وزارة الصحة
Ministry of Health

DSC
مركز سلامة الدواء
Drug Safety Center

Guideline on Public Communication of Regulatory Information and Decisions

Drug Safety Center

2026

First Edition

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4 Acronyms

CD	Concerned Department
DG-DSC	Director General, Drug Safety Center
DSC	Drug Safety Center
ITFP	Information Technology Focal Point
MOH	Ministry of Health, Sultanate of Oman
SOP	Standard Operating Procedure

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7 Definitions

Confidential Information	Any document, material, or information of a proprietary, personal, or non-public nature that DSC or a third party is obliged to protect from unauthorized disclosure.
Concerned Department	The DSC department or section responsible for the regulatory activity that gives rise to the information or decision being communicated.
Public Communication	The act of making regulatory information or a regulatory decision available to the public or to specific stakeholders through an approved channel.
Publication Channel	An approved medium through which DSC makes information public, such as the official DSC/MOH website, an official bulletin, or a press release.
Regulatory Decision	A formal determination issued by DSC in the exercise of its regulatory functions, including an approval, rejection, suspension, cancellation, or other action affecting a medicine, medical device, establishment, facility, or regulated activity.
Restricted Information	Information that is not classified as confidential but that is disclosed only to specified stakeholders rather than the general public.
Stakeholder	Any person, organization, or entity with an interest in DSC's regulatory activities, including pharmaceutical establishments, healthcare professionals, patients, and the general public.

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CHAPTER ONE

Introduction

The Drug Safety Center (DSC) is responsible for regulatory decisions that affect public health, and for the legislation, regulations, guidelines, and procedures under which those decisions are made. Operating transparently and communicating regulatory information to the public in a timely and accurate manner, is a core part of how DSC discharges that responsibility and maintains the trust of regulated industry, healthcare professionals, and the public.

This Guideline sets out a single, consistent process for how regulatory information and decisions move from being finalized internally to being made available externally, so that publication is accurate, appropriately authorized, and properly recorded regardless of which DSC department originates it.

Legal Basis

- Royal Decree No. 35/2015 promulgating the Law Regulating the Practice of the Pharmacy Profession and Pharmaceutical Establishments.
- Ministerial Decision No. 113/2020 issuing the Executive Regulation of RD No. 35/2015.
- Royal Decree No. 6/2022 promulgating the Personal Data Protection Law.

Purpose

The purpose of this guideline is to establish a consistent process for identifying, classifying, reviewing, and publishing regulatory information and decisions.

Scope

This guideline applies to all DSC personnel involved in communicating regulatory information and decisions, including legislation, regulatory documents, final decisions, safety and other regulatory information.

Structure

This is the first version of this guideline, and it consists of four chapters. CHAPTER ONE covers the introduction, the purpose, the Scope and the Structure of the guideline. CHAPTER TWO explains the procedure of the guideline. CHAPTER THREE covers the responsibilities. CHAPTER FOUR comprises the document history and version control table, references and Annexes included.

CHAPTER TWO

Methods and Procedures

2.1 Guiding Principles

DSC's public communication is guided by the following principles:

- **Accuracy:** published information reflects the final, approved regulatory record.
- **Timeliness:** information is published within the timeframes set out in Appendix 2 once a decision is final.
- **Accessibility:** information is published in a location and format the intended audience can reasonably find and understand.
- **Consistency:** the same category of information is published through the same channel and format on every occasion.
- **Confidentiality by exception:** information is public by default; it is withheld only where it meets a defined confidentiality or restriction criterion.
- **Accountability:** every publication has a documented origin, reviewer, and approver.

2.2 Categories of Public Information

2.2.1 Legislative and Procedural Information

The laws, regulations, guidelines, procedures and other document types that DSC administers are published and kept current. Where a document is for internal use only (such as Standard Operating Procedure (SOP) or an internal work instruction), it is excluded from public communication, and this is recorded at the point the document is approved.

2.2.2 Regulatory Decisions

Final regulatory decisions are communicated to the public, together with the information needed to understand the basis for the decision. This includes both decisions to approve and decisions to reject, suspend, or cancel, except where a specific legal provision restricts the publication of a negative decision.

As required by law, final decisions to suspend a professional or establishment licence, or cancel or close a pharmaceutical establishment, are published in two daily newspapers at the affected party's expense and through DSC's approved electronic channels.

2.2.3 Information to Be Published for Each Category

For each category of public information, DSC publishes the information necessary to identify the relevant document, decision, product, establishment, or regulatory action and to understand or verify its current status. The applicable publication format, channel, and timeframe are set out in the relevant appendix.

2.3 Public Communication Process

2.3.1 ***Identify and initiate:*** the concerned department (CD) identifies, on finalizing a regulatory action, decision, or document, that the item falls within a category of information required to be publicly communicated under this guideline, and initiates the public communication process.

2.3.2 ***Prepare the information:*** the CD prepares accurate, complete content reflecting the approved decision or document, in the required format and language.

2.3.3 ***Review accuracy and disclosure:*** the prepared content is reviewed for accuracy and completeness by the head of the CD, and is classified as Public.

2.3.4 ***Authorize release:*** clearance to publish is obtained from the head of the CD; matters of significant public interest are cleared by DG-DSC before release.

2.3.5 ***Publish and verify:*** publish the approved content through the appropriate channel and verify its accuracy and accessibility. For website publication, submit the approved content and required metadata to ITFP in accordance with the relevant DSC guideline

2.3.6 ***Maintain access:*** keep published information accessible while it remains current.

2.3.7 ***Update and retain:*** regularly review published information, update, correct, or withdraw it as needed, issue correction notices where necessary, and retain the content and approval records according to DSC requirements.

2.4 Publication Channels

Regulatory information and decisions are published through one or more of the following approved channels:

- The official DSC / Ministry of Health website.
- Official bulletins or gazette notices.
- Press releases and media statements, for matters of significant public interest.
- Other electronic or e-government platforms designated by DSC.
- Media channels, including newspapers, television, and social media, particularly where publication through a specific medium is required by law or otherwise warranted by the significance of the matter.

2.5 Confidential and Restricted Information

Information is withheld from public communication, in whole or in part, where it falls into one of the following categories:

- Personal data relating to an identifiable individual, beyond what is necessary to identify a regulated product, entity, or decision, handled in accordance with Oman's Personal Data Protection Law.
- Commercially sensitive or proprietary information supplied by stakeholders, such as trade secrets or undisclosed technical data.
- Information whose disclosure is restricted by a specific legal provision.
- Information relating to an ongoing investigation, inspection, or assessment, where premature disclosure could prejudice that process.

2.6 Language and Accessibility

Regulatory information is published in English, with Arabic provided where required or appropriate for the intended audience.

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138 ## Responsibilities:

Role	Responsibilities
DG-DSC	Final clearance for public communications of significant public interest.
DSC Departments	Identifying and classifying public communications and ensuring their accuracy within each department's roles and responsibilities.
ITFP	Maintaining DSC's publication channels

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CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	
2		
3		

References:

Sultanate of Oman (2015). Royal Decree No. 35/2015 promulgating *the Law Regulating the Practice of the Pharmacy Profession and Pharmaceutical Establishments*. Muscat: Sultanate of Oman.

Ministry of Health, Sultanate of Oman (2020). Ministerial Decision *No.* 113/2020 issuing *the Executive Regulation of the Law Regulating the Practice of the Pharmacy Profession and Pharmaceutical Establishments*. Muscat: Ministry of Health.

Sultanate of Oman (2022). Royal Decree No. 6/2022 promulgating *the Personal Data Protection Law.* Muscat: Sultanate of Oman.

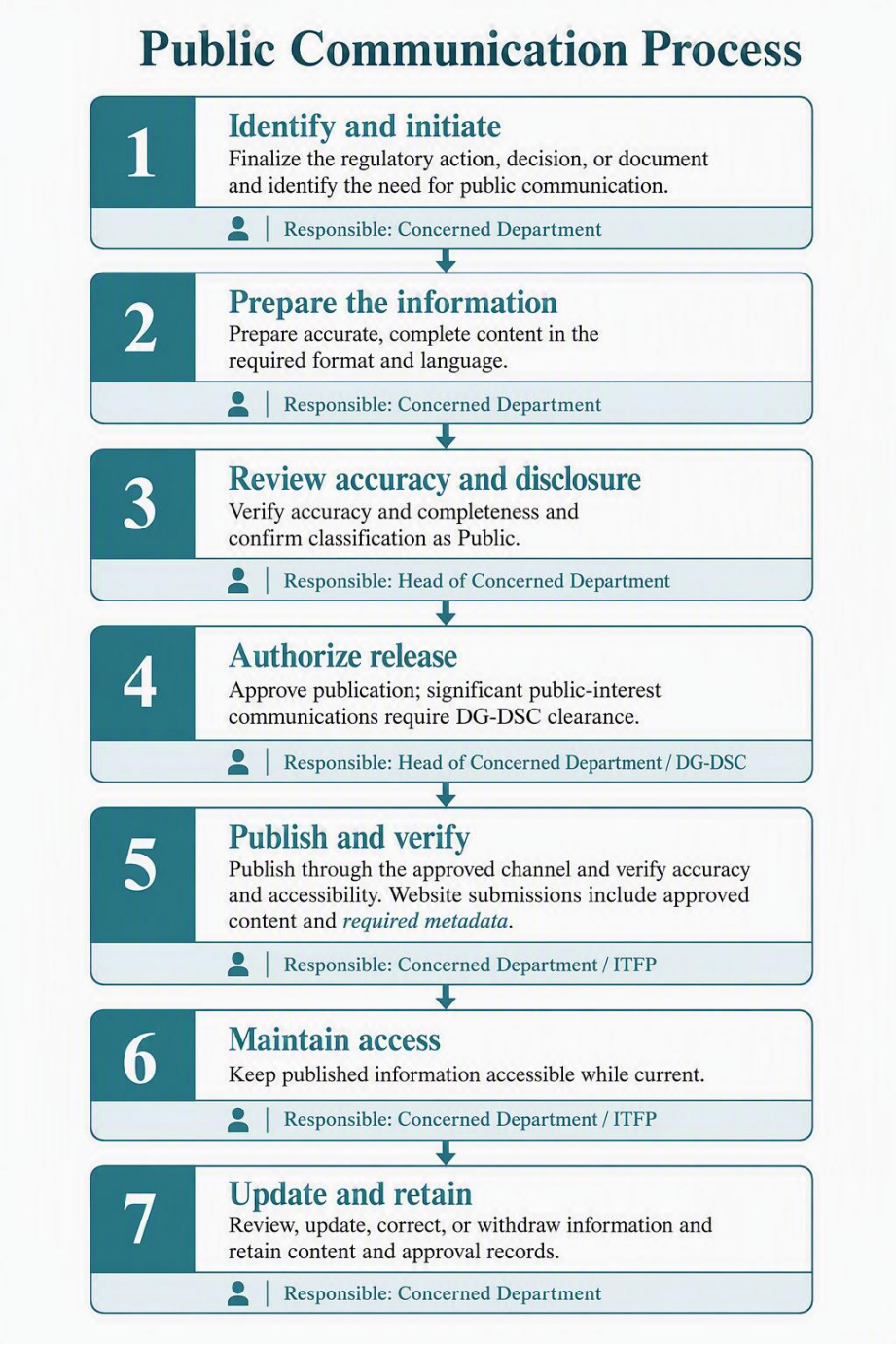
World Health Organization (2021). *WHO Global Benchmarking Tool for Evaluation of National Regulatory Systems of Medicines and Vaccines.* Revision VI, indicators RS09.02–RS09.06, Category 08: Transparency, Accountability and Communication. Geneva: World Health Organization.

World Health Organization (2021). '*Good regulatory practices in the regulation of medical products'*, in WHO Expert Committee on Specifications for Pharmaceutical Preparations*: Fifty-fifth Report*. WHO Technical Report Series, No. 1033, Annex 11. Geneva: World Health Organization.

World Health Organization (2001). How to *Develop* and *Implement* a *National Drug Policy*. 2nd edn. Geneva: World Health Organization.

Annexes

Appendix 1 Public Communication Process



Appendix 2 Publication Formats, Channels and Timeframes

Content Type	Format	Channel	Target Timeframe
Laws, regulations, guidelines, procedures	Full text of the document, as approved	DSC / MOH website	Within 10 working days of approval or amendment
Regulatory decisions (approvals, rejections, suspensions, cancellations)	Formal decision notice, including a summary of the basis for the decision	DSC / MOH website; official bulletin	Within 10 working days of the decision becoming final
Registers products / licensed establishments	Searchable or browsable register or list	DSC / MOH website	Updated continuously
Matters of significant public interest (e.g., safety-related recalls)	Press release or public statement	Press release; DSC / MOH website	As soon as practicable following clearance
Media publications (e.g., newspapers, television, social media), including where a specific medium is required by law	Public notice text, in the form required by the applicable medium	Newspapers, television, social media, or other media appropriate to the matter	As required by the applicable legal provision; otherwise as soon as practicable following clearance

Appendix 3 Procedure for Submission of Content to ITFP for Website Publication

To ensure a streamlined process for publishing approved content to the Ministry of Health website, the CD follows these steps:

Document Preparation and Internal Approval

- **Content Finalization:** ensuring the document is complete, accurate, and adheres to the standards set by DSC.
- **Internal Review:** conducting a thorough review within the CD to validate the content and ensure consistency with existing regulations, policies, and guidelines.
- **Approval Acquisition:** obtaining the necessary approvals from authorized personnel or committees within the CD, with the approval process documented for record-keeping.

Metadata Compilation

The following metadata is prepared to accompany the document:

- **Document Title:** a title that clearly reflects the content and purpose of the document.
- **Document Type:** the type of document (for example, Guideline, Circular, or Policy).
- **Version Number:** the applicable version (for example, v1.0, v2.1).
- **Effective Date:** the date from which the document is applicable, in DD-MM-YYYY format.
- **Issuing Department/Section:** the name of the Department or Section responsible for the document.
- **Summary:** a brief overview of the document's purpose and key points.
- **Keywords/Tags:** relevant terms that facilitate searchability on the MOH website.

Submission to ITFP

- **Cover Communication:** an official email, memorandum, or Al Barwa system entry is sent using the standardized template provided by ITFP.

- **Attachments:** the finalized document, in PDF format, and the compiled metadata, provided either as a separate document or within the body of the communication, are attached.
- **Submission:** the complete package is sent to the designated ITFP contact responsible for website content management.

ITFP Processing and Upload

- **Receipt Confirmation:** ITFP acknowledges receipt of the submission to the CD.
- **Content Review:** the document and metadata are reviewed by ITFP for completeness and conformity with website standards.
- **Website Upload:** the document is uploaded to the appropriate section of the MOH website.
- **Notification:** confirmation of successful upload is sent to the CD by MOH email or Al Barwa.

Post-Upload Verification

- **Content Verification:** the CD reviews the uploaded document to confirm accuracy, proper formatting, and correct placement on the website.
- **Discrepancy Reporting:** any issues or discrepancies identified are promptly reported to ITFP for rectification.