DRAFT FOR COMMENTS:

Guideline on Withdrawal, Suspension, Rejection, Cancellation of Marketing Authorization of medicinal product

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Table of Contents

Acronyms:

COO	Country of Origin
DSC	Drug Safety Center
GMP	Good Manufacturing Practice
MA	Marketing Authorization
MAH	Marketing Authorization Holder
MOH	Ministry of Health
WHO	World Health Organization

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Definitions

Applicant/Local agent (for MA)	A licensed drug store, Pharmaceutical Consulting Offices, local manufacturer or local scientific office, that is authorized by the marketing authorization holder to represent them with MOH in order to finalizes the regulatory issues and the product distribution.
Cancellation	Regulatory action taken by the DSC where a marketing authorization is declared invalid, effectively ending the legal permission to market (import/sell/distribute) the medicinal product.
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.
Marketing Authorization Holder (MAH)	A legal entity that has been granted the marketing authorization to place a medicinal product on the market, and who is legally responsible for marketing that medicine and post marketing activities.
Medicinal Product	Any substance or combination of substances prepared, sold or presented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it or restoring, correcting or modifying organic functions in human beings, including biologics and vaccines.
Rejection	Regulatory action taken by the DSC for rejecting the product application prior to the registration due to the failure of fulfil the requirements issued by the DSC or due to the rejection of the company.
Suspension	Temporary regulatory action to hold or freeze the regulatory applications or activities or status related to a marketing authorization.
Withdrawal	The permanent discontinuation of the medicinal product by the marketing authorization holder (MAH) for the applications under registration. The MAH shall declare whether the reason for the withdrawal was due quality, safety and/or efficacy concerns.

CHAPTER ONE

Introduction

This guideline outlines the regulatory guidance for withdrawing, suspending, rejecting, or canceling the marketing authorization of medicinal products due to quality, safety, efficacy or administrative non-compliance. DSC ensures timely regulatory actions based on thorough assessments of complaints, product defects or adverse events.

Legal Basis

Minister of Health decision no.113/2020, Articles no. 57, 63 (Para 6), 70,71,72 and 73 stating cases and condition to suspend, cancel, reject marketing authorization.

Purpose

To provide clarity on conditions and procedures for MA withdrawal, suspension, rejection or cancellation, ensuring coordinated actions among stakeholders.

Scope

Applicable to all medicinal products whether the MA application was granted or still under assessment.

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

Procedures

2.1 Withdrawal of Application

A Marketing Authorization Holder (MAH) may request to withdraw a product from the registration process by submitting a formal letter to the Drug Safety Center (DSC), clearly stating the reasons for withdrawal. After the acceptance of the withdrawal, a new application should be submitted with new fees.

2.2 Suspension of Marketing Authorization

2.2.1 The DSC may suspend a marketing authorization if one or more of the following conditions apply:

- The MAH has violated MOH-DSC laws and regulations.
- changes or variations have been made to the product without approval from DSC
- The manufacturing site shows non-compliance with cGMP or any reason that led to suspended/cancelled/banned.
- Product proven toxicity, serious adverse effects, or banned by WHO/reference authorities.
- Product Suspension or cancellation in COO.
- Product Non-compliance with bioequivalence requirements.

2.2.2 Suspension Notification Requirements

A written notification shall be sent by the DSC to the MAH, including:

- Reasons for suspension
- Required corrective actions and timeline

2.3 Rejection of Marketing Authorization application

The DSC may reject a Marketing Authorization application if:

- The MAH fails to respond to official queries within the timeline given.
- The applicant failed to comply with Marketing authorization requirements.

Rejection decisions will be communicated via written notice stating the reasons.

2.4 Cancellation of Marketing Authorization

Cancellation of a product's marketing authorization may occur under the following conditions:

- MAH formally requests cancellation with valid justification (Annexure I).
- Product is banned in the country of origin.
- Failure to submit the re-registration dossier within the DSC-specified deadline.
- Serious life-threatening adverse events are reported.
- Manufacturer or MAH suspended previously for non-compliance with cGMP requirements and failed to satisfy the compliance requirement within the suspension period.
- The product was not marketed for two consecutive years after marketing authorization approval.
- The product is proven to be ineffective for the approved indication(s).

DSC will issue a formal cancellation notice with justification for the decision.

2.5 Appeal Process

MAHs may appeal against decisions related to suspension, rejection, or cancellation by submitting an official appeal letter within two (2) months from the notification date. Appeals will be reviewed by the relevant DSC committee, and the final decision shall be issued accordingly.

CHAPTER THREE

Responsibilities:

Pharmaceutical companies	• To assure that the request for withdrawal and cancellation of MA application are provided with clear justification. • To adhere to the decisions related to this guideline.
Marketing Authorization Holders (MAHs)	
Regulatory Affairs Professionals/Applicants	
Pharmaceutical Consulting Offices	

Technical Committees of Registration	• Decision making based on the cases and conditions.
Sections of Medicinal and Biological Products	• Verification of the application submitted for cancellation and withdrawal. • Raise the recommendations on applications intended to cancellation, rejection and suspension to the technical committees of registration. • Issuance of the notification's letters based on committees' decisions.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	**Initial Release**	**December 2025**
2		
3		

References:

African Medicines Regulatory Harmonization Programme (2023) *Guideline for Cancellation, Suspension, and Withdrawal of Market Authorization of Medical Products*.

Guidelines for the Cancellation/Suspension of Marketing Authorization for Medical Products [PDF document].

[Ministry of Health, Oman] (2020) *Executive Regulation of the Law Regulating the Practice of Pharmacy and Pharmaceutical Establishments* (Ministerial Decision No. 113/2020). *Official Gazette*, 1561 (Published 11 August 2020).

[Oman] (*Pharmacy Law*) (Sultani Decree No. 35/2015). *Official Gazette*, 1118 (Published 11 October 2015).

TWG-MAG (Technical Working Group for Guidelines in Marketing Authorization) (2022) *Guideline on Withdrawal of Marketing Authorization*, Version 1 – Updated Final (20221202-GLWithdrawalV1TWG-MAG-updated-final.pdf).

Annexes

Appendix 1:

Product Cancellation Request Form

To be filled by the Applicant

Trade Name	**Active ingredient(s)**
Reg. no.	Dosage Form
Route(s) of administration	Strength/unit
Package Size and type	Approved CIF Price
Marketing authorization holder (MAH)	Name and site of Manufacturer
Local Agent	

Justification for Cancellation Request:

☐	**Reason for Cancellation**	**Additional Notes**
☐	Production line shutdown	
☐	Product has not been marketed since first registration	
☐	Product has not been marketed since:	_____
☐	Low price	
☐	Increased production expenses	
☐	Problems in manufacturing	
☐	MAH changed	Specify: _____
☐	MAH changed with new address	Specify: _____
☐	Manufacturer changed	Specify: _____
☐	No / Low market demand	
☐	Reported adverse events / Safety reasons	
☐	Availability of another pack size(s) of the product	Specify: _____
☐	Availability of another presentation(s) / concentration(s)	Specify: _____
☐	Availability of other alternatives marketed by other MAHs	Specify: _____
☐	Others	Specify: _____

Quantities imported to Oman during the last five years
(Institutions for which product was imported should be stated)

Year	**20..**	**20..**	**20..**	**20..**
Amount	Institutions			

List of countries in which the product is still marketed:

1.
2.
3.
4.

List of countries in which the product has been cancelled

Country	**Date**	**Reasons for cancellation**

Applicant's Name:
Date and Signature Applicant's Stamp: