DRAFT FOR COMMENTS:

Guideline On Registration of Medicines According to Verification and Abridged

Draft Disclaimer

This document is a draft, and its content is not final. The text may be revised prior to publication. It must not be reviewed, cited, quoted, reproduced, transmitted, distributed, translated, or adapted, in whole or in part, by any means or in any form without prior authorization from the Drug Safety Center.

Guideline On Registration of Medicines According to Verification and Abridged

Table of Contents

Acronyms:

CTD	Common Technical Document
DSC	Drug Safety Center
eCTD	Electronic Common Technical Document
EMA	European Medicine Agency
FDA	US food and drug administration
MOH	Ministry of Health
NCE	New chemical entity

Definitions

Verification	A pre-assessment screening step conducted by the Registration Section to confirm that the submitted application dossier is complete, accurate, consistent, and eligible to proceed to technical assessment.
Abridged	A reduced set of documents/data compared with a full dossier, because the authority can rely on existing knowledge.
Reliance	The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.
Reference Health Authority	USFDA, EMA, MHRA, Swissmedic, Health Canada, PMDA and TGA.
Recognition	Acceptance of the regulatory decision of another regulator or trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.
Abridged Review	A partial review conducted by the NRA based on prior evaluation by a trusted authority.
Work Sharing	A collaborative regulatory process wherein two or more NRAs jointly review a submission.

CHAPTER ONE

Introduction

The Drug Safety Center has prepared this guideline to assist applicants in the registration of medicine using the verification and abridged procedures.

Purpose

The purpose of this guideline is to provide clear and standardized instructions for the preparation and submission of medicine registration dossiers (eCTD) with required documents for verification and bridging.

Scope

This guideline provides comprehensive instructions for the registration of medicine through the **Verification** and **Bridging (Abridged)** procedures. It covers all types of medicine, their regulatory activities, with particular emphasis on:

- Medicine addressing priority diseases with unmet medical needs.
- Products intended for public health emergencies or periods of shortages.
- Orphan and pediatric medicine.

The guideline applies to the following categories of pharmaceutical products:

- New Chemical Entities (NCEs)
- Biological Products
- Vaccines

Structure

This is the first version of this guideline and is organized into four chapters. CHAPTER ONE covers the Introduction, Purpose, Scope, and Structure. CHAPTER TWO outlines the detailed procedures. CHAPTER THREE defines responsibilities in relation to this guideline. CHAPTER FOUR includes the document history and version control table, references, and the Annex.

CHAPTER TWO

Procedure

1. Verification

The Drug Safety Center (DSC) may apply regulatory verification leveraging GMP inspection outcomes and marketing authorization decisions from recognized reference authorities (e.g., US FDA, EMA) to reduce duplication, while retaining the right to verify documents, assess local requirements, and request additional information where needed. It is process where the product has been approved and marketed by both of the drug regulatory agencies EMA and FDA.

2. Abridged

The DSC conducts a streamlined review that relies partly or fully on assessment reports and/or GMP inspection outcomes from recognized reference authorities (e.g., US FDA, EMA), while focusing on Oman-specific regulatory requirements and retaining the right to request additional information as needed. It is a process where the product has been approved and marketed by either of the drug regulatory agencies EMA or FDA.

3. Work Sharing and Joint Review

DSC participates to jointly review regulatory submissions and share scientific assessments and outcomes.

4. Submission requirements:

4.1. Verification:

4.1.1. Module 1: application fulfil the requirements based on the relevant approved DSC guidelines with additional documents in -additional data- as following:

- Declaration letter stating that all submitted information of product are identical to that approved by FDA & EMA. At the time of submission.
- Approvals from FDA & EMA mentioning the date of the approvals (for last 2years).
- Full assessment FDA & EMA reports.

- Declaration letter stating that the product and its intended use has not been rejected, withdrawn, suspended by any drug regulatory agency for safety or efficacy reasons.

4.1.2. Module 2&3: Stability studies according to the Guidelines for Stability testing of active pharmaceutical ingredients and finished pharmaceutical products.

4.2. Abridging:

4.2.1. Module 1: application fulfil the requirements based on the relevant approved DSC guidelines with additional documents in -additional data- as following:

- Declaration letter stating that all submitted information of product are identical to that approved by FDA or EMA. At the time of submission.
- Approvals from FDA or EMA mentioning the date of the approvals (for last 2years).
- Full assessment FDA or EMA reports.
- Declaration letter stating that the product and its intended use has not been rejected, withdrawn, suspended by any drug regulatory agency for safety or efficacy reasons.

4.2.2. Module 2&3: Stability studies according to the Guidelines for Stability testing of active pharmaceutical ingredients and finished pharmaceutical products.

5. Procedure of submission:

5.1: a formal request for verification/abridge must be presented by the applicant through dscpho@moh.gov.om (appendix 1), accompanied by details showing that the product falls within the scope of the eligibility criteria and satisfies the requirements.

5.2: DSC response / evaluates the eligibility request and supporting documentation, and then provides the applicant with DSC's opinion via e-mail on whether the request is accepted or not.

5.3: Application - As the request is accepted, the applicants should submit the application to the DSC based on the agreed format.

5.4: Assessment of the application

- the application will assess as expedited timelines.

-Any further requirements/clarifications will be communicated within reasonable timelines.

5.5: Decision

- Final decision will be taken by the Technical Committee of Registration.
- A communication will be sent to the applicant with decision.

6. Performance target:

The target of this guideline is to **expedite the submission and evaluation of medicine** while maintaining the required regulatory standards. Utilizing the Verification and Bridging procedures allows regulatory authorities to optimize resources, reduce duplication of effort, and shorten timelines compared to standard registration pathways.

The anticipated timelines for product registration under this guideline are:

1. **Verification:** within **90 working days**
2. **Bridging (Abridged):** within **180 working days**

7. Regulatory notes:

7.1. Approval by reference drug regulatory agency does not oblige the DSC to approve the application.

7.2. During evaluation and for safety, efficacy or quality concerns, the related departments might request to transfer the application to the regular pathway. However, DSC commits to clarify the decisions for any case.

7.3. Confidential information which submitted by the companies to support their registration application is protected and will not be shared by any means with other parties.

CHAPTER THREE

Responsibilities:

Pharmaceutical companies Marketing Authorization Holders (MAHs) Regulatory Affairs Professionals/Applicants Pharmaceutical Consulting Offices	• Ensure all submission documents comply with DSC requirements and guidelines. • Timely respond to inquiries or requests for additional information during the review process. • Maintain accurate records and communication with the DSC through the MOH-portal.
Technical Committee of Registration	• Evaluate submissions for quality, safety, efficacy, and compliance with regulatory standards. • To review submitted application and decide to approve, reject, or request further clarification
Medicinal and Biological Products Section	• Conduct business validation of submitted files. • Coordinate the assessment and distribution of applications to relevant departments and committees. • Manage communication with applicants, including notifications of validation results, inquiries, and final decisions. • Maintain documentation control, including versioning and archiving of submissions.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	August 2025
2		
3		

References:

Egyptian Drug Authority (EDA) (2024) ***Guidelines on reliance practices during registration of medicinal products***, Version 4/2024. Available at: https://www.edaegypt.gov.eg/media/2rydqaxz/guide-line-reliance-practices-during-registration-of-medicinal-products.pdf (Accessed: 23 November 2025).

FDA (Food and Drug Administration) Philippines (2022) ***Guidelines prescribing the principle of reliance for regulatory decisions of the Food and Drug Administration***. Available at: https://www.fda.gov.ph/wp-content/uploads/2022/11/Guidelines-Prescribing-the-Principle-of-Reliance-for-Regulatory-Decisions-of-the-Food-and-Drug-Administration.pdf (Accessed: 23 November 2025).

SFDA (Saudi Food and Drug Authority) ***Registration according to verification and abridged***, Version 2.1. (Publication details unknown; document referenced in other official guidelines).

Annexes

Appendix 1

[COMPANY LETTERHEAD]

(Insert Company Name, Logo, and Address here)

Date: [Insert Date]

To: Drug Safety Center (DSC)

Subject: Formal Request for Pre-designation – [Verification/Abridged] Pathway

Dear Sir/Madam,

We, **[Company Name]**, acting as the **[Applicant/Local Representative]**, formally submit this request for a pre-designation of the registration pathway for the following medicinal product:

1. PRODUCT PROFILE

- **Trade Name:** [Insert Product Trade Name]
- **Generic Name (API):** [Insert Active Ingredient]
- **Dosage Form & Strength:** [e.g., Tablet, 500mg]
- **Pharmacological Class:** [Insert Class]
- **Manufacturing Site: [Manufacturer Name]** in **[Country]**.

2. ELIGIBILITY JUSTIFICATION

We confirm that this application meets the **DSC Eligibility Criteria** for the **[Verification / Abridged]** pathway:

- **Product Reference Approvals:** Approved by the **[Reference Agency Name, e.g., US FDA / EMA]** on **[Date]**, which is within the 2years.
- **Manufacturing Site Reference Approvals:** list of countries (country & date of approval,..)
- **Global Safety Record:** The product has not been rejected, withdrawn, or suspended by any drug regulatory agency for safety or efficacy reasons.

3. REQUESTED ACTION

We kindly request the **Drug Safety Center (DSC)** to review our submission and provide a formal

designation letter. This will enable us to proceed with the eCTD submission via the accelerated track.

4. ATTACHMENTS

- **Appendix 1:** Official Reference Agency Approval Certificate.
- **Appendix 2:** Approved Summary of Product Characteristics (SmPC).
- **Appendix 3:** Valid GMP Certificate for the manufacturing facility.
- **Appendix 4:** Declaration of Sameness (if applicable).

Thank you for your cooperation and support.

Sincerely,

(Signature)

[Name of Authorized Signatory]

[Job Title]

[Company Stamp]