Guideline for Application for Reliance Pathway for Laboratory Testing of Medical Products For Human Use

2022

Version No: 1.0
Issue Date: 12/12/ 2022
Effective date: 12/12 /2022

E-mail: dc.gatechsupport@edaegypt.gov.eg
Website: https://www.edaegypt.gov.eg/

Table of Contents

1. Introduction:

In alignment with the Egyptian Drug Authority's strategic objective to strengthen its regulatory capacity and achieve harmonization with WHO listed authorities, EDA adopts reliance practices in various stages throughout the product's life cycle.

Chapter 3; article 16; paragraph 7 of EDA Establishing Law no.151 for the year 2019 allows the authority to: "cooperate and coordinate with national and international entities and organizations concerned with medical products and public health and those concerned with the issuance of relevant standards, within the scope of achieving EDA's objectives".

Furthermore, the EDA Chairman Decree no. 780 for the year 2022 promulgates the application of the principle of reliance on reference regulatory authorities in the registration and laboratory testing of imported medical products for human use that have been granted a Certificate of Pharmaceutical Product by one or more of the NRAs listed in the Technical Committee's approved list of reference authorities.

In this document, CADC (EDA's NCL) elaborates a guideline for reliance practices in laboratory testing. This guideline shall be subject to periodic revision and update in accordance with evaluation of its implementation.

2. Scope

The guideline detailed in this document applies to shipments of finished medical products for human use approved by reference regulatory authorities, which enter the Egyptian market for any purpose throughout the product life cycle.

Applications for implementation of reliance are accepted for products collected by the Central Administration of Operations (regulatory inspection), through lot sampling from ports of entry, and submitted to CADC for laboratory testing.

3. Definitions

3.1 Reliance:

As per WHO Good Reliance Practices, reliance is defined as “The act whereby the NRA in one jurisdiction may consider and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others”.

3.2 Verification of Sameness:

The product submitted for assessment and the product approved by the reference regulatory authority should be essentially the same in terms of qualitative and quantitative composition, strength, pharmaceutical form, intended use, manufacturing process, suppliers of active pharmaceutical ingredients and quality of all excipients. Additionally, the results of supporting studies of safety, efficacy and quality, indications and conditions of use should be the same.

3.3 Abridged Regulatory procedures:

Whereby reliance is applied to reach a regulatory decision, and while ensuring EDA'S standards of regulatory oversight are maintained through technical assessment and evaluation of documents submitted for review coupled with laboratory testing, reliance on data and decisions of the reference authority will be used to save time.

4. Procedures:

4.1 Eligibility criteria for application of reliance:

For products fulfilling the following criteria, an application for reliance pathway may be submitted:

4.1.1 The product in question must be approved by NRAs listed in the Technical Committee's approved list of reference authorities.

4.1.2 The product in question must have no issued global alerts, withdrawals or reports of non compliance by any of the aforementioned regulatory authorities.

4.1.3 The applicant must be the license holder, a legally authorized representative or marketing authorization holder.

4.1.4 Imported products that are not approved by reference authorities shall default to the regular pathway, as per CADC's guidelines and procedures.

4.2 Application for Reliance pathway

4.2.1 Applicants shall submit the application, along with the attached requisite documents, via EDA'S electronic services platform.

4.2.2 A pre-submission assessment step is provided by the Administration of Technical Assessment and Evaluation to assist applicants in determining the eligibility of their products for implementation of reliance.

4.3 Abridged Assessment of products

4.3.1 Verification of sameness shall always be assured before proceeding to assess the submitted products.

4.3.2 For products fulfilling the criteria specified in the above mentioned sub clause **4.1:**

4.3.2.1 The documents specified in **Annex I** shall be required.

4.3.2.2 An abridged assessment of the product shall apply, whereby the product specifications approved by the reference authority will be relied on, and selection of the tests to be performed will be subject to technical assessment of the documents submitted by the applicant, and risk prioritization of the product.

4.3.2.3 Prioritization shall be according to the following criteria:

- Product Indication.
- Product qualification.
- Pharmacological action.
- Route of administration.

4.4 Failure to provide documents

In case of the applicant's failure to provide any of the requisite documents and information, CADC reserves the right to revert the application to a different pathway, including the default procedure.

4.5 Issue of Final Reports

The Final Report shall be issued and forwarded to the Central Administration of Operations (responsible for the regulatory inspection function), and in certain cases, as required, to other EDA Administrations. A copy is also e-mailed to the product owner/manufacturer.

4.6 Timeframe for Release of Final Report

The timeframe for analyzing the submitted samples and releasing the Final Reports for the reliance pathway is **21 working day**s, after fulfillment of assessment requirements.

5. Glossary:

CADC: Central Administration of Drug

CTD: Common Technical Document

EDA: Egyptian Drug Authority

EMA: European Medicine Agency

FDA: Food & Drug Administration

NCL: National Quality Control Laboratory

NRA: National Regulatory Authority

SOP: Standard Operating Procedures

WHO: World Health Organization

6. References

6.1 WHO Expert Committee on Specifications for Pharmaceutical Products; 55th Report: Annex 10; Good reliance practices in the regulation of medical products: High-level principles and considerations.

6.2 EDA Chairman Decree No. 780 for the year 2022, promulgating the application of reliance on reference regulatory authorities in the registration and laboratory testing of imported medical products for human use that have been granted a Certificate of Pharmaceutical Product by one or more of the NRAs listed in the Technical Committee's approved list of reference authorities.

7. Annexes

7.1 Annex I: Required Documents

Annex I

Required Documents

1. **A declaration letter by the product owner /applicant stating that all aspects of the product's quality, safety and efficacy are identical to the currently approved by the reference authority, with the same dose, indication, warnings and precaution, and that all submitted documents must be the same as those submitted to the reference regulatory authority.**
2. **Full access to the following sections in P-part of the Quality Module 3 of the CTD.**
    - **P1-composition and description.**
    - **P5-control of drug product.**
    - **P6-reference standard.**
3. **All chromatograms and data of analysis, including the In- Process Controls and batch record (if applicable).**
4. **Certificate of analysis of the submitted batch approved from NRA of one of the reference countries if present.**
5. **Summary of comparative dissolution if applicable.**
6. **Full assessment report (if applicable) along with other relevant supporting documents from the reference regulatory agency such as:**
    - **Reports pertaining to post marketing commitments, supporting documents on comparative quality and efficacy studies submitted to the reference authority.**
    - **Question & Answer documents between the applicant and the reference authority with all Annexes.**
    - **Any correspondence between the applicant and the reference authority relating to quality and efficacy or queries.**
7. **Cold chain Storage & transportation procedures.**
8. **List of any recalls in the past three years related to products with quality defects (if found).**
9. **Any warning letter or equivalent regulatory action (if found)**