



Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Good Review Practice

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority		Document Created on: 13.02.2020	
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SUMMARY OF CHANGES

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	13.02.2020	-	Creation of the document	Mohamed Fazeen, Director, Pharmaceuticals
2	28.09.2026	Overall Document	Review of overall document	Mariyam Laiza, Assistant Medicine Regulatory Officer

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1 INTRODUCTION

The Medicines and Therapeutic Goods (MTG) Division of the MFDA is constantly endeavoring to improve its performance and ensure the quality of its regulatory systems. Good Review Practices (GRevPs) are an integral part of overall good regulatory practices, that focus on the pharmaceutical product review aspect of regulatory work. Review is a highly complex, multidisciplinary assessment of the medical product applications in meeting scientific and evidentiary standards. It forms the scientific foundation for regulatory decisions.

MTG is cognizant of the fact that the extent to which a regulatory authority can achieve the review goals of timeliness, predictability, consistency, transparency, clarity, efficiency and high quality can have significant impact on public health. It is terms of that recognition that these guidelines have been drawn up – to ensure that the review goals are consistently met. Through this structured approach, MTG ensures monitoring and improvement of the review process.

By definition, GRevPs are documented best practices for any aspect related to the process, format, content and management of a pharmaceutical product review. The goal of GRevPs is to promote the timeliness, predictability, consistency, transparency, clarity, efficiency and high quality of the content and the management of reviews. This is done through the development of review tools such as Standard Operating Procedures (SOPs), and review templates and reviewer learning activities such as training courses, mentoring, discussion sessions.

2 PURPOSE

The purpose of this document is to guide staff at the Maldives Food and Drug Authority (MFDA) on the approved Good Review Practices for MFDA in order to ensure consistent and professional performance. The guide also seeks to make the review process for pharmaceutical products transparent, by ensuring that the various stakeholders understand the internal processes and how they are implemented.

This guide is based on the WHO guide for national regulatory authorities on the basic principles and processes for Good Review Practices.

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3 SCOPE

This document provides high level guidance on GRevP principles and processes. It does not provide detailed instructions on how scientific reviews are actually conducted.

This document applies to the review of safety, efficacy/effectiveness and quality data in medical product applications filed with MFDA for marketing authorization. This document applies to pharmaceutical and biological drugs and higher-risk medical devices used in humans. However, the concepts described here may also be applied to other types of medical products.

4 Principles of a Good Review

4.1 The following principles shall be followed throughout the review system for successful outcomes.

Principle	Description
1. Balanced	Any review conducted by MTG shall be objective and unbiased. The conclusions made shall be based on factual evidence and without allowing personal views, assumptions, preferences or other irrelevant considerations to influence the assessment.
2. Considers Context	MTG shall consider the data and information provided by the applicant for the medical product or device and wherever applicable shall consider the perspective of patients, health care professionals and other NRAs.
3. Evidence-Based	MTG shall conduct reviews on current and available scientific and regulatory evidence. Reviews shall integrate applicable legislative, regulatory and policy frameworks with emerging scientific knowledge
4. Identifies Signals	MTG shall establish a system for tracking and highlighting potential areas of concerns in regards to the quality, safety and efficacy of medical products and devices identified by the applicants and

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	reviewers.
5. Investigates and Solves the Problems	Reviews conducted by MTG shall provide in-depth analysis and findings of key scientific data from both the applicant and the reviewers. Reviewers shall apply problem-solving, regulatory flexibility, risk-based analysis and synthesis skills to devise and recommend appropriate solutions and alternatives where necessary.
6. Makes linkages	Reviews conducted by MTG shall provide an integrated analysis across the relevant aspects of an application, including preclinical and nonclinical data, clinical data, chemistry/biocompatibility, manufacturing and risk management plans, as applicable. Reviews shall include timely communication and consultation with applicants and relevant internal stakeholders and, where necessary, external stakeholders with appropriate expertise.
7. Thorough	MTG shall ensure adequate actions are taken to follow through with any issues identified during the review.
8. Critical Analysis	MTG shall critically assess the scientific integrity, relevance and completeness of the data presented by the applicant. Also, shall implement tasks to improve the critical thinking skills of reviewers to optimize the interpretation of the reviews conducted.
9. Well-documented	MTG shall retain well-written and thorough documentation throughout the review process of the finding and conclusions and the rationale behind the regulatory decisions. This shall be done based on the applicable SOPs for Record management and based on the ISO 9001 standard. Furthermore, as the reports generated shall be clear and sound enough to be leveraged by other NRAs.

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10. Well-managed

MTG shall apply project management and quality management aspects in all stages of the review process with clearly defined tasks, steps, control and targets.

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5 Managing Reviews

- 5.1** To apply the basic principle of managing the review procedure, MTG shall ensure systems and procedures are in place to actively manage the process of reviewing pharmaceutical product applications to achieve best outcomes and the effective and efficient use of review resources.
- 5.2** The following components 4.2.3 to 4.2.7, shall be defined with clear and separate steps with clearly-defined work instructions, each with specific activities and targets. These shall support planning and monitoring of the review activities with timely, informative communications to maximize the efficiency and effectiveness of the review.

5.3 Project Management

- 5.3.1** MTG shall apply appropriate project management practices to the review process including planning, organization and allocation of necessary resources to achieve a complete and high-quality review for each application while maintaining consistency and timeliness.
- 5.3.2** MTG shall apply the most suitable techniques for monitoring the progress of individual or multiple applications with use of tools, software.
- 5.3.3** There shall be mechanisms in place to periodically collect data based on set indicators which reflect the objectives of good review practices.
- 5.3.4** The data collected and interpreted:
- assess the effectiveness of the review strategy.
 - enable MTG to make informed decisions regarding workload and balancing it against the available resources

5.4 Quality Management

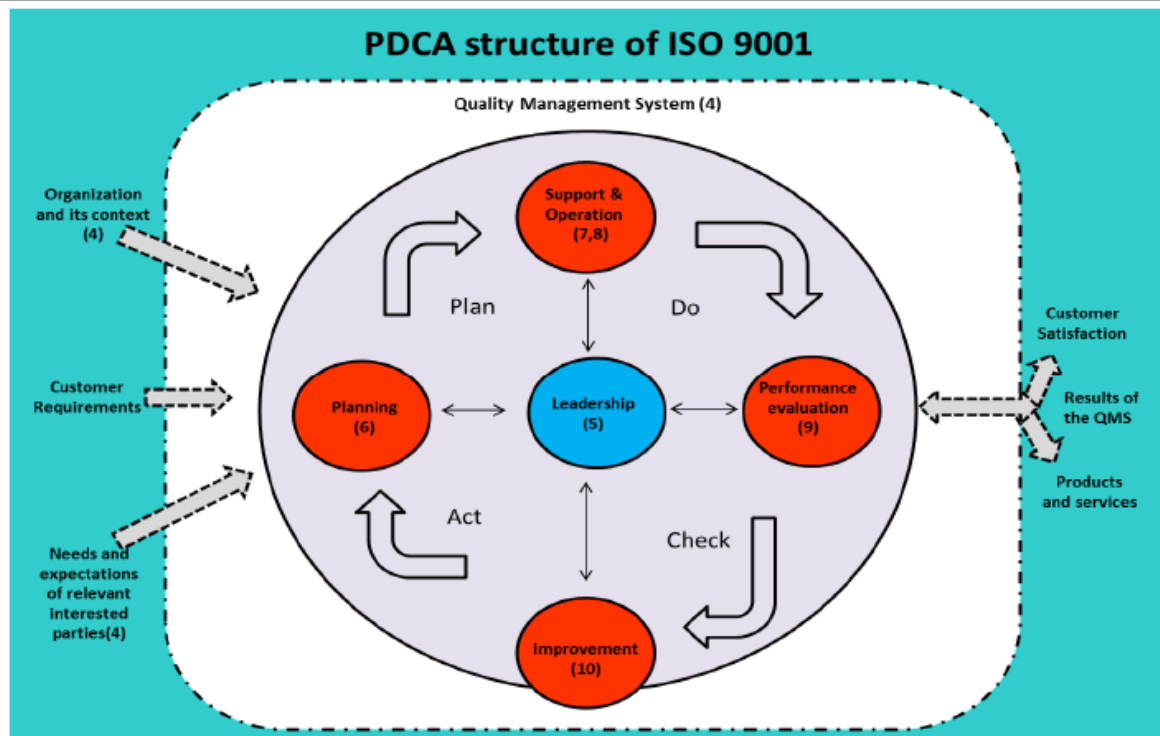
- 5.4.1** MTG shall have standardized procedures that can provide consistency and predictability in GRevP.

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5.4.2 These procedures can be in the form of guidelines, SOPs, and process manuals and shall be based on factors such as size and resources available to MTG, the competency of reviewers, objectives, processes and the organizational structure of the Authority.

5.4.3 MTG employs ISO 9001 standards for the planning, organizing, implementing and monitoring its QMS based on the following cycle:

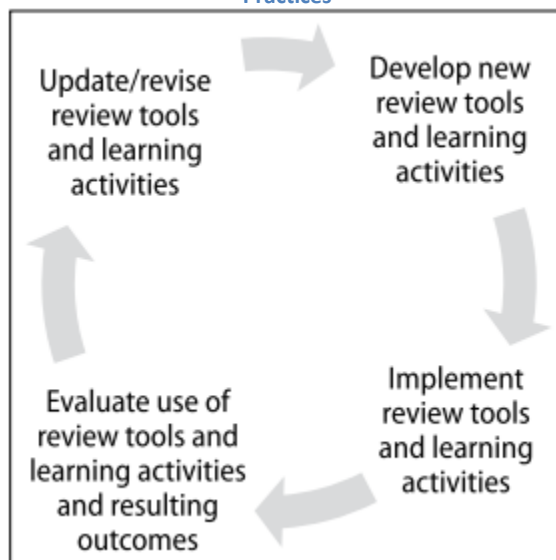
PDCA Structure of ISO 9001:2015



5.4.4 This cycle can be adopted for the purposes of GRevP in the following approach:

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Figure 1 Quality Management Cycle for Good Review Practices



5.4.5 The main components of this cycle are as follows:

1. Plan (Say what you do)

- MTG shall have SOPs and templates for checklists and other assessment tools
- Have a defined process for decision-making with control measures such as timelines, communication and shall specify how external experts, meetings and peer-review is utilized.

2. Action (Do what you say)

- MTG shall implement all relevant guidelines, SOPs and records for the purpose of review and adhere to the given timelines and controls.
- MTG shall have systems in place for the development of reviewers including offers for professional development, mentoring and on-the-job training.
- There shall be mechanisms in place for record taking and retaining such as minutes of meeting (eg: of National Pharmaceutical Board), letters, assessment reports etc.

3. Check (Prove it)

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- MTG shall have monitoring and measuring procedures to periodically evaluate internal procedures and also the practices of external experts.
- This is through the implementation of internal and external audits, review of external suppliers and experts, quality objectives, performance indicators, management reviews, internal and external feedback.
- MTG shall also assess the impact of regulatory decisions on public health, disease outcomes and the health care system, and identify any unintended consequences, where applicable.

4. Act (Improve it)

- MTG shall use the results of monitoring, measurement, audits, reviews, feedback and other relevant information to identify opportunities for improvement and implement appropriate actions to improve the effectiveness, consistency and quality of the review process.
- Where deficiencies or opportunities for improvement are identified, MTG shall take appropriate corrective or preventive actions in accordance with the applicable QMS procedures.

6 Review Process Stages

6.1 Product applications are considered on a first-come, first-served basis. However, consideration may be given to the public health priority of a product, as each application may present unique and varied scientific questions, challenges and opportunities.

6.2 There shall be mechanisms in place to support the appropriate use of information from other NRAs, whether publicly available or provided by applicants, in accordance with the MTG Guideline for Good Reliance Practices, to:

- encourage greater transparency and public availability of non-confidential regulatory information

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- promote confidence and trust in the national regulatory system and its reports and regulatory decisions
- ensure that the principles of GRevP are consistently applied when integrating the scientific reviews and decisions of other RAs into the domestic review process.

6.3 There are two key stages in the process of reviewing medical products and device applications: screening/validation and scientific review.

- **Screening:** The screening/validation stage occurs before the scientific review with the aim of ensuring completeness of the submission, which shall subsequently facilitate the scientific review.

Screening/validation involves an examination of the application to ensure that it is well-organized and all required forms and relevant documents have been submitted. Identifying application deficiencies prior to scientific review enables MTG to avoid spending time and review resources on an application that does not allow critical analysis, signal identification or regulatory decision-making.

- **Scientific review:** Scientific review shall involve a comprehensive and systematic assessment of the information and supporting documentation submitted in the application to determine whether the applicable requirements for quality, safety and efficacy are met.

6.4 There are a number of internal processes that may be implemented to help ensure an efficient, consistent and effective review process. These include:

- periodic meetings to allow consideration of the views of different reviewers;
- peer review, in the context of a co-rapporteur, or a team meeting;
- an internal panel review;
- an external panel review (in the form of technical advice provided by the National Pharmaceutical Board and the Scientific Review Committee);

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- the involvement of senior management (For checking, approving and authorizing the regulatory decisions; monitoring the performance and progress of review practices)

6.4.1 All stages and processes of the review shall conform to the general principles outlined in this guideline.

6.5 Review Personnel

6.5.1 The quality, timeliness and success of pharmaceutical product application reviews are dependent on adequate review capacity. MTG shall ensure that reviewers have core competencies required to carry out reviews. There shall be continued investment into the knowledge, skills, abilities and attitudes of reviewers.

6.5.2 All reviewers shall have adequate professional qualifications, training and expertise in scientific or medical fields that relate to the assessment of pharmaceutical product safety, efficacy/effectiveness and/or quality. The general skills and specific competencies shall be in line with the “WHO Global Competency Framework for Regulators of Medicines” and its specifications for Role-specific activities and competencies for reviewers.

6.5.3 To ensure the integrity of product reviews and recommendations, MTG shall put in place measures to ensure that reviewers are free from actual or perceived conflicts of interest. This is intended to ensure that review decisions or recommendations are not influenced by personal, family, financial or professional interests, including those of employers where an external expert is also a consultant to the regulated industry.

6.5.4 Critical Thinking

6.5.4.1 Reviewers shall be reasonable, objective and have a systematic approach to the analysis of information, following up on concerns and shall use available data and scientific evidence to support regulatory decision-making rather than relying on personal experience, intuition or assumptions.

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- 6.5.4.2 Reviewers shall focus on issues that are relevant to the regulatory decision and shall apply appropriate regulatory flexibility, where permitted by applicable legislation and regulatory requirements, to maximize public health benefits while minimizing adverse or unintended consequences.
- 6.5.4.3 Reviewers are encouraged to remain up to date in their scientific expertise. Opportunities shall be made available for reviewers to attend relevant conferences, courses and international meetings. Reviewers are also encouraged to read scientific journals and maintain memberships in professional societies or relevant organizations.
- 6.5.4.4 MTG shall support the development of critical thinking and regulatory judgement through appropriate training, mentoring, discussion among reviewers and consultation with external experts, where appropriate.

7 Communication

7.1 Communication within the organization and with applicants is pivotal to the review process. There shall be adequate mechanisms for clear, timely and consistent communication in the following areas.

- **Intra-agency:** MTG shall provide a platform for open, clear and constructive communications regarding the progress of the review, review findings, differing data interpretations and discussion of possible solutions and actions among its reviewers, to facilitate peer-reviews and for the regulatory decisions taken by the senior management.

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- **Inter-agency:** As a means of peer collaboration and cooperation, inter-agency communication facilitates greater regulatory convergence such that the decisions made by MTG are not at glaring variance from other regulators in the region and internationally. MTG may communicate and collaborate with other regulatory authorities to exchange relevant regulatory information, support regulatory convergence and, where appropriate, undertake joint regulatory activities. Information-sharing shall safeguard confidential and protected information and the rights of applicants.
- **With applicants:** MTG shall make relevant regulatory information publicly available through guidelines, notices, circulars, frequently asked questions and answers, presentations and other appropriate communication channels to promote applicants' understanding of regulatory requirements and expectations and support the submission of quality applications.

MTG shall communicate with applicants before, during and after the review process, as applicable, including acknowledgement of applications, product-specific queries, review progress and regulatory decisions. MTG may also provide opportunities for applicants to raise challenges and propose alternative approaches that address applicable requirements, where appropriate. MTG shall also have a mechanism in place for appeals for regulatory decisions taken. (Refer to Guideline for Appeals, Incidents and Complaints)

- **With external experts:** Where external experts are engaged in the review process, MTG shall apply appropriate measures to protect confidential information and manage actual or potential conflicts of interest. The appointment of external experts shall be made in accordance with the applicable SOP and legislations.

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- **With the public:** MFDA shall promote transparency and public confidence by providing relevant information to the public regarding its mandate, organization, operations, regulatory processes and decision-making. Information may be made available through the MFDA website and other appropriate communication channels, including published documents, guidelines, notices, circulars, alerts, reports, product application decisions and product safety actions such as recalls.

Where appropriate, MFDA may provide opportunities for the public and relevant stakeholders to provide input on matters related to pharmaceutical products and public health, including product needs, efficacy expectations and risk considerations. Such consultation may be conducted through appropriate mechanisms, including public meetings, surveys, focus groups, workshops and advisory boards.

Where appropriate and in accordance with applicable requirements for confidentiality and protection of information, MFDA may also conduct public consultation on specific applications or regulatory matters under consideration.

8 REFERENCES

- World Health Organization (WHO). Good Review Practices: Guidelines for National and Regional Regulatory Authorities. WHO Technical Report Series No. 992, Annex 9. Geneva: WHO; 2015.
- ISO 9001:2015 Standard for Quality Management Systems
- MTG Quality Manual

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