
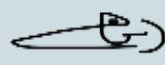


Guideline on Communication, Decision-Making, Escalation and Coordination for Drug Safety Center

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Acronyms:

CAPA	Corrective and Preventive Action
CQCLD	Central Quality Control Laboratory
DCD	Drug Control Department
DSC	Drug Safety Center
MAH	Marketing Authorization Holder
MDCD	Medical Device Control Department
MOH	Ministry of Health
PE	Pharmaceutical Establishments
PLD	Pharmaceutical Licensing Department
PVDID	Pharmacovigilance & Drug Information Department
RMP	Risk Management Plan
SOP	Standard Operating Procedure

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Definitions

Communication Channel	A structured pathway for information exchange externally and among DSC departments to ensure efficiency and regulatory compliance.
Decision-Making Process	The structured approach DSC departments follow to assess, discuss, and implement regulatory and operational decisions.
Stakeholder Engagement	The interaction between DSC and external entities such as pharmaceutical companies, healthcare professionals, and regulatory bodies.
Albarwa System	The MOH internal correspondence and communication platform used across all MOH departments and offices.
MOH e-Portal	A centralized online platform managed by the Ministry of Health that provides a wide range of electronic health services to different user groups—citizens, residents, healthcare professionals, government entities, and private organizations

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CHAPTER ONE

Introduction

Clear communication and effective decision-making and escalation pathways are essential to ensure regulatory consistency and transparency within the Drug Safety Center (DSC).

Purpose

The aim of this guideline is to:

- Define standardized communication channels
- Establish a clear decision-making framework.
- Enhance interdepartmental collaboration.
- Ensure timely and efficient regulatory responses.
- Improve documentation and reporting of decisions.

Scope

This guideline applies to all regulatory activities conducted by the DSC.

Structure

This first edition of the guideline is organized into four main chapters: CHAPTER ONE covers the introduction, purpose, scope, and structure of the document. CHAPTER TWO covers methods & procedures. CHAPTER THREE covers the responsibilities, while CHAPTER FOUR covers the document version control, references and annex.

CHAPTER TWO

Methods

2.1 Internal Communication Channels

The DSC Departments and Sections will communicate through the following structured channels:

- **DSC & Departments Formal Email:** For formal updates, notifications, requests, approvals, and official correspondence.
- **Scheduled Meetings:** Regularly convened coordination meetings to share ongoing regulatory activities, plan operations, and follow up on action items.
- **Emergency Alerts:** Immediate communication using secure messaging or phone calls for urgent and critical safety concerns.
- **Shared Central Databases:** Centralized data storage for reports and records.
- **Albarwa System:** The official MOH internal correspondence platform for all formals inter-DSC communications, ensuring traceability and structure.

2.2 External Communication Channels

All external communications from DSC regarding regulatory decisions and other matters are distributed to stakeholders via the appropriate channels. The external communication channels include:

- **DSC & Departments Formal Email:** Notifications, decisions, acknowledgements, updates and responses to stakeholders.
- **Scheduled Stakeholder Meetings:** Regular meetings to discuss active and other regulatory matters.
- **MOH e-Portal:** Official online interface allowing stakeholders (e.g. MAHs, local agents, PEs, and Health institutions) to submit documents, receive approvals, and access updates.

- **MOH / DSC website:** Serves as a platform for sharing timely information and for providing public access to legal provisions, guidelines, safety notices, circulars and decisions.
- **Official Letters:** Serve as the formal means by which the DSC communicates with external stakeholders—submitting requests, providing explanations, or documenting official decisions.
- **Official Circulars:** DSC regulatory communications (e.g., recalls, safety alerts or updates, regulatory updates) published publicly on the MOH website.
- **Phone & Fax:** Reserved for urgent notifications or time-sensitive interaction where immediate confirmation is needed
- **Workshops & Seminars:** DSC-led training sessions or outreach events (e.g., to pharmaceutical establishments) for communicating new or revised regulations, ensuring stakeholder awareness and compliance.
- **Press and Media Communications:** DSC utilize these channels to ensure wider public awareness, regulatory transparency, and engagement via both traditional media (print, TV, radio) and digital/social platforms.
- **Newsletters & Bulletins:** Issued at regular intervals to update stakeholders and the public on safety information, regulatory developments, and educational content. These serve as reminders of previous public communications and reinforce ongoing messaging.
- **Annual Reports:** Comprehensive yearly publications that provide transparency on DSC's performance, regulatory outcomes, key safety interventions, statistical summaries and strategic priorities—serving both internal and public accountability.

2.3 Decision-Making Levels

Decisions within DSC follow a hierarchical framework:

1. **Routine Decisions** (Department/Section level): Managed within individual departments and sections (e.g., report evaluations, report assessments, licensing updates).
2. **Intermediate Decisions** (Cross-department/ section level): Require collaboration between departments and or sections (e.g., recalls, risk assessments).

3. **Strategic Decisions** (Executive or MOH-level): Major decisions needing MOH-level involvement (e.g., policy changes, high-risk regulatory matters).

2.4 Escalation Procedures

For unresolved or high-risk issues, the following escalation protocols are as follows:

1. **Department/ Section Level** – Initial attempts to resolve within the originating department/ section.
2. **Inter-departmental Consultation** – If unresolved, engage broader departmental discussion involving all relevant stakeholders.
3. **Referral to DSC Director General** – For final resolution at the DSC executive level.
4. **MOH Involvement** – For high-level policy or national regulatory decisions, escalate to MOH leadership or Under-Secretary level for ministry-wide coordination.

2.5 Mechanisms for Coordination

To ensure effective coordination among DSC Departments and Sections:

- **Interdepartmental Committees:** Establish committees with representatives from each department/ section to address cross technical regulatory issues.
- **Joint Task Forces:** Form temporary task forces for specific projects or emerging issues requiring multi-departmental expertise.
- **Focal Points:** Each department assigns a designated contact point to streamline communication, follow-up, and consistency across departments/ sections.

CHAPTER THREE

Responsibilities:

1. DSC Departments

DSC Departments	Primary Responsibilities in Communication & Decision-Making
PVDID	Initiates signal reporting, safety communications, and internal/external escalation of ADRs or quality issues.
CQCL	Communicates laboratory findings and quality assurance data to inform risk assessments and regulatory decisions.
DC	Manages registration and pricing of medicines, regulates import/export and control of controlled substances, and oversees release of medical products from customs. Communicates regulatory status and compliance updates to internal and external stakeholders.
MDC	Issues alerts or recalls related to medical devices and coordinates action across departments.
PL	Communicates licensing decisions, compliance requirements, and engages in stakeholder liaison.

2. Stakeholders (e.g. MAHs, PEs, Health Institutions, Public):

Receive and respond to DSC communications via formal channels (e-portal, email, official letters, workshops).

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	October 2025
2		
3		

References:

European Medicines Agency (EMA). (2012a) *Guideline on good pharmacovigilance practices (GVP) – Module I: Pharmacovigilance systems and their quality systems*. EMA/541760/2011.

European Medicines Agency (EMA). (2013) *Guideline on good pharmacovigilance practices (GVP) – Module XV: Safety communication (Rev 1)*. EMA/118465/2012 Rev 1.

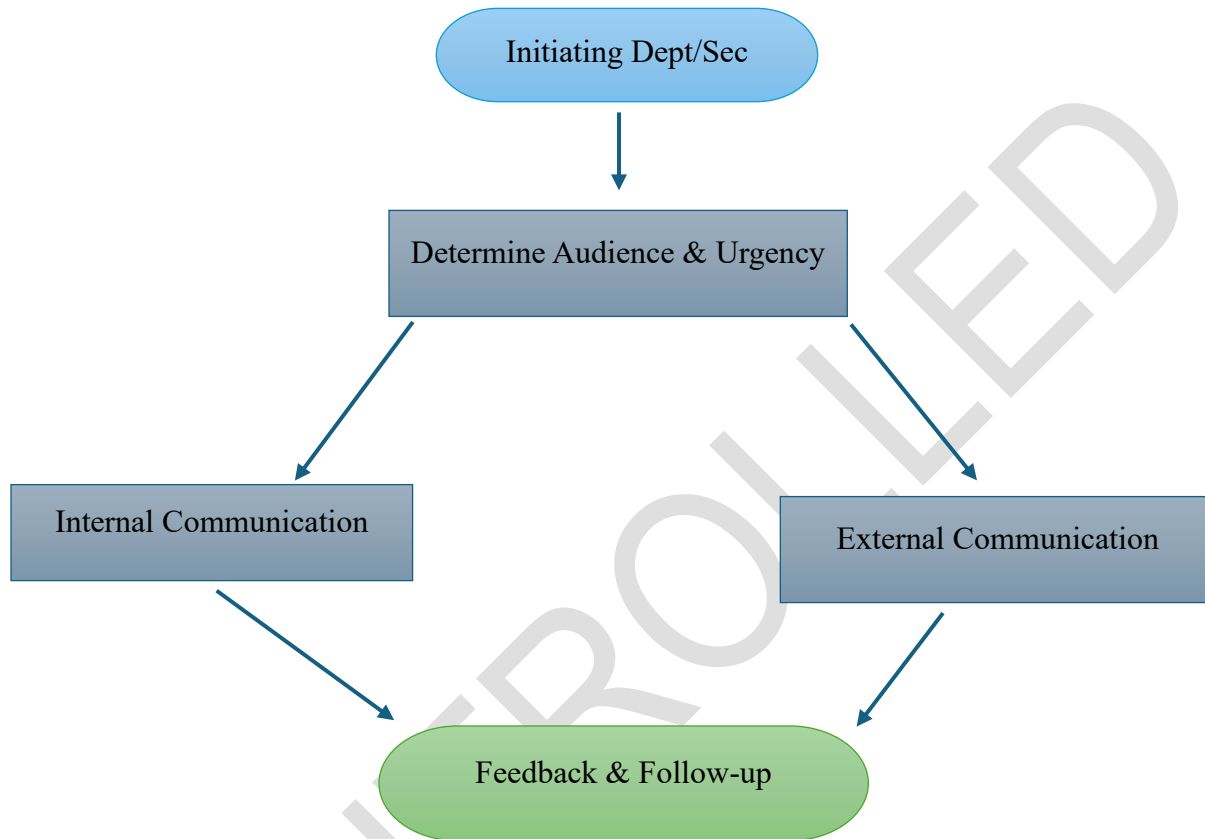
International Organization for Standardization (2015) *ISO 9001:2015(E) Quality management systems — Requirements*. Geneva, Switzerland: ISO.

League of Arab States / WHO-UMC (2015) *Guideline on Good Pharmacovigilance Practices for Arab Countries*, Version 3.

Ministry of Health, Oman (2017) *Guideline on Good Pharmacovigilance Practices in Oman for MAHs/Pharmaceutical Companies*, Version 1.

Annexes

Appendix 1: DSC Communication Channel Flowchart



Appendix 2: DSC Escalation Process Flowchart

