DRAFT FOR COMMENTS:

Guideline on Conditional Approval of medicines and Emergency Use

Draft Disclaimer

Guideline on Conditional Approval of medicines and Emergency Use Authorization

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Acronyms:

CTD	Common Technical Document
DSC	Drug Safety Center
eCTD	Electronic Common Technical Document
GCC	Gulf Countries
PVD	Pharmacovigilance Departments
PIL	Patient Information Leaflet
PSUR	Periodic safety update reports
SPC	Summary of Product Characteristics

Definitions

Conditional MA	The approval of a medicine that addresses unmet medical needs of patients and in the interests of public health, on the basis of less comprehensive data than normally required. The available data must indicate that the medicine's benefits outweigh its risks and the applicant should be in a position to provide the comprehensive clinical data in the future.
life-threatening diseases	are chronic, usually incurable diseases, which have the effect of considerably limiting a person's life expectancy. These include, cancer, diabetes, neurological conditions, coronary heart disease and HIV/Aids.
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.
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.
Orphan medicines	is a drug intended for use in a rare disease.
Pandemic	is an epidemic of an infectious disease that has a sudden increase in cases and spreads across a large region, for instance multiple continents or worldwide, affecting a substantial number of individuals.
Rolling Submission	is an ad hoc procedure that allows DSC to continuously assess the data for upcoming highly promising medicinal products as they become available.

CHAPTER ONE

Introduction

The Drug Safety Center supports the development of new medicines to address the unmet medical need in the treatment of a serious or life-threatening condition. In the interest of public health, applicants may be granted a conditional marketing authorization for such medicines on less comprehensive clinical data than normally required, where the benefit of immediate availability of the medicine outweighs the risk inherent in the fact that additional data are still required.

Medicines for human use are eligible if they are intended for treating, preventing or diagnosing seriously debilitating or life-threatening diseases. This includes orphan medicines.

Its use is also intended for a public health emergency (e.g., a pandemic). For these medicines, less comprehensive pharmaceutical and non-clinical data may also be accepted.

Legal Basis

Article 32 and 33 of Chapter 4 of the Royal Decree 35/2015 (Issuing the Law Regulating the Practice of Pharmacy and Pharmaceutical Enterprises).

Purpose

To standardize the submission process, including applications for Conditional Marketing Authorization, by adopting harmonized dossier formats to ensure clarity, consistency, and efficiency in the regulatory review of medicinal products.

Scope

This document shall apply to new medicinal products for human use and subjected to specific obligations in accordance with DSC’s requirements.

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

GRANTING OF A CONDITIONAL APPROVAL

1. Eligibility Criteria

This document shall apply to new medicinal products for human use and belong to one of the following categories:

1.1. Medicinal products which aim at the treatment, the prevention or the medical diagnosis of seriously debilitating diseases or life-threatening diseases. The severity of the disease, i.e., its seriously debilitating, or life-threatening nature needs to be justified, based on objective and quantifiable medical or epidemiologic information. Whereas a life-threatening disease is relatively easy to describe based on figures of mortality and life expectancy, justifying that a disease is seriously debilitating will have to consider morbidity and its consequences on patients' day-today functioning. For a disease to be considered seriously debilitating it would need to have a well-established major impact on patients' day-to-day functioning either already early in the course of the disease, or in the later stages. These aspects should be quantified in objective terms, as far as possible.

1.2. Medicinal products to be used in emergency situations; such as in the situation of a pandemic; in response to public health threats duly recognized either by the World Health Organization or by the Ministry of Health of Sultanate of Oman.

2. Requirements

A conditional approval may be granted for conditionally approved designated products where DSC finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all of the following requirements are met:

2.1. The risk-benefit balance of the medicinal product is positive for the demonstration of a positive benefit-risk balance, the available evidence should be sufficient to demonstrate the benefits of the medicinal product to a degree that allows them to be assessed against the risks identified in the studies conducted and the risks related to the absence of some of the data. A

comprehensive non-clinical and pharmaceutical data should be available and only the clinical data could be less comprehensive than is normally the case. Occasionally, DSC may, in its discretion, accept incomplete preclinical or pharmaceutical data, such applications will be assessed on a case-by-case basis. The data that are not available at the time of application and authorization should be discussed by the applicant, and the acceptability of less comprehensive data justified, based on the strength of available results, and taking into account the requirement for a positive benefit-risk balance. The establishment of beneficial effects at the time of authorization could potentially be based on endpoints that are fully validated surrogate endpoints and reasonably likely to translate into clinical benefit, but do not directly measure the clinical benefit. The safety profile of the medicinal product should be adequately defined and appropriate to justify a positive benefit-risk balance. The acceptability of safety of the medicinal product must be assessed on a case-by-case basis, based on the available safety data and taking into account the demonstrated benefits of the medicinal product.

2.2. It is likely that the applicant will be in a position to provide the comprehensive clinical data by way of specific obligations, the holder of a conditional approval shall be required to complete ongoing studies or to conduct new studies, with a view to provide comprehensive clinical data confirming that the benefit-risk balance is positive. The applicant should explain how comprehensive data can be provided within an agreed timeframe. The applicant is strongly encouraged to discuss in advance of the submission of an application the overall development plan and design of studies that, on one hand, are planned to be completed before authorization and, on the other hand, will be conducted as specific obligations following the granting of a conditional approval.

2.3. Unmet medical needs will be fulfilled the unmet medical needs mean a condition for which there exists no satisfactory method of diagnosis, prevention or treatment or, even if such a method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected. To address this requirement, applicants should justify that there exists an unmet medical need and that it is necessary to introduce new methods when no satisfactory methods exist, or that it is necessary to provide a major improvement over the existing methods. The demonstration of fulfilment of an unmet medical need has to be justified on a case-by-case basis. The justifications should quantify the unmet medical need based on medical or epidemiologic data. In general, major therapeutic advantage would normally be based on meaningful improvement of efficacy or clinical safety. The advantages should be demonstrated over existing methods used in clinical practice (if any), using robust evidence, normally from well conducted

randomized controlled trials (evidence-based demonstration of benefit). In order to support the claim that unmet medical needs will be fulfilled, the applicant shall provide: - A critical review of available methods of prevention, medical diagnosis or treatment, highlighting an unmet medical need. - Quantification of the unmet medical need taking into account technical argumentation (e.g., quantifiable medical or epidemiologic data). - A justification of the extent to which the medicinal product will address the unmet medical need.

2.4. The benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required the applicant will have to provide a justification to substantiate the claim that the benefits to public health of the immediate availability of the medicinal product outweigh the risks inherent in the fact that additional data are still required. The justification should assess the impact of immediate availability on public health, based as far as possible on objective and quantifiable epidemiological information, as opposed to availability when comprehensive clinical data are expected to be available. Similarly, the risks inherent in the fact that additional data are still required shall be quantified as far as possible on objective and quantifiable terms. In order to support the claim that the benefits to public health outweigh the risks inherent in the fact that additional data are still required, the applicant will have to provide a justification addressing the following points:

- Benefits to public health of the immediate availability on the market of the medicinal product. - Risks inherent in the fact that additional data are still required.

- How the benefits to public health in the context of immediate availability outweigh the risks.

3.Product Information: Enhanced transparency regarding the assessment of such applications and clear information should be provided to patients and healthcare professionals on the conditional nature of the authorizations. Add the inverted equilateral black triangle symbol and the explanatory statement at the top of the summary of product characteristics and the package leaflet for medicinal products subject to additional monitoring (preferably to follow the **Guideline on the Presentation of Labeling Information, PIL and SPC**, any exemptions should be approved by DSC).

4.Post-approval Obligations Given the intent to speed up regulatory approval processes for new therapies, the holder of conditional approval shall be required to provide further data from ongoing studies or to conduct new studies within specified deadlines in order to clarify any outstanding

questions on quality, safety and efficacy to confirm that the benefits continue to outweigh the risks. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data and an updated risk management plan file in accordance with Guideline on Good Pharmacovigilance Practices in Oman (ver.01/2017). The time schedule for submitting periodic safety update reports (PSUR) should be adapted to accommodate the validity of the conditional approval.

The company should submit the summary monthly report after getting the approval from DSC for 6 months and should include as a minimum:

- Interval / cumulative exposure of product in Sultanate of Oman and worldwide
- Interval / cumulative number of serious and non-serious case reports, overall and by age groups and in special populations (e.g., pregnant women)
- Actions taken by regulatory agencies for safety reasons
- Changes to reference safety information
- New, ongoing and closed signals with signal evaluation
- Causality assessment evaluation of serious adverse events, including fatal cases
- Summary of efficacy and safety findings from clinical studies (completed or ongoing)
- Benefit-risk evaluation However, DSC can also take regulatory action if the company failed to comply with the imposed obligations for conditional approval.

5.APPLICATION FOR CONDITIONAL APPROVAL

Prior to Conditional Approval Application, applicants may request DSC advice, as applicable, on whether a specific medicinal product being developed for a specific therapeutic indication falls within one of the categories set out in eligibility criteria, and fulfils the requirements.

The applicants are reminded that prospective planning of conditional approval is important for avoiding delays in assessment procedure, and is especially important in cases when rolling review is undertaken. As medicinal products addressing unmet medicinal needs are expected to be of major interest from the point of view of public health, applicants are encouraged to duly consider the appropriateness of seeking rolling submission for medicinal products suitable for a conditional

approval. On a case-by-case basis, DSC may accept rolling submissions during the evaluation phase, where this information might have an impact on the registration decision.

6.Application Process

Step 1: Requesting conditional approval - A formal request for conditional approval must be presented by the applicant through dscpho@moh.gov.om (appendix 1), accompanied by details showing that the product falls within the scope of the eligibility criteria and satisfies the requirements. Applicants are advised to organize a pre-submission meeting with DSC to discuss planned applications for conditional approval. Applicants should identify the available format of the file. (i.e. eCTD/CTD/NeeS)

Step 2: DSC response / evaluates the eligibility request and supporting documentation, and then provides the applicant with DSC's opinion via e-mail on whether the request is accepted or not.

Step 3: Application - As the request is accepted, the applicants should submit the application via rolling submission (as described below) to the DSC based on the agreed format.

Step 4: Assessment of the application

- the application will assess as expedited timelines to meet the medical need.

-Any further requirements/clarifications will be communicated within reasonable timelines.

Step 5: Decision

- The decision to grant conditional approval will be provided to the applicant with a conditional approval letter.

- The decision to approve is always made based on the benefits/ risks outweigh.

- Applicants must fulfill specific post-approval obligations within predefined timelines.

LAPSING OF CONDITIONAL APPROVAL, the conditional approval is effective for one year and can be renewed annually. This approval is not intended to remain conditional indefinitely. Upon review of information collected during the conditional approval period, a drug could be:

- Withdrawn if new data show that the product's benefits no longer outweigh its risks. DSC can also take regulatory action, such as suspending or revoking the approval if the applicant fails to fulfil post approval obligations.

- Transition to full registration once the company fulfil the obligations imposed and the complete data confirm that the product's benefits continue to outweigh its risks.

Transition to full registration When submitting the last specific obligation data and in view of a possible change to a standard marketing authorization, the marketing authorization holder should address this in their submission and provide updated product information and a clinical expert statement in support of the possible granting of a standard marketing authorization. Once the specific obligations are fulfilled and the marketing authorization is issued, the marketing authorization will be valid for 5 years.

7.Rolling Submission is an ad hoc procedure that allows DSC to continuously assess the data for upcoming highly promising medicinal products as they become available. A rolling review can only be used for products of strategic importance in addressing unmet medical needs. On a case-by-case basis, rolling submission is available only for Conditional Approval to accelerate every step of the regulatory pathway.

7.1.Content of a Rolling Review Submission

- Identification of the submission in the cover letter as a REQUEST FOR ROLLING REVIEW in bold, uppercase letters.

- Each submission occurs preferably in eCTD/CTD format with an application form to the newly available data, based on Guideline for medicinal product application submission and GCC Module 1 Specifications.

- Rolling submission plan outlining the sequence and timelines of the subsequent study data (planned and in progress) submission, if available, should also be provided.

7.2. **Portions of an Application Eligible for Rolling Submission**: Generally, DSC accepts a complete section only for submission, such as the entire CMC (chemistry, manufacturing, and controls), pre-clinical, or clinical sections. Occasionally, it may, in its discretion, accept less than a complete section if it determines that such a subsection would constitute a reviewable unit and be useful in making a decision.

7.3.**Review of Portions of an Application for Conditional Approval:** Following the rolling review, once DSC considers that the data package is sufficiently complete to proceed to formal regulatory submission, submission by the company of the formal conditional approval application

is expected. The duration of the procedure will depend on the amount of data not yet assessed as part of rolling review submissions.

7.4. **Rolling Submission Request To plan for such rolling submission:**

- applicants should make the initial contact through the dscpho@moh.gov.om mailbox with:

- A justification for assessing the product via rolling submission procedure;
- Data supporting the proposed role of the product.
- Rolling submission plan with timelines of submissions.

- Permission to proceed with a rolling submission: applicants will receive DSC decision through email within 10 working days.

- DSC also encourages applicants to request a pre-submission meeting to present their development and submission plans, and it is committed to provide guidance on application and support throughout the process.

CHAPTER THREE

Responsibilities:

Pharmaceutical companies Marketing Authorization Holders (MAHs) Regulatory Affairs Professionals/Applicants Pharmaceutical Consulting Offices	• Ensure all submission documents comply with DSC requirements and guidelines. • Timely respond to inquiries or requests for additional information during the review process. • Maintain accurate records and communication with the DSC.
Technical Committee of Registration	• Evaluate submissions for quality, safety, efficacy, and compliance with regulatory standards. • To review submitted application and decide to approve, reject, or request further clarification
Medicinal and Biological Products Section	• Conduct business validation of submitted files. • Coordinate the assessment and distribution of applications to relevant departments and committees. • Manage communication with applicants, including notifications of validation results, inquiries, and final decisions. • Maintain documentation control, including versioning and archiving of submissions.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	August 2025
2		
3		

References:

EMA (European Medicines Agency) (no date) ***Conditional marketing authorization***. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/conditional-marketing-authorisation (Accessed: 23 November 2025).

SFDA (Saudi Food and Drug Authority) (no date) ***Conditional approval for medicine products for human use***, ver. 1.0. (Publication details unknown; document seen on third-party sites).

SFDA (Saudi Food and Drug Authority) (2022) ***Guidance for submission***, ver. 5.0. Riyadh: SFDA. Available at: https://www.sfda.gov.sa/sites/default/files/2022-10/GuidanceSubmissionV5.pdf (Accessed: 23 November 2025).

Annexes

Appendix 1: application form

Section 1: Applicant Information

Field	Details
Name of Applicant / MAH	
Local Agent (if applicable)	
Address	
Telephone	
Email	
Authorized Regulatory Contact Person	Name: Title: Signature: Date:

Section 2: Medicinal Product Information

Field	Details / Fillable
Trade Name	
International Nonproprietary Name (INN)	
Dosage Form(s)	
Strength(s)	
Route(s) of Administration	
Therapeutic Indication(s)	
ATC Code (if available)	

Section 3: Type of Application

Select type of request (✓):

Conditional approval of medicinal product

☐ New ☐ Renewal

Section 4: Regulatory Basis for Conditional Approval

Field	**Details / Fillable**
Legal / Regulatory justification	
Reference Authority Approval (if applicable)	☐ EMA ☐ FDA ☐ Other:
Date of approval by reference authority	

Section 5: Public Health Justification

Field	Details / Fillable
Description of unmet medical need	
Severity / Rarity of condition	
Expected public health benefit	

Section 6: Clinical and Scientific Justification

Field	Details / Fillable
Summary of available clinical data	
Reason for incomplete clinical data	
Ongoing / Planned clinical studies (timeline)	
Benefit–risk assessment summary	

Section 7: Risk Management and Pharmacovigilance

Field	Details / Fillable
Risk Management Plan (RMP) summary	
Pharmacovigilance system	
Additional risk minimization measures	

Section 8: Conditions and Post-Authorization Commitments

Field	Details / Fillable
Proposed validity period	
Post-authorization study commitments	
Timeline for submission of additional data	

Section 9: Declaration and Undertaking

I hereby declare that the information provided in this application is accurate and complete. I undertake to comply with all conditions imposed as part of the conditional approval and to submit required post-authorization data within the agreed timelines.

Field	Details / Fillable
Name	
Title	
Signature	
Date	

For Official Use Only

Field	Details / Fillable

Application Reference Number	
Date of Receipt	
Assessment Outcome	☐ Approved ☐ Conditionally Approved ☐ Rejected
Remarks	

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