration in which they acknowledge their commitment to the provisions of the Intellectual Property Protection Law No. 82 of 2002, and that if proven to have violated the aforementioned law, they bear the full responsibility, and the Central Administration for Biological and Innovative Products and Clinical Studies has the right to cancel the registration procedures or cancel the registration based on a recommendation from the Technical Committee for Drug Control.

10.2. Writing the name of the manufacturer, the Marketing Authorization Holder (MAH) company, production date, expiration date, batch number, barcode, registration number, and price on the outer packaging, and printing the name of the manufacturer, production date, expiration date, and batch number on the inner packaging.

10.3. Not making any variation to the product except after referring to the Central Administration for Biological and Innovative Products and Clinical Studies in accordance with the variation guidelines. Approval for variations is obtained from the Innovative Products Registration Administration.

10.4. Ensuring the availability of innovative products that have obtained an innovative product registration licence within a year and a half from the date of the registration licence issuance.

10.5. Declaring that all data provided in the product's registration dossier are correct and under their full responsibility.

10.6. Declaring full responsibility for the storage of raw materials, all stages of product manufacturing, and compliance with technical specifications until full distribution, in accordance with the Egyptian Drug Authority (EDA)’s applicable rules for good distribution and storage.

10.7. *In case of toll manufacturing*, it is required that the manufacturing site be licensed by the Egyptian Drug Authority (EDA) and that it commits to all obligations set forth in this guideline and to Good Manufacturing Practice (GMP) guidelines.

10.8. Collecting and submitting all safety information related to the innovative product and following up on all requirements set forth in the guidelines issued by the Pharmaceutical Vigilance General Administration (PVGA) at EDA.

10.9. Collecting all Adverse Events and report it to the Pharmaceutical Vigilance General Administration (PVGA) in expedited manner, including reports of Lack of Efficacy, Off-label Use, and Medication Errors, and completing the follow-up with the reporter using the appropriate Targeted Follow-up Forms.

10.10. Submitting a Summary Monthly Safety Report for the innovative product to the Pharmaceutical Vigilance General Administration (PVGA).

10.11. Submitting a proposal for the Periodic Benefit-Risk Evaluation Report (PBRER) submission cycle within one month from the date of obtaining the Marketing Authorization to the Pharmaceutical Vigilance General Administration (PVGA).

10.12. Submitting and implementing the Egyptian Integrated Risk Management Plan (RMP), including the required Surveillance Activities and approved Risk Minimization Activities.

10.13. Submitting evidence that the plasma derivatives supplier (if used as excipients for an innovative product) is committed to inform the MAH of any information regarding the safety and efficacy of the used plasma derivatives if they are not registered within the Arab Republic of Egypt.

10.14. Notifying the Central Administration for Biological and Innovative Products and Clinical Studies of the names of all its authorized distributors and any change that occurs to their data and ensuring that the authorized distributors comply with Good Storage and Distribution Practice (GSDP).

10.15. In case there is any update to the data of the applicant company for registration, the company is committed to making this update in the electronic company registry (company profile) available on the Egyptian Drug Authority (EDA)'s website.

10.16. The product is re-registered upon a request submitted by the MAH to the General Administration of Innovative Products according to which a transfer letter is directed to the General Administration for Registration of Human Products at the Central Administration of Pharmaceutical Products, or the General Administration of Biological Products at the Central Administration for Biological and Innovative Products and Clinical Studies according to the applicable guidelines. This should be done during the last year of the registration licence validity; otherwise, the product's registration is cancelled.

11. General Rules

11.1. The company must adhere to the timeframes specified in this guideline, which are renewable only once, and in case the stated timeframes are exceeded, the registration request is considered cancelled in accordance with the EDA Chairman's Decree No. 388/2023 for the registration of innovative products.

11.2. A meeting is held with the company, when necessary, and the company is committed to submitting any agreed upon requirements or amendments and adhere to the timelines specified in the meeting minutes.

11.3. The General Administration of Innovative Products may seek the advice of specialized experts, whenever needed, during the scientific assessment of the product's quality, safety, and/or efficacy to ensure that all necessary expertise and specializations relevant to the type and nature of the product and the assessment are considered. Confidentiality and the absence of any conflict of interest are strictly ensured by taking all necessary measures

followed in this regard and in accordance with the World Health Organization (WHO)'s Good Regulatory Practices (GRP) and Good Review Practices (GRevP).

11.4. Innovative products granted registration numbers are announced on the Egyptian Drug Authority (EDA)'s website, and Public Assessment Reports (PARs) are published on the Egyptian Drug Authority (EDA) website within 30 working days from the date of issuance of the registration licence, and any concerned party has the right to object to any of the announced registered products within two months from the date of announcement.

6- References

- EDA Chairman's Decree No. (388) of 2023 issuing the rules for the registration of innovative products.
- The Egyptian Drug Authority's Establishment Law No. (151) of 2019 and its Executive Regulations.

7- Attachments/ Annexes

Annex I

List of Documents needed for designation application

I- Scientific rationale & added value:

Applicants must outline the basis for the innovation and provide strong scientific evidence supporting the innovative product, the innovation category and the added value of the product. Describe why patients need the product and what clinical unmet need is addressed. Outline the current standard of care and explain where your product fits within this landscape.

A detailed description of the novel aspects of the product is required, highlighting its differences from existing treatments for the specified indication. Rational choice of the reference product (comparator) should be provided if applicable.

II- Quality / CMC Part:

The applicant should include the needed information to reflect manufacturing mastery and a robust control strategy based on the applicant's own data.

In this section, the applicant should describe the evidence that establishes that the type of dosage form selected, and the formulation proposed are suitable for the intended use. This section should include sufficient information in each part to provide an understanding of the development of the drug product and its manufacturing process.

Summary tables and graphs are encouraged where they add clarity and facilitate review.

1. Product Control/ Control Strategy

At the designation stage, a fully validated commercial process is not expected. However, the applicant must establish a preliminary phase-appropriate control strategy.

This strategy must:

- Identify initial CQAs.
- Define safety-critical specifications (e.g limits for impurities, degradation, dose dumping, …).
- Demonstrate sufficient platform mastery to guarantee that the batches used in early clinical studies are safe, consistent and reproducible.

2. Drug Substance

In this section, the applicant should provide the characterization, physicochemical and biological properties of the drug substance that can influence the performance of the drug product and its manufacturability.

3. Excipients

In this section, the applicant provides the excipients chosen, their concentration, and the characteristics that can influence the drug product performance (e.g., stability, bioavailability) or manufacturability. This should be discussed relative to the respective function of each excipient.

This should include all excipients used in the manufacture of the drug product, whether they appear in the finished product or not (e.g., processing aids).

Compatibility of excipients with other excipients, where relevant (for example, combination of preservatives in a dual preservative system) should be established. The ability of excipients (e.g., antioxidants, penetration enhancers, disintegrants, release controlling agents) to provide their intended functionality and to perform throughout the intended drug product shelf life should also be demonstrated.

Information regarding the use of novel excipients, their quality and safety information should be properly provided.

4. Drug Product:

4.1 Formulation Development

The development of the formulation, including identification of those attributes that are critical to the quality of the drug product, taking into consideration intended usage and route of administration.

The summary should highlight the evolution of the formulation design from initial concept up to the final design. This summary should also take into consideration the choice of drug product components (e.g., the properties of the drug substance, excipients, container closure system, any relevant dosing device), the manufacturing process, and, if appropriate, knowledge gained from the development of similar drug product(s). The compatibility of the drug substance with excipients listed should be submitted. For products that contain more than one drug substance, the compatibility of the drug substances with each other should also be submitted.

4.2 Stability

Include physical and chemical stability testing demonstrating the stability-indicating capacity of the methods.

III- Non-clinical & Clinical part

This should specify the following aspects

1. Non-clinical safety & toxicology information based on the formulation and route
2. Clinical studies according to the drug development program, including efficacy and any specialized clinical safety.
3. Dose regimen and dose interval.
4. Critical overview and summary of the existing standard of care treatments, their limitations and how the submitted product offers advantages clarifying any benefits that this product

could bring to the healthcare system.

5. Supportive studies for the claimed added value that include a summary of the evidence presented to support the product. (e.g. peer reviewed journal articles, clinical treatment guidelines and health economic reports)

IV- Timeline plan:

Provide estimated timelines for the proposed development program including pharmaceutical development, stability, non-clinical, and clinical studies, as appropriate.

History Table

Version No.	Issue date	Summary of Changes
1.0	20/06/2023	New Issue
2.0	7/9/2026	-Amendment in Registration Steps and Annexes -Update to add CA of inspection on pharmaceutical institutions to replace CA of operations according to Decree No. 444/2025