DRAFT FOR COMMENTS:

Guideline on Oman regulatory framework for medicinal company and Products Approval

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Acronyms:

DSC	Drug Safety Center
EMA	European Medicines Agency
GCC	Gulf Health Council
GHC-DR	Gulf Health Council - Drug Registration
MA	Marketing Authorization
MAA	Marketing Authorization Application
MHRA	Medicines and Healthcare products Regulatory Agency
MOH	Ministry of Health
NCE	New Chemical Entity
PMDA	Pharmaceuticals and Medical Devices Agency
RA	Regulatory Affairs
SFDA	Saudi Food and Drug Administration
SRA	Stringent Regulatory Authorities
Swissmedic	Swiss Agency for Therapeutic Products
TCR & P	Technical Committee for Registration & Pricing
TGA	Therapeutic Goods Administration
US FDA	United States of America Food and Drug Administration

Definitions

Biosimilars	Therapeutic proteins produced by recombinant DNA technology or gene expression method following the footsteps of one licensed reference biotechnological product after the expiration of the innovator's patent. They are complex and heterogeneous in their nature; hence they are not considered generics, but as closely similar to the innovator's drug as possible
Validation (Business & technical)	The process of checking if documents satisfy a certain criterion
Common Technical Document (CTD)	An international harmonized format for submissions for approval of pharmaceuticals. The CTD provides a standardization of the presentation of the content
Drug	An article intended for use in the diagnosis, cure mitigation, treatment, or prevention of disease and which is intended to affect the structure or function of the body
Drug Application	A drug application includes the application form, the product file and the drug samples
Generic (multisource) product	A product created to be equivalent to the innovative / brand name product in dosage form, strength, route of administration, quality, performance characteristics and therapeutic indication(s) ➢ ***Note:*** Drug application will be considered as Generic irrespective of whether the innovative product registered or not at GCC
Marketing Authorization (MA)	Approval issued by the DSC to market a medicinal product in Sultanate of Oman with a legal document for the purpose of marketing or distribution of a product within the country after evaluation for safety, efficacy and quality in the marketing authorization assessment process.
New (innovative) product /Brand	A product that includes new chemical entity and launched in the market by the innovator company
Reliance	the act whereby the national regulatory authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision
Renewal of marketing authorization	A process of renewing the marketing authorization license every five years.
Stringent Regulatory Authority (SRA)	USFDA, EMA, MHRA, Swissmedic, Health Canada, PMDA and TGA.
Variation	A process of informing GCC of any minor or major changes in the drug product
Wave	Set of inquiries from one or multiple departments sent to applicants during assessment process.

CHAPTER ONE

Introduction

This guideline outlines the regulatory framework of submitting medicinal and biological product applications to the Ministry of Health. It covers new applications, re-registrations, and variations.

Legal Basis

Minister of Health decision no.113/2020, Article no. 63 (Para 6), 66,68 and 69, for registration, re-registration and variation of medicinal product.

Purpose

To standardize the submission process, ensuring clarity, consistency, and efficiency in the regulatory review of medicinal products by adopting harmonized dossier formats.

Scope

Applies to all medicinal and biological products submissions to the MOH Drug Safety Centre, including new applications, re-registrations, and variations.

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

1. NEW/RE-REGISTARTION OF MEDICINAL COMPANY APPLICATION:

Submission

The process of submitting company application steps:

1. The applicant must apply through the Ministry of Health (MOH) portal by completing the application form and paying the required fees.
2. The required documents.

Validation

The submitted company dossier will undergo business validation to ensure all requirements are met.

1. The application will be validated to ensure that all information provided is according to the requirements and guidelines.
2. If any information is missing or incorrect, an electronic inquiry will be forwarded to the applicant through the MOH- portal. The applicant will be given an opportunity to complete the file within 30 working days.
3. The completed files will be forwarded to the next stage to finalize the assessment.

Note:

- The application will be rejected if the applicant does not respond within **30 working days**.
- A new application must be submitted with **new fees**.

Assessment

1. The application will be assessed within 30 days.
2. If additional information or clarification is needed, an electronic inquiry will be sent via the MOH portal as a single wave. The applicant must respond within 30 working days.
3. Once the evaluation is completed, the company file will be forwarded to the Technical Committee of Registration and Prices (TCR&P).
4. The Registration Committee will review the registration request and decide whether to approve, reject, require an inspection, or request additional information. The applicant may appeal the Committee's decision within **60 calendar days**; otherwise, the decision will be deemed accepted.
5. The company may be eligible for an inspection waiver if all of the following apply:
    - The company holds a valid approval/inspection outcome issued within the last **2 years** by a reference regulatory authority (e.g., **US FDA, EMA, TGA, MHRA, Health Canada, Japan PMDA, SFDA, Swissmedic**).
    - The manufacturer is fully compliant with all applicable regulatory requirements and obligations.
    - There have been **no product quality complaints** and **no reported ADRs**.
6. The applicant shall be notified with TCR&P decisions through the MOH portal.
7. For locally submitted applications, the certificate will be issued with a validity of five (5) years. For company submissions based on GCC-DR, the validity shall be aligned with the GCC registration certificate
8. For applications pending inspection, the company will be instructed to coordinate with the Regulatory Compliance Department to schedule the inspection date.
9. Following issuance of the final GMP inspection report, the application will be forwarded to the Technical Committee for Registration and Prices (TCR&P) for a decision.

Rejection criteria:

- If the applicant does not provide the requested additional information or clarification within 30 working days.
- If the company fails to comply with GMP requirements.

Activity type	Total Performance target (Working days)
Company application validation	15
Assessment	15
Complete applications for TCR&P decision	60
Certificate Issuance	15

Note that the above performance target timeframe excludes inspection, CAPA, and the periods during which the application is pending the applicant's response.

2. NEW MARKETING AUTHORIZATION APPLICATION (MAA):

The MAA of pharmaceutical product will be subjected to the followings processes:

Submission

The process of submitting a New MAA consists of two steps:

1. Online submission

1.1. The applicant must apply through the Ministry of Health (MOH) portal by completing the application form and paying the required fees.

1.2. The product dossier must be uploaded in accordance with the components and specifications outlined in the guidelines published on the Drug Safety Center (DSC) website.

2. Validation

The submitted product dossier will undergo technical and business validation to ensure all requirements are met. This validation comprises two stages:

2.1. Technical validation

The concerned department will validate the submission after the company upload the file on the in MOH- portal. The applicant will be notified with the validation's result.

2.2. Business validation

2.2.1. The product file will be validated to ensure that all information provided is according to the requirements and guidelines.

2.2.2. If any information is missing or incorrect, an electronic inquiry will be forwarded to the applicant through the MOH- portal. The applicant will be given an opportunity to complete the file within 30 working days.

2.2.3. The completed files, after verifying their type, global registration status will have designated pathways including reliance and will processed to the next steps to complete the assessment by different departments.

Note:

- The application will be rejected if no response from the applicant within 30 working days.
- A new application should be submitted with new fees.

Assessment

The application for new registration submissions will be designated for assessment as the following pathways:

- **Fast track**, applicable for:
    1. NCE New Chemical Entities (NCE) with approval from a Stringent Regulatory Authority (SRA)
    2. Vaccines with SRA approval/WHO Prequalification (WHO PQ)
    3. Biologicals with SRA approval
    4. Biosimilars with SRA approval
    5. Local Manufactures product
    6. 1st & 2nd Generics
    7. Gulf Health Council – Drug Registration (GHC-DR) registered products
- **Normal track**: Applicable to all medicinal products not eligible for fast-track.

The assessment steps include:

Prior to the assessment the eligibility criteria for reliance will be verified, to includes:

- Approval from Stringent Regulatory Authority (SRA) (SFDA, UAE and Kuwait/with CoA) within the last 2 years.
- A declaration letter confirming that all submitted product information is identical to that approved by the reference authority.
- 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.
- Modules 2&3 should include Stability studies according to the GCC Guidelines for Stability Testing (zone IV hot humid / tropical zone).
- Module 1 should meet the eCTD requirements with all required additional documents in the 'Additional Data' section.

Process based on Reliance:

1. Upon completion of application verification, the product file will be forwarded to the Pricing Section to process the application for submission to the Technical Committee for Registration and Prices (TCR&P).
2. The Registration Committee will review the registration request and decide whether to approve, reject, or request additional information.
3. For approved registration requests, the applicant will be notified through the portal of the decision and the approved prices (which may be lower than the requested price). If the approved price is not acceptable, the company may submit an appeal within 30 working days.
4. For locally submitted applications, the certificate will be issued with a validity of five (5) years. For company submissions based on GCC-DR, the validity shall be aligned with the GCC registration certificate.

Process based on full assessment:

1. The DSC will distribute the application to relevant departments and committees for evaluation of quality, safety, and efficacy. The initial assessment report will be issued within 90 days.
2. If additional information or clarification is needed, an electronic inquiry will be sent via the MOH portal as a single wave. The applicant must respond within 90 working days.

3. Once the evaluation is completed, the product file will be forwarded to pricing section, in order to processed the application to the technical committee of registration and prices (TCR&P).
4. The Registration Committee will review the registration request for approval, rejection or request further information.
5. For approved registration request, the applicant will be notified through the portal about the decision and approved prices (which may be lower than the requested price), so the company can submit appeal if not acceptable to them within 30 working days.

6. For locally submitted application the certificate will be issued with validity of five (5) years, whereas the approval of company submission based on GCC-DR, the validity shall align with the GCC registration certificate.

Note:

-All days are considered as working days.
-Each application can have not more than 3 waves.

Products designation	Assessment type	Total Performance target (working days)
Fast Track	Process based on Reliance	90
Fast Track	Process based on full assessment	180
Normal Track	Process based on full assessment	280

Note that:

- The above performance target timeframe excludes the periods during which the application is pending for the applicant's response.
- Products that require a company inspection are excluded from the above timeline.

Appeal Process:

The applicant has the right to appeal the Committee's decision within 60 working days; otherwise, the decision will be deemed accepted.

3. VARIATION OF MARKETING AUTHORIZATION

Any changes on a registered product have to be submitted to the DSC as a Variation of MAA. The variations are classified into two main categories:

A. Minor changes

- **Type IA**: minor variations that does not require prior approval before implementation ("**Do and Tell" procedure**). Type IAIN variations should be submitted immediately, within 14 days following implementation.
- **Type IB**: minor variations that must be submitted to the DSC by MAH before implementation, but do not require a formal approval. However, the MAH must wait a period of 120 working days to ensure that the application is deemed acceptable by the DSC before implementing the change ("**Tell, Wait and Do" procedure**).

B. Major variation

- **Type II**: major variations in which there might be a significant impact on the Quality, Safety or Efficacy of a pharmaceutical product and require prior approval before implementation.

Variation Submission Process

The submission of a variation to an MAA involves the following steps:

1. Online submission

1.1. The applicant shall apply through MOH-portal to fill the application form.

1.2. The product dossier must be uploaded according to the components and guidelines outlined on the DSC website.

2. validation:

2.1. Technical validation

The concerned department will validate the submission after the company upload the file on the in **MOH- portal**. The applicant will be notified with the validation's result.

2.2. Business Validation

1. The product file will be validated to ensure that all information provided is according to the requirements and/or guidelines.
2. The application will be returned to pay the fees within 5 working days.
3. If any information is missing or incorrect, an electronic inquiry will be forwarded to the applicant through the portal. The applicant will be given an opportunity to complete the file within 30 working days.
4. The completed file will proceed to the next step for Assessment.

Rejection Criteria:

- No response from the applicant within 30 working days.
- A new application should be submitted.

3. Assessment

Depending on the type of variation, the application will be reviewed/assessed by the concerned departments and committees.

3.1.Evaluation / Inspection:

The variation request will be distributed to the relevant departments and committees – as needed;

a) Company-related Variations:

- In case Variation required company inspection, please refer to the new/re-registration of medicinal company application (assessment para).
- Variation don't require inspection will be processed by the section.

Rejection Criteria:

- No response from the applicant within specified time lines.
- If the company did not comply with GMP requirements.

b) Product variation approval

- Prior to assessment, the Registration Section will verify the status of the variation approval (reliance) and process the application accordingly.
- A declaration letter must be provided confirming that all submitted variation information is identical to that approved by the reference health authorities.
- The Registration Section will distribute the variation request to the relevant departments and committees to assess quality, safety, and efficacy. The first assessment report will be issued within 90 working days.
- If additional information or clarification is required, an electronic inquiry will be issued through the MOH portal. The applicant must respond within 90 working days.
- The approval decision will be communicated to the applicant through the portal.

General variation notes:

- For applications submitted via the portal, once an application under a specific category is completed (approved or rejected), a new application under the same category may be submitted.

- If an application includes more than one variation type, the overall performance target shall be based on the maximum applicable timeframe. For example, if the application includes Type IB and Type II variations, the total performance target will be 300 working days.

Note:

-All days are considered as working days.
- No more than three (3) requests for additional requirements/documents shall be issued per application.

Variation Type	Total Performance target (Working days)

Type IB	**120**
Type II	**180**

Note that the above performance target time excluded the application waiting the applicant to respond timelines

4. RENEWAL OF MARKETING AUTHORIZATION

An applicant shall submit a renewal request every five years. The request for renewal should be six months prior to the certificate expiry.

Submission

The process of submitting a renewal of MA consists of two steps:

1. Online submission:

1.1. The applicant shall apply through MOH-portal to fill the application form and pay the fees.

1.2. Upload the renewal file; The components of the file shall follow the requirements and guidelines published on DSC website.

Validation

1. Technical validation

The concerned department will validate the submission after the company upload the file on the in MOH- portal. The applicant will be notified with the validation's result.

2. Business Validation:

2.1. The product file will be validated to ensure that all information provided are according to the requirements and/or guidelines.

2.2. If any information is missing or incorrect, an electronic Inquiry will be forwarded to the applicant through portal. The applicant will be given an opportunity to complete the file within 30 working days.

2.3. 3. Once the file is complete, it will be forwarded to the Pricing Section to process the application for submission to the Technical Committee for Registration and Prices (TCR&P).

Renewal requests will be rejected if:

- The applicant does not respond within 30 working days.
- Failure to provide acceptable clarifications after the 2 waves.

1. Product re-registration

- The Registration Committee will review the re registration request for approval, rejection or ask for further information (if needed).

- For approved re-registration request, the applicant will be notified through portal about the decision and approved prices (less than the requested price), so the company can submit appeal if not acceptable to them within 30 calendar days. (The price appeal will follow the published pricing methodology)

- Re-Registration certificate will be issued and be valid for five years if the committee approved the registration with same prices approved before.

Note: The rejected renewal applications obligate the applicant to submit a new one.

Renewal performance targets:

- All days below are considered as working days.

Phases of Renewal	Total Performance target (Working days)
Business validation	5
Complete applications for TCR&P decision	90

Total performance target	**95**

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 technical and 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:

GCC-DR (Gulf Central Committee for Drug Registration) (2024) ***GCC regulatory framework for drug approval***, 2024 Edition. Riyadh: GCC-DR.

GCC-DR (Gulf Central Committee for Drug Registration) (no date) ***GCC guidelines for stability studies of drug substances and products***. Riyadh: GCC-DR.

[DSC] (2025) ***Guideline for medicinal product application submission***, Version 4.

WHO (World Health Organization) (no date) ***Guidance on good manufacturing practice (GMP) for medicinal products***. Geneva: WHO Technical Report Series.