DRAFT FOR COMMENTS:

Guideline on Public Consultation by the Drug Safety Center

Draft Disclaimer

Guideline on Public Consultation by the Drug Safety Center

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Acronyms:

DSC	Drug Safety Center
ITS	Information Technology Section
MAH	Marketing Authorization Holder
MOH	Ministry of Health
PC	Pharmaceutical Companies
PE	Pharmaceutical Establishment
QASM	Quality Assurance and Safety Management Section

Definitions

Public Consultation	The process where stakeholders and the public are invited to provide feedback on draft regulations, guidelines, or documents.
Stakeholders	Entities or individuals affected by or interested in the document under consultation, including healthcare professionals, patients, marketing authorization holders (MAHs) and pharmaceutical companies (PCs).

CHAPTER ONE

Introduction

The Drug Safety Center (DSC) plays a crucial role in ensuring the safety, efficacy, and quality of medicines, medical devices, and related products in the Sultanate of Oman. Public consultation of documents is an essential mechanism that enables the DSC to engage stakeholders in the development and review of regulatory guidelines, procedures, and safety measures. This guideline has been developed to formalize the process of public consultation and ensure inclusivity, transparency, and accountability.

Legal basis

Purpose

The purpose of this guideline is to outline the procedures for conducting public consultations for DSC documents, ensuring that all relevant stakeholders have an opportunity to participate in the development and review of regulations. The guideline aims to ensure that DSC documents are comprehensive, clear, and aligned with best practices and stakeholder needs.

Scope

This guideline applies to all public consultation processes conducted by the DSC, including consultations on draft regulations, guidelines, and safety measures for human medicines, herbal products, medical devices, and related products.

Structure

This is the first version of this guideline, and it consists of four chapters. CHAPTER ONE covers introduction to the guideline as well as its purpose, scope and structure. CHAPTER TWO covers the procedure. CHAPTER THREE covers the responsibilities. CHAPTER FOUR comprises of the document version control, followed by references and an annexe.

CHAPTER TWO

Procedure

2.1 Initiating the Consultation

The consultation process is initiated when a draft document from any DSC department is deemed ready for stakeholder feedback. A notification is sent to stakeholders, and the draft document is published on the Ministry of Health (MOH) website for review.

2.2 Stakeholder Engagement

Relevant stakeholders, including healthcare professionals, MAHs, PCs and the public, are invited to participate in the consultation. The consultation period is typically 15-30 days, depending on the complexity of the document. Stakeholders can submit feedback via the MOH e-portal or other approved communication channels.

2.3 Feedback Review and Analysis

At the end of the consultation period, the relevant DSC department reviews all feedback and suggestions recorded in the public consultation feedback entry logbook. Based on the collected input, the department prepares a report summarizing the stakeholder feedback and detailing the proposed revisions to the draft document.

2.4 Finalizing the Document

The document is revised based on the feedback analysis. If significant changes are made, a second round of consultation may be initiated. Once finalized, the document is submitted for approval by the DSC and subsequently published on the MOH website.

CHAPTER THREE

Responsibilities

- *DSC Departments:* Responsible for preparing and submitting draft documents for consultation.
- *QASM:* Manages the documents validation.
- *ITS*: Responsible for uploading the draft and final documents to the MOH website.
- *Stakeholders*: Provide feedback within the specified timeframe, ensuring their input is relevant and constructive.

CHAPTER FOUR

Document History and Version Control Table

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

References

United Nations Development Programme, 2012. *Manual on public consultations for the Provincial People's Councils*. UNDP.

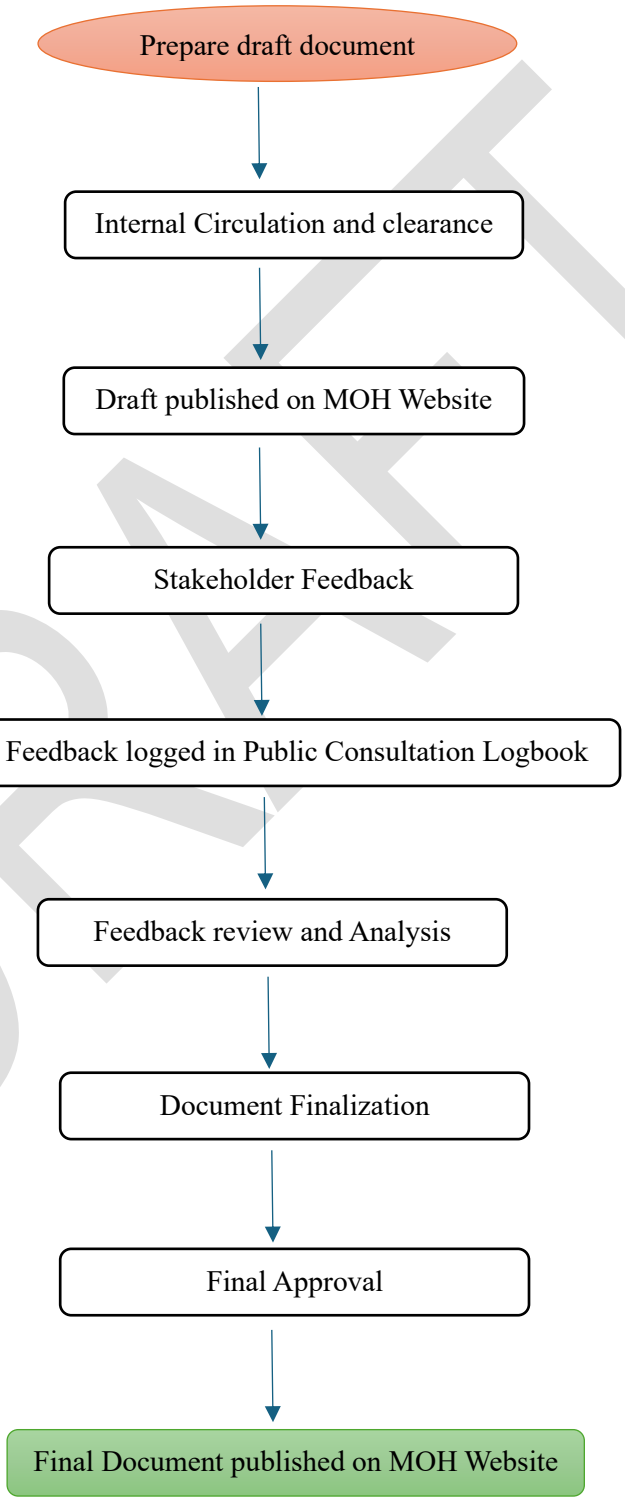
Office of Best Practice Regulation, 2025. *Best Practice Consultation Guidance Note*. Queensland Government.

International Council for Harmonisation (ICH), n.d. *Public consultations on draft technical guidelines*. ICH.

World Health Organization, 2023**.** *Public consultation on WHO guidance for best practices for clinical trials: call for input on draft guidance*. WHO, 19 July-15 September 2023.

Annex

Appendix 1 Public Consultation Process Flow Chart



Appendix 2: Template for Public Consultation Notification

Public Consultation Notification

Date: / /

Circular No:

Subject: Invitation for Public Consultation on [Document Title] (Version [version number])

Dear Stakeholders,

The Drug Safety Center (DSC) invites you to participate in the public consultation on the draft document titled **[Document Title]**, version **[version number]**. This document has been developed by the **[Department Name]** to [brief description of the document's purpose].

Consultation Details:

- *Consultation Period*: From [start date] to [end date]
- *Document Available At*: [Link to MOH/DSC website where the document can be accessed]
- *Submission of Feedback:* Please submit your feedback using the *Public Consultation Feedback Submission Form*. Completed forms can be submitted via:
  - Email: **[contact email]**
  - MOH e-Portal: **[portal link]**

Key Information:

- The DSC values the participation of all stakeholders, including [state the stakeholders], in reviewing this draft document.
- All feedback will be considered, and the document will be revised accordingly. A summary of the consultation outcomes will be shared with all contributors.
- The consultation period will end on **[end date]**.

We look forward to your valuable input to help ensure that our regulatory processes are transparent and inclusive.

For any inquiries, please contact:

- Name: [Contact Person]
- Position: [Position]
- Email: [Email Address]
- Phone: [Phone Number]

Thank you for your participation.

Sincerely,
[Name]
[Title]
Drug Safety Center (DSC)
Ministry of Health

Appendix 3: Template for Public Consultation Notification on the MOH Website

Public Consultation Notification on the MOH Website

Subject: Invitation for Public Consultation on [Document Title] (Version [version number])

Overview:

The Drug Safety Center (DSC) is inviting stakeholders and the public to participate in a public consultation on the draft document titled *[Document Title]*. This document has been developed by the *[Department Name]* to *[brief description of the document's purpose]*.

Consultation Details:

- **Start Date**: [start date]
- **End Date**: [end date]
- **Feedback Submission Deadline**: [end date]
- **Target Audience**: [List the stakeholders]

How to Participate:

1. **Review the Draft Document**:
   The draft document **[Document Title]** (Version [version number]) is available for download: [Link to document or PDF download]
2. **Submit Your Feedback**:
   Please submit your comments and suggestions using the *Public Consultation Feedback Submission Form.*
   You can submit feedback through one of the following channels:
   - **Email**: Send the completed form to **[email@example.com]**
   - **MOH e-Portal**: Submit your feedback through the e-Portal: [Portal link]
3. **Consultation Timeline**:
   - The public consultation will run from **[start date]** to **[end date]**.
   - Feedback submitted after **[end date]** will not be considered in the final document revision.

Key Areas for Feedback:

We encourage feedback on the following areas of the draft document:

- Clarity and comprehensiveness of the document
- Impact of the proposed regulations/guidelines on stakeholders
- Suggestions for improvement
- Specific areas where additional information or guidance is needed

Contact Information:

If you have any questions or require further information, please contact:

- **Contact Person**: [Name]
- **Email**: [Email Address] **Phone**: [Phone number]

What Happens Next?

Once the consultation period ends, all feedback will be reviewed by the relevant department. A report summarizing the feedback, and any changes made to the document will be shared with stakeholders. The final version of the document will be published on the MOH website.

Thank you for your participation and valuable feedback in shaping the future of health regulation in the Sultanate.

Drug Safety Center (DSC)
[Date]

Appendix 4: Template for Public Consultation Feedback Submission ***(English)***

Public Consultation Feedback Submission Form

Date of Submission: / /

Submission of Comments on: [Document Titel]

1. Stakeholder Information

Name of Organization/Individual	
Email Address	
Phone Number	

2. Feedback

Line Number (s)	Feedback/Suggestion

(Please attach additional pages if necessary)

Section 3: General Comments