



**Central Administration of Biological and Innovative Products and Clinical Studies  
General Administration of Innovative Products**

# **The Regulatory Guideline for Implementing the EDA Chairman Decree No. 388/2023 on the Registration of Innovative Products Year 2026**

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## 1. Introduction

The purpose 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 Decree No. 388 of 2023 issued by the Chairman of the Authority.

## 2. Scope

This guideline applies to innovative medicinal or biological products manufactured locally and have not been previously registered inside or outside the Arab Republic of Egypt and are submitted for registration with the aim of adding a new therapeutic advantage. The product must be submitted for registration to the Egyptian Drug Authority (EDA) by a company that is registered in the EDA Company Profile database.

\*This Decree does not apply to the registration of herbal products, dietary supplements with therapeutic claims, or medical devices.

\*If the company wishes to obtain a protection period for the submitted innovative product, it must first apply to the Egyptian Patent Office to register the idea, then submit an inquiry request to the Egyptian Drug Authority. The Egyptian Patent Office shall bear the responsibility for whether or not the innovative product can be granted a protection period in accordance with the law regulating intellectual property protection and without any impact on the decision of registering the innovative product by Egyptian Drug Authority.

## 3. Abbreviations

**3.1 WDs:** Working Days

<b>4. Definitions</b>	25
<b>4.1 Innovative Products:</b> Medicinal or biological products manufactured locally, not previously registered inside or outside Egypt, submitted for registration with the aim of adding a new therapeutic advantage. Such products may include:	26 27 28
A medicinal product that contains a new active substance, or a new formulation with a different mechanism of action, or a new modification, which include:	29 30
<ul style="list-style-type: none"> <li>• Breakthrough innovation</li> <li>• Incremental innovation</li> </ul>	31 32
Such as a new molecular entity, new indication, new manufacturing technology, new fixed-dose combination, .....etc.	33 34 35
<b>4.2 Therapeutic Advantage:</b> The added value provided by the innovative product, such as addressing an unmet medical need, offering a new therapeutic option, demonstrating enhanced efficacy, providing a better safety profile, improving patient compliance, or any other therapeutic advantages.	36 37 38 39 40
<b>4.3 Locally Manufactured Products:</b> Products on which at least one manufacturing step - excluding packaging and labelling- is carried out in a manufacturing facility within the Arab Republic of Egypt.	41 42 43 44
<b>5. Main topic</b>	45
<b>Article One: Inquiry Request</b>	46
<b>1.1</b> The applicant company must submit an inquiry request for the innovative product using the inquiry request form, accompanied by the documents specified in the form to the Inquiries Unit in the Innovative Products’ Registration Administration via the specified e-mail, taking into account that a maximum of (1) inquiry request for each Toll company per month.	47 48 49 50
<b>1.2</b> The Inquiries Unit reviews the inquiry request within (30 WDs) from the date of receiving the complete request from the company. The company must fulfill any required documents within (10 WDs, renewable once) from the date the company is notified, otherwise, the inquiry request will be considered cancelled.	51 52 53 54
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- 1.3 The product may be presented to the Technical Committee, when necessary, such as when there is a technical committee decision that conflicts with the principle of the product's innovative idea, or when there is a need to evaluate the product's idea itself and determine whether to proceed with its registration or not. 56  
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- 1.4 The company is notified of the submitted request status—approval or rejection—within (30 WDs) from the date of receiving the complete request, or within (7 WDs) from the date of receiving the Technical Committee's decision. 60  
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- 1.5 Only one request is received per innovative idea. If more than one company submits the same innovative idea, subsequent requests are added to a waiting list according to the order of submission. If the company holding priority fails to complete the registration procedures within the specified timelines, the priority is transferred to next company on the list. Once the product is registered for the company holding priority, the remaining companies on the waiting list are notified that the list has been cancelled. 63  
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- 1.6 Importation and sealed medical customs release of pharmaceutical raw materials and packaging materials used in manufacturing innovative products is be permitted based on the approval of the inquiry request, provided that the company is committed to submit the documents required to issue the importation approval and the letter of Sealed Medical Customs Release in accordance with the regulatory guideline of the rules and procedures regulating importation and medical customs release of medicinal products, their raw materials and packing and packaging materials. 69  
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- Article Two: Trade Names and Pricing** 76
- 2.1 Within (30 WDs, renewable once) from the issuance date of the inquiry approval, the company shall submit the proposed trade names list for the product to the Innovative Products' Registration Administration, after reviewing the proposed names through the Egyptian Drug Authority's EDA Naming Checker program, in order to ensure absence of preliminary conflict of the proposed names with the names of products available in the EDA database. An official letter is issued to the company by the General Administration of Innovative Products approving the product's trade name in accordance with the applicable naming guidelines. 77  
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- 2.2 The company can apply to the Pricing Policies Administration at the Central Administration for Pharmaceutical Policies and Market Access based on the inquiry request approval including classification of the innovative product, to determine its price before submitting the registration dossier. 85  
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**Article Three: Submission of the Innovative Product Dossier  
(Designation Application)**

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**Article Four: Presentation To the Scientific Committee**

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4.4 If the product is rejected based on the recommendation of the Scientific Committee for Innovative Products Evaluation, the company is notified of the reasons for rejection within (10 WDs) from the issuance of the recommendation. Appeals can be submitted by the company within (30 WDs, renewable once) from the date of issuing the letter, provided that the company has new information or updates to support representing the product to the Scientific Committee and after paying the relevant service fee. The appeal is submitted for the first time to the General Administration of Innovative Products, and in the second and last time to the Head of the Central Administration for Biological, Innovative Products and Clinical Studies.

### Article Five: Preparation of the Registration Dossier

5.1. The company must prepare an appropriate timeline not exceeding thirty-six (36) months to fulfill the requirements of the registration dossier and submit it within (30 WDs, renewable once) from the date the technical report is issued.

5.2. The company is required to update the status of the product on a quarterly basis. The company may also adopt a rolling submission and rolling review system for dossier sections or submit scientific advice requests in accordance with the applicable regulations during this period.

5.3. If the product status is not updated, the company is contacted within (10 WDs, renewable once) from exceeding the specified period. If no response is received, a memorandum is prepared to be presented to the Head of the Central Administration to take the necessary action in accordance with Article Eight of Decree No. 388/2023.

### Article Six: Inspection

6.1 Inspection Shall be conducted on all relevant manufacturing sites, including active ingredient factories, bulk production sites, and finished product manufacturing sites— in accordance with the regulatory inspection guideline applied by the Central Administration of inspection on pharmaceutical institutions on all Pharmaceutical and Biological products on all Pharmaceutical and Biological products. Central Administration of inspection on pharmaceutical institutions notifies the Central Administration for Biological and Innovative Products and Clinical Studies of the inspection visit results.

6.2 Certified Manufacturing sites by a reference regulatory authority or pre-qualified by the World Health Organization (WHO), as well as raw materials for human medicinal products listed in the Egyptian Drug Authority white-list, are exempted from inspection visits.

6.3 After the product is registered, it is included in the inspection plan based on risk assessment.

### **Article Seven: Submission of the Registration Dossier**

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| <b>7.1</b> The registration dossier must be submitted complete to the Reception Unit in accordance with ICH M4 Common Technical Document (CTD) format within (36 months) from the date of issuance of the final report.  | 156<br>157<br>158<br>159 |
| <b>7.2</b> A preliminary review of the submitted registration dossier is conducted within (20 WDs) to ensure that it meets the technical assessment requirements, and the applicant is notified whether the requirements have been fulfilled or not.   | 160<br>161<br>162        |
| <b>7.3</b> The applicant must provide any required documents within (30 WDs). The submitted documents are reviewed, and the applicant is notified whether the requirements have been fulfilled or not.   | 163<br>164<br>165        |
| <b>7.4</b> If the applicant fails to fulfill the requirements, an additional (30 WDs) is granted; otherwise, the application is considered cancelled.  | 166<br>167               |
| <b>7.5</b> The technical assessment is carried out by the relevant departments once the complete dossier is received, and the assessment is conducted according to global standards and updated ICH guidelines.  | 168<br>169<br>170        |
| <b>7.6</b> The applicant is notified of any further required documents within (60 WDs) and must respond within (30 WDs)  | 171<br>172               |
| <b>7.7</b> A preliminary review of the submitted documents is conducted within (5 WDs) to ensure they are complete before proceeding with the assessment process. The technical assessment process is completed within (10 WDs).   | 173<br>174<br>175        |
| <b>7.8</b> The applicant is notified of any additional requirements, if present, and must provide them within (30 WDs), If the applicant fails to fulfill the required requirements for the second time, the registration request is considered cancelled.                                   | 176<br>177<br>178        |
| <b>7.9</b> The assessment of the registration dossier is finalized within (35 WDs) after all requirements have been fulfilled and inquiries addressed.   | 179<br>180               |
| <b>7.10</b> The Reception Unit at the Innovative Products Registration Department prepares the technical report for the product within (30 WDs) from receiving all final assessments from the relevant units, and the product may be re-presented to the Scientific Committee, if necessary. | 181<br>182<br>183        |

### **Article Eight: Pre-Marketing Authorization Analysis**

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| <b>8.1</b> Pre-marketing authorization analysis is conducted by the relevant laboratories according to the innovative product type and in accordance with the certificate of analysis provided by the manufacturer. | 184<br>185<br>186<br>187 |
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8.2	Central Administration of inspection on pharmaceutical institutions is notified of the required number of samples to be tested by the Central Administration for Biological and Innovative Products and Clinical Studies.	188 189 190
8.3	For innovative biological products, one production batch is tested before issuing the registration license, after which the product follows the Lot release policy which applicable after registration.	191 192 193
8.4	For innovative pharmaceutical products, one production batch is analyzed before issuing the registration license, followed by the analysis of three production batches after the issuance of the final registration license and before marketing.	194 195 196
8.5	The company must submit samples from one production batch of the final product within (60 WDs, renewable once) from the date of issuance of the sample-quantity letter; this period may be renewed only once.	197 198 199
<b>Article Nine: Presentation to the Technical Committee</b>		200
9.1	The General Administration of Innovative Products shall present the product to the Technical Committee for Drug Control to take the appropriate decision regarding the product's registration, within (30 WDs) from the date of preparing the report and upon receipt of the following:	201 202 203 204
	<ul style="list-style-type: none"> <li>• The technical report, including the evaluation of quality information, clinical studies, and pre-clinical studies.</li> <li>• Approval of the bioequivalence, bioavailability, or comparative dissolution study, where applicable.</li> <li>• Conformity of the registration analysis</li> <li>• Approval of the central administration of inspection on pharmaceutical institutions.</li> <li>• Approval of the General Administration of Pharmacovigilance of the Central Administration of Pharmaceutical Care for the company's pharmacovigilance files.</li> <li>• Approval of the inner and external packaging of the product.</li> <li>• Approval of the product's package insert (patient information leaflet).</li> <li>• Certificate of final pricing.</li> </ul>	205 206 207 208 209 210 211 212 213 214 215
9.2	If the Technical Committee for Drug Control approves the product, a registration licence is issued with a validity period of (5 years). If the Technical Committee for Drug Control rejects the product, the company is notified through an officially substantiated letter. The company has the right to submit an appeal within (60 WDs) from the decision issuance date to request representation, subject to an additional service fee, and only once.	216 217 218 219 220



- 9.3 The company may file a grievance against the final decision issued by the Technical Committee for Drug Control within (60 working days) from the issuing date of the decision. The grievance shall be aired to the Grievance Committee formed in accordance with the Law on Establishing the Egyptian Drug Authority and shall be based on a reasoned request submitted to the committee and supported by the documents and information on which the company desires to rely when considering the grievance.
- Article Ten: Obligations and General Provisions**
- 10.1 The product's owner shall adhere to submitting a pledge that he shall comply with the provisions of the Intellectual Property Rights Law no. (82) of 2002 and that he shall accept full liability if he is proven to violate this law. The Central Administration of Biological and Innovative Products and Clinical Studies have the right to nullify the track of registration procedures or to withdraw registration upon a recommendation of the Technical Committee for Drug Control.
- 10.2 Writing the manufacturer name, the product-owning company, manufacturing date, expiry date, batch number, the barcode, registration number and price on the external package and printing the manufacturer name, manufacturing date, expiry date and batch number on the internal package.
- 10.3 Making no changes to the product until refereeing the Central Administration of Biological and Innovative Products and Clinical Studies to submit the file of the variations which the product shall undergo so that they can be assessed in accordance with the rules approved by the Technical Committee for Drug Control and obtaining approval for these changes from the Innovative Products' Registration Administration.
- 10.4 Making the products that have been granted a Marketing Authorization License in accordance with this decree available within one and a half year of the date of issuing the Marketing Authorization License
- 10.5 Giving a pledge that all submitted data in the product registration file are correct and that he is fully responsible for them
- 10.6 Acknowledging the full responsibility for the storage of the raw material, the manufacturing phases of the product and the product conformity to the technical specifications up to its complete distribution.
- 10.7 In the case of toll manufacturing, the manufacturing site is required to be licensed by the Egyptian Drug Authority and to abide by all obligations provided herein and by the good manufacturing practices

<b>10.8</b>	Undertaking to inform the General Administration of Pharmacovigilance of any adverse effects that are observed about the product and to implement all required vigilance activities in compliance with the applicable principles of good pharmacovigilance practices	254 255 256
<b>10.9</b>	submitting the periodic safety update report for assessing the product benefits and risks to the General Administration of Pharmacovigilance in accordance with the pharmacovigilance rules otherwise the product shall be suspended	257 258 259
<b>10.10</b>	Submitting a statement (in the case of using a plasma derived product as excipient in an innovative biological product) proving that the supplier of this substance conforms with informing the registration-requesting person of any data pertaining to the safety and efficacy of this substance. This requirement applies to plasma derivatives which are not registered in the Arab Republic of Egypt.	260 261 262 263 264
<b>10.11</b>	Notifying the Central Administration for Biological and Innovative Products and Clinical Studies of the names of all his authorized distributors and of any change that may be made to their data and ensuring that his authorized distributors implement good storage and distribution practices	265 266 267 268
<b>10.12</b>	Updating the electronic companies register (Company profile), which is available on the website of the Egyptian Drug Authority, in the event that there is any update in the data of the company owning the registration request.	269 270 271
<b>10.13</b>	The product is registered upon a request submitted by the marketing authorization holder to the General Administration of Innovative Products. A transfer letter is then issued to the General Administration for Human Medicines Registration or the General Administration for Biological Products Registration during the final year of the notification's validity; otherwise, the product registration will be cancelled.	272 273 274 275 276 277
<b>6. References:</b>		278
-	EDA Chairman Decree No. 388 of 2023 concerning issuing the rules for registration of innovative products.	279 280
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<b>7. Annexes:</b>	282
<b>Annex I</b>	283
<b>Documents needed for designation application</b>	284
<b>I- <u>Administrative Documents:</u></b>	285
1. Designation Application Form for Innovative Products	286
2. Payment receipt	287
3. Letter of authorization.	288
4. Declaration that all documents are true and accurate.	289
<b>II- <u>Scientific rationale &amp; added value:</u></b>	290
Applicants must provide strong scientific evidence for the innovative product and the innovation category and added value of the product	291
The focus should be on clearly defining and demonstrating the innovative properties and potential impact of the product within current treatment paradigms and the broader scientific and technological landscape.	292
A detailed description of the novel aspects of the product is required, highlighting its differences from existing treatments for the specified indication. Rational for choice of the reference product (comparator) should be provided if applicable.	293
Explain why these differences are significant and what the broader implications of the innovation are.	294
Outline the basis for the innovation and whether it is based on new understanding and insights into the indication, drug development or medical fields in general.	295
Describe why patients need the product and what clinical unmet need, it addresses. Outline the current standard of care and explain where your product fits within this landscape.	296
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<b>III- <u>Quality / CMC Part:</u></b>	308
The applicant should include the needed information to reflect manufacturing mastery and a robust control strategy based on the applicant's own data.	309 310
In this section Applicant should describe the knowledge 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.	311 312 313 314
Summary tables and graphs are encouraged where they add clarity and facilitate review.	315
<b>1. Product Control/ Control Strategy</b>	316
At the designation stage, a fully validated commercial process is not expected. However, the applicant must establish a preliminary phase-appropriate control strategy.	317 318
This strategy must:	319
- Identify initial CQAs.	320
- Define safety-critical specifications (e.g limits for impurities, degradation, dose dumping, ...).	321 322
- Demonstrate sufficient platform mastery to guarantee that the batches used in early clinical studies are safe, consistent and reproducible.	323 324 325
Describe the knowledge that establishes that the type of dosage form selected, and the formulation proposed are suitable for the intended use.	326 327
Summary tables and graphs are encouraged where they add clarity and facilitate review.	328
<b>2. Drug Substance</b>	329
In This section 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.	330 331 332
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.	333 334 335

### 3. Excipients

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

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

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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.

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The information on excipient performance can be used, as appropriate, to justify the choice and quality attributes of the excipient, and to support the justification of the drug product specification.

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

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### 4. Drug Product:

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#### 4.1 Formulation Development

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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.

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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).

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#### 4.2 Stability

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

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<b>IV- <u>Safety &amp; clinical plan</u></b>	365
<b>1. Clinical efficacy pathway</b>	366
Applicant must select the one highest tier that applies to their submission:	367
- Tier 1: pharmacokinetic bridge Only (Applicable to: Convenience FDCs, identical systemic route changes).	368 369
- Tier 2: Pharmacodynamic / surrogate bridge	370
- Tier 3: Bridged Phase 3 clinical efficacy trial (Applicable to: new indications, new local/mucosal routes, synergistic FDC, high risk ER).	371 372
- Tier 4: Phase 3 Clinical Efficacy Trial	373 374
<b>2. Non-clinical safety &amp; toxicology pathway</b>	375
Applicant must select all that apply based on their formulation and route:	376
- Standard bridging toxicology: Appended are standard bridging toxicology studies linking the test formulation safety profile to the reference product.	377 378
- Advanced platform / ATMP / Encapsulated nucleic acids: Appended are comprehensive biodistribution studies defining systemic dissemination, and GLP repeated-dose toxicity studies incorporating targeted microscopic histopathological assessments of vulnerable organs (e.g., heart, liver) to detect low-grade platform-induced inflammation.	379 380 381 382
- New Local / Mucosal / Topical route: Appended are mandatory GLP local tissue tolerance studies (for example 14-day mucosal irritation models) appropriate for the specific new route of administration.	383 384 385 386
<b>3. Specialized Clinical Safety and Justification Assessments</b>	387
Applicant must select all that apply based on their product type:	388
- Systemic absorption assessment (Mandatory for new local/mucosal routes). Appended is a PK study to evaluate the safety of systemic drug spillover over the newly intended continuous duration of exposure.	389 390 391 392

- Exposure-response and Risk justification (Mandatory for Modified Release/Hybrids)	393
Appended is the scientific justification detailing the drug Therapeutic Window (safety relevance), exposure-response curve steepness (efficacy relevance), and adverse event severity profile to justify the selected Tier in Part A	394 395 396
- Formulation robustness assessment (Mandatory for Modified Release). Appended are food-effect PK studies and in-vitro alcohol dose-dumping assessments.	397 398
- Drug-Drug Interaction (DDI): If your product contains more than one active ingredient, please clarify if there is a drug-drug interaction between its active ingredients, including references.	399 400 401 402
<b>4. Dose regimen and dose interval</b>	<b>403</b>
If your product contains more than one active ingredient, please clarify if they have the same dosing interval and dose timing and rationale if different dosing interval or dose timing	404 405
<b>5. Adherence to treatment guidelines</b>	<b>406</b>
Provide a critical overview and summary of the existing standard of care treatments, their limitations and how your product offers advantages. Clarify any benefits that this product could bring to the healthcare system.	407 408 409
<b>6. Supportive studies for your claimed Added value:</b>	<b>410</b>
Provide a summary of the evidence presented to support your product. Examples of acceptable documents include:	411 412
• Peer reviewed journal articles	413
• Clinical treatment guidelines	414
• Health economic reports	415
Including full-text references as pdf	416
<b>V- <u>Timeline plan:</u></b>	<b>417</b>
Provide estimated timelines including pharmaceutical development, stability, non-clinical (if needed), and clinical studies.	418 419