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Ministry of Health

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Drug Safety Center

Guideline on Drug Safety Center Inter-Departmental Coordination on Market Surveillance & Control Activities

Drug Safety Center

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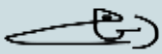
Signature		**Signature**	
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Acronyms:

DSC	Drug Safety Center
MC	Market Surveillance and Control
SF	Substandard and Falsified Medicine
PVDID	Pharmacovigilance and Drug Information Department
DCD	Drug Control Department
PLD	Pharmaceutical Licensing Department
CQCL	Central Quality Control Laboratory

Definitions

Substandard Medicine	Also called "out of specification", these are authorized medicine that fail to meet either their quality standards or specifications, or both.
Falsified Medicine	Medicines that deliberately misrepresent their identity, composition, or source.
Promotional Control	Regulatory review of advertising content to ensure accuracy, ethics, and public interest.

CHAPTER ONE

Introduction

The DSC is responsible for four core Market Surveillance and Control (MC) functions:

1. Control of import activities
2. Prevention, detection, and response to SF products
3. Surveillance of medicine quality across the supply chain
4. Oversight of promotional, marketing, and advertising practices

Each DSC department contributes to the implementation of these themes. This guideline establishes a comprehensive coordination framework to ensure consistency, alignment, and integrated execution across all departments.

Legal Basis

The MC is established under Royal Decree 35/2015, which regulates pharmacy practice and pharmaceutical establishments in Oman, encompassing provisions for importation, licensing, and post-market surveillance. Ministerial Decision No. 67/2015 further specifies the roles and responsibilities of the DSC departments. The implementation of the MC is additionally reinforced by Executive Regulation No. 113/2020, which outlines the procedures for inspection, medicine recalls, and marketing authorisation. Furthermore, Ministerial Decision No. 135/2025 sets out the conditions and procedures for the advertisement of medicines

Purpose

The purpose of this guideline is to define consistent coordination mechanisms across DSC departments to support detection, risk assessment, enforcement, and stakeholder communication of MC activities.

Scope

Applies to DSC departments managing MC functions:

- Drug Control Department
- Pharmacovigilance Drug Information Department
- Pharmaceutical Licensing Department
- Central Quality Control Laboratory

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 and methods. 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

2.1 Detection & Notification

2.1.1 Control of Import Activities

- The Drug Control Department (DCD) systematically inspects pharmaceutical consignments at entry points (sea, air, land). Any import suspected to be substandard or falsified is flagged for coordination with PVDID, PLD and CQCL.

2.1.2 Prevention, Detection & Response to SF Medicines

- The PVDID receives and evaluates adverse drug reaction (ADR) reports and product defect reports. Potential SF medicine alerts are logged and analysed, including review of causality and product traceability.
- High-risk or confirmed SF incidents are escalated internally for regulatory review and coordination.

2.1.3 Market Surveillance of Supply Chain Quality

- The CQCL conducts systematic sampling and testing; the PLD inspects pharmaceutical establishments

2.1.4 Control of Promotional, Marketing & Advertising Activities

- The PLD reviews and approves advertising materials.
- The PLD conducts ongoing monitoring and media scanning and inspections to detect unapproved or misleading ADMs.

2.2 Coordination Mechanism

- Monthly or ad-hoc meetings are conducted with designated representatives from each department. During these meetings, participants share surveillance insights, review emerging risks, and propose coordinated actions.
- The agenda includes: summary of detected issues across themes, risk triage, preliminary recommendations, and follow-up action plans.

2.3 Risk Assessment & Escalation

- The Department representatives conduct a joint evaluation of risk severity, medicine impact, and public health implications.
- High-risk cases and significant SF events may escalate to senior DSC leadership or technical advisory committees for final decision.

2.4 Regulatory Decision & Enforcement

- The DSC issues formal regulatory actions (e.g., recall circular, prohibition of medicine or license suspensions), based on multi-department input and legal mandate.

2.5 Communication & Public Advisory

- The DSC publishes official circulars and safety advisories through the DSC communication channels, ensuring transparency and stakeholder awareness.

2.6 Implementation & Compliance Monitoring

- The PLD executes field-level compliance activities, and CQCL re-tests as necessary.
- Completion reports are submitted for closure and records.

2.7 Continuous Improvement

- During monthly coordination reviews, the team evaluates enforcement timeliness, process adherence, and incident response effectiveness.
- Procedural gaps, recurring themes, and workflow inefficiencies are recorded and recommendations proposed. Updates to the guideline are made semi-annually or following major MC events to strengthen coordination

CHAPTER THREE

Responsibilities

MC Theme	Responsible Department(s)
Import Control	DCD
SF Detection & Response	PVDID, PLD and CQCL
Supply-Chain Quality Surveillance	PLD and CQCL
Promotional & Advertising Control	PLD and PVDID
Coordination Platform Meetings	Representatives from the concerned departments

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	October 2025
2		
3		

References:

Ministry of Health, Oman – Pharmacovigilance & Drug Information Department (2017). *Guideline on Good Pharmacovigilance Practices in Oman for Marketing Authorization Holders*. Muscat: Ministry of Health.

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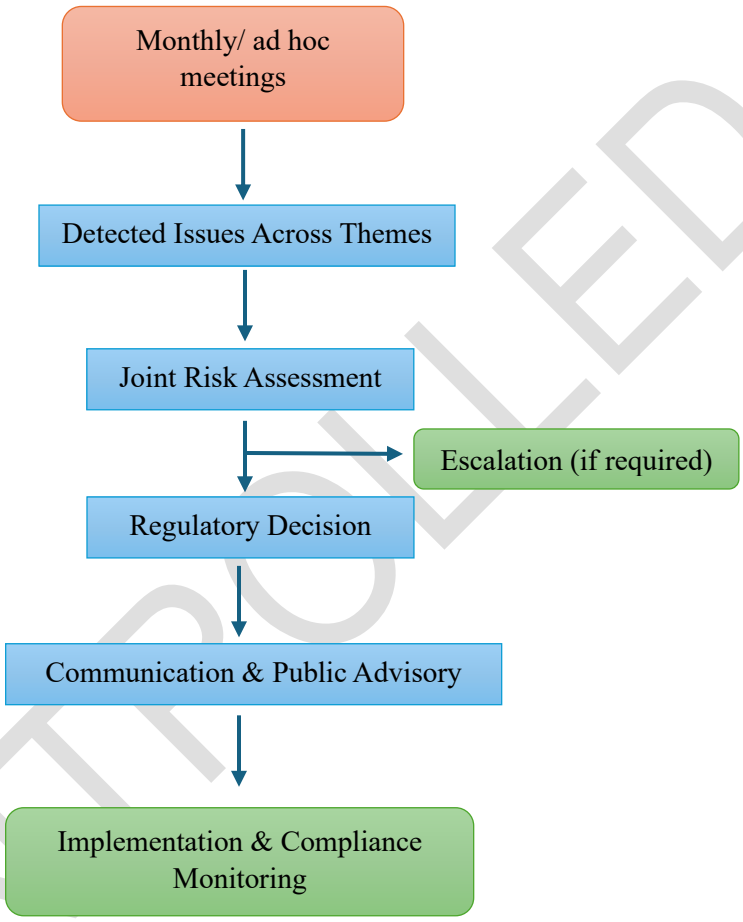
Ministry of Health 2020, *Ministerial Decision No. 135/2025 on the Conditions and Procedures for Medicine Advertising*, Official Gazette, Muscat.

World Health Organization (2020) *Guidance for Post-Market Surveillance and Market Surveillance of Medical Devices, Including In Vitro Diagnostics*. Geneva: World Health Organization.

Annexes

Appendix 1: Inter-Departmental Coordination Process Flow Chart



Appendix 2: Coordination Meeting Minutes Template

(For Monthly/ ad hoc inter-departmental meetings)

Meeting Date	
Meeting Type	☐ Regular ☐ Urgent
Chairperson	
Departments Present	☐ DCD ☐ PV&DID ☐ PLD ☐ CQCL ☐ Others
Agenda Points	1. 2. 3.
Key Issues Discussed	
Risk Triage Summary	
Agreed Actions & Responsible Department(s)	
Deadline for Follow-up	
Next Meeting	
Prepared by	