Guideline

Procedures for registration of biological products through reliance pathways
2026

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1. Introduction

Reliance is a core principle in the World Health Organization's approach to strengthening regulatory systems and underpins efficient, effective regulation of medical products. In line with Biological Products Registration Regulations and the updated Ministerial Decree 343/2021, the Egyptian Drug Authority (EDA) has developed this guidance to support applicants using reliance pathways.

These reliance pathways help accelerate access to safe, effective, high-quality products while reducing regulatory workload and conserving resources. In a globalized pharmaceutical market, especially for biological products.

The framework enables EDA to leverage assessments and decisions from trusted Reference Regulatory Authorities and international organizations, in line with WHO Good Reliance Practices. Reliance is a strategic approach—not reduced oversight—that optimizes resources, making the best use of the available resources, strengthens decision-making, and improves access to quality biological products.

This guide should be read in conjunction with the following regulatory guidelines:

- Regulatory guideline for mechanisms and rules of implementing the decree of Egyptian Drug Authority's Chairman No. (343) / 2021 Code: EDREX.GL. BioInn.001
- Guideline for file content of biological products submitted for registration & re-registration file Code: EDREX.GL.Bioinn.004

2. Scope

This document outlines the regulatory activities undertaken by the EDA to implement reliance principles in the registration of biological products. It establishes the requirements and procedural framework for submitting new biological product applications through reliance pathways, and defines the criteria for submission as well as the subsequent regulatory processes.

3.Abbreviations

API	Active Pharmaceutical Ingredient
CTD	Common Technical Document
EDA	Egyptian Drug Authority
EDREX	Egyptian Drug Regulatory Index
EMA	European Medicines Agency
FDA	U.S. Food and Drug Administration
FPP	Finished Pharmaceutical Product.
GL	Guideline

GMP	Good Manufacturing Practice
IPRP	International Pharmaceutical Regulators Program
NRA	National Regulatory Authority
WDs	Working Days
WHO	World Health Organization

4. Definitions

Reliance: The act whereby the NRA in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

Reference regulatory authority: A national or regional regulatory authority, or a trusted institution, whose regulatory decisions and/or work products are utilized by another regulatory authority to support and inform its own regulatory decision-making, as recognized in the Technical Committee's approved list of reference authorities.

Sameness: means that two products have identical essential characteristics. All relevant aspects of drugs, including those related to the quality of the product and its components, should be considered to confirm that the product is the same or sufficiently similar (e.g. same qualitative and quantitative composition, same strength, same pharmaceutical form, same intended use, same manufacturing process, same suppliers of active pharmaceutical ingredients, same quality of all excipients). Additionally, the results of supporting studies of safety, efficacy and quality, indications and conditions of use should be the same.

5. Main topic

5.1. Eligibility Criteria of the candidate products:

- The application should be identical to that approved by the reference authority (in terms of dosage form, strength, formulation, manufacturing sites, therapeutic indications…)
- The same qualitative and quantitative formulation
- The same manufacturing site(s) for API and FPP including specific block(s)/unit(s), chain, processes, control of materials and final product, and in the case of vaccines also by the same batch release scheme
- The same specifications for excipient, API and FPP
- The same essential elements of product information

Note: Some differences between the dossier submitted to EDA and that submitted to the reference regulatory authority may exist; these differences must be scientifically justified and will be evaluated on a case-by-case basis.

- The submitted product and its intended use (indications, dosage form, and patient groups) have not been rejected, withdrawn, suspended by any drug regulatory authority for safety or efficacy reasons.
- The submitted product should be registered and marketed on the market of the reference country.

5.2 Levels of reliance practice at EDA:

Two approaches with different levels of reliance and different time frames are set according to the submitted documents as follows:

5.2.1 Level 1 (20 WDs)

- The product must be approved by EMA and/or FDA.
- The applicant should submit unredacted assessment report along with other relevant supporting documents from the reference regulatory authority such as: reports pertaining to post-approval variations, post marketing commitments, supporting documents on comparative safety and efficacy studies submitted to the reference regulatory authority **and/or** questions & answers documents between applicant and the reference regulatory authority with all annexes.
- The applicant should submit complete CTD as that approved by the reference authority.

5.2.2. Level 2 (40 WDs)

- The product must be approved by EMA and/or FDA.
- The applicant should submit complete CTD as that approved by reference country

5.3 Registration steps for reliance pathway:

Inquiry request

- The applicant shall submit an inquiry request through the automated inquiry system at EDA website for this purpose, accompanied by the required documents.
- The applicant shall be informed with the status of the application within **5 WDs**.

- The applicant should complete the inquiry with the requested documents / data within **20 WDs** from the date of notification; otherwise, the inquiry request shall be cancelled.
- The application for names is submitted through the electronic program designated for this purpose on the EDA's website, in conjunction with the inquiry request.
- The applicant shall submit a separate inquiry for each concentration, pharmaceutical form, or volume of the product.

Pricing

- After issuing inquiry approval, the required documents for pricing shall be submitted to the central administration of drug policies and market support within **30 WDs** from date of Issuing inquiry approval, otherwise, the inquiry approval shall be cancelled
- Pricing of biological products are determined within a maximum of **30 WDs** from the date of receipt of the complete pricing file.

Inspection

EDA waive routine on-site inspections when a valid GMP certificate issued by a recognized reference regulatory authority is available, unless risk-based considerations require additional inspection. Whereas EDA shall review some documents **(Refer to Annex 1)**

Submitting registration file

Note: The registration file may be submitted in parallel with the pricing step.

Preliminary validation:

- The submitted registration file will undergo preliminary validation to ensure that the CTD file is complete, and it meets the technical evaluation requirements.
- This preliminary validation will be within **5 WDs** for reliance level 1 track, and within **10 WDs** for reliance level 2 track, at the relevant central administrations (the central administration of biological and innovative products and clinical studies, the central administration of inspection on pharmaceutical institutions, and the central administration of pharmaceutical care).
- The applicant will be notified of the file status, including whether it fulfills the specified requirements or not.
- The applicant shall complete the requirements within **60 WDs.**

- After submission of the requirements if the required documents are incomplete the applicant shall complete the requirements within another **60 WDs** otherwise the registration application shall be cancelled.

Technical evaluation:

- Evaluation pathways may differ based on the nature of the application and the quality of reliance documents submitted it includes, but not limited to the following
    1. Sameness validation to ensure that the product application submitted for registration is the same as the product registered by the specified reference regulatory authority
    2. Evaluation of specific aspects of the dossier

- The technical evaluation is conducted upon receipt of the complete CTD file along with the required reliance documents by the relevant administrations (the central administration of biological, innovative products, and clinical studies, the central administration of inspection on pharmaceutical institutions, and the central administration of pharmaceutical care).

Detailed steps and corresponding timelines:

For reliance level 1:

- The applicant will be notified of the required queries / supplementary documents (if any) within **10WDs**
- The applicant shall complete these inquiries/ supplementary documents within **60 WDs**, renewed once**.**
- The initial review of the submitted inquiries / supplementary documents is conducted within **2 WDs** to ensure its completeness before resuming the evaluation process.
- The technical evaluation shall be completed within **8 WDs**
- All previous technical evaluation steps shall be completed within **20 WDs**

For reliance level 2:

- The applicant will be notified of the required queries / supplementary documents (if any) within **15 WDs**
- The applicant shall complete these inquiries / supplementary documents within **60 WDs**, renewed once

- The initial review of the submitted inquiries/ supplementary documents is conducted within **5 WDs** to ensure its completeness before resuming the evaluation process
- The technical evaluation shall be completed within **10 WDs**
- The applicant will be notified of any additional queries/ supplementary documents (if any) which shall be addressed within **60 WDs**.
- In the event that no response is provided to the inquiries, a meeting shall be held with the registration applicant to determine the reasons for the delay in submitting the responses. Thereafter, if the inquiries remain unanswered, the registration application shall be cancelled.
- The registration file evaluation will be completed after all requirements have been completed and inquiries have been clarified within **10 WDs**
- All previous technical evaluation steps shall be completed within **40 WDs**

Analysis for registration

- The central administration of biological and innovative products and clinical studies will notify the applicant and the central administration of inspection on pharmaceutical institutions of the number of samples required for analysis within **8 WDs** of receiving the CTD registration file.
- Bio-Inn labs shall determine the need for pre-registration testing & testing level according to the submitted product type, public health relevance (e.g.: address unmet medical need), and the feasibility and resources optimization.
- The applicant shall submit the analysis requirements and samples from a single batch of the finished product within **60 WDs** from the date of issuance of the letter specifying the number of samples. This period may be renewed once.
- If multiple manufacturing facilities are involved in producing the raw material, bulk, finished product, or solvent, and these facilities were evaluated within the product's registration file during registration along with the analysis of a single finished product batch, the marketing authorization license shall require that analysis also has to be performed for the other facilities listed in the marketing authorization license, in line with the EDA's Lot release policy.

Considerations for registration through reliance level 1:

- The sample analysis could be postponed to the first shipment before being placed into the market.
- A conditional marketing authorization approval will be issued to grant analysis before placing first shipment into the market

Considerations for registration through reliance level 2:

- The sample analysis will be conducted in pre-authorization stage.

Technical committee step

- The product will be presented to the Technical Committee for Drug Control within **5 WDs** from the date of receipt of all required evaluation reports from the relevant stakeholders responsible for evaluating the registration file to take final decision on whether to approve or reject the product's registration.
- In case of approval, the product shall be granted a marketing authorization license valid for five years.
- In case of rejection of the product's registration, the applicant shall be notified in a letter stating the reason for the rejection.
- The applicant has the right to request that the product to be resubmitted by the Technical Committee for drug control in case of registration rejection. The applicant may also appeal the final decision within **60 WDs** from the date of its issuance, through a substantiated request submitted to the Grievances Committee established in accordance with the Law on the Establishment of the EDA, supported by the documents and information the applicant wishes to rely upon in the appeal process.

Regulatory notes:

1. Reliance doesn't mean dependence.
2. Approval by reference drug regulatory authority does not oblige the EDA to approve the application.
3. During the evaluation, the request could be transferred to regular pathway. However, EDA commits to clarify the decisions for any case.

6. References:

- Good reliance practices in regulatory decision-making for medical products: high-level principles and considerations. Draft working document, WHO, Rev.1, August 2020.
- EDA Chairman Decree (343/2021)
- EDA Chairman Decree (157/2026)
- IPRP Questions and Answers document on reliance (09/2022)

7.Annexes

Annex 1: Documentation requirements for reliance levels

8. History table

History Table

Version No.	Issue date	Summary of changes
1	18/7/2022	Initial Issue
2	29/06/2026	Additional details are outlined in the step-by-step registration procedures.

Annex 1: Documentation requirements for reliance levels:

1	CTD dossier should be the same as that approved by the reference regulatory authority for modules 2-5.
2	Sameness letter
3	Unredacted assessment report along with other relevant supporting documents from the reference regulatory authority such as: reports pertaining to post-approval variations, post marketing commitments, supporting documents on comparative safety and efficacy studies submitted to the reference authority **(Reliance level one only)**
4	Reference regulatory authority variation application with annexes
5	Correspondence between the applicant and the reference regulatory authority relating to safety and efficacy or queries, the risk management plan, or benefit-risk decisions should be provided
6	List of variations after first MA issued from country-of-origin reference regulatory authority
7	Questions & answer documents between applicant and the reference regulatory authority with all annexes
Inspection requirements:	
1	Update Site Master File for all sites included in the product manufacturing
2	Valid GMP certificate for all sites included in the product manufacturing
3	Last annual product review
4	Manufacture license for all sites included in the product manufacturing
5	List of recall and complaints last 5 years (if found)
6	Process validation
7	Manufacturing process for drug substance and drug product including manufacturing flow chart
8	Last inspection report for inspection performed by a stringent regulatory authority in the past three years and their outcomes
9	**Periodic review for the product should be performed post product registration by reviewing the following documents (If needed):** - Annual product review - List of deviation - List of change control - List of out of specifications - List of complaint and recall