RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FDA GUIDELINES FOR GOOD REVIEW PRACTICES

JUNE, 2021

Doc. No.: DAR/GDL/045	Revision Date: 11/06/2021	Review Due Date: 11/06/2024
Revision No.: 0	Effective Date: 14/06/2021	

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	25/05/2021
ADOPTION BY RWANDA FDA	26/05/2021
STAKEHOLDERS CONSULTATION	08/06/2021
ADOPTION OF STAKEHOLDERS' COMMENTS	09/06/2021
DATE FOR COMING INTO EFFECT	14/06/2021

FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and efficacy of medical products in order to protect public health and improve access to quality assured medical products in Rwanda.
Considering the provisions of the Rwanda FDA regulations No CBD/ TRG/010 Rev_0 governing registration of medical products in its articles 12 &13, the Authority has to develop Guidelines No. DHT/GDL/045 for Good Review Practices.

The purpose of this document is to provide guidance on the principles and processes of good review practices (GRevPs) for use within Rwanda FDA. It is an integral part of overall good regulatory practices and focus on the medical product review aspect of regulatory work. It will enable the Authority to achieve timeliness of the review, as well as predictability, consistency, transparency, clarity, efficiency and high quality. Implementation of GRevPs helps to achieve these outcomes by ensuring that those involved in the review process have the critical thinking skills and tools needed to optimize scientifically sound, evidence-based decisions.

This document was developed with reference to good review practices developed by WHO and Health Canada.

The Authority acknowledges all the efforts and contribution from our stakeholders who participated in the development and validation of these guidelines.

Dr. Charles KARANGWA
Ag Director General

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

GRevP	Good Review Practice
ICH	International Conference on Harmonization
QM	Quality Management
QMS	Quality Management System
RA	Regulatory authority
Rwanda FDA	Rwanda Food and Drug Authority
SOP	Standard operating procedure
SRA	Stringent Regulatory Authority
WHO	World Health Organization

1. INTRODUCTION

The objective of this document is to provide high level guidance on the principles and processes of good review practices (GRevPs) for use within Rwanda FDA. It is not intended to provide detailed instruction on how to conduct a scientific review.

GRevPs are an integral part of overall good regulatory practices and focus on the medical product review aspect of regulatory work. Review is a highly complex, multidisciplinary assessment of the medical product applications to ensure that they meet the scientific and evidentiary standards for safety, efficacy and quality. It forms the scientific foundation for regulatory decisions. The extent to which the Authority can achieve timeliness of the review (i.e. completion within a specified time frame), as well as predictability, consistency, transparency, clarity, efficiency and high quality, can have a significant impact on public health (for example, in relation to patients' access to important medical products, and costs to both government and applicants). Implementation of GRevPs helps to achieve these outcomes by ensuring that those involved in the review process have the critical thinking skills and tools needed to optimize scientifically sound, evidence-based decisions.

2. SCOPE

This document applies to the review of quality, safety, efficacy, performance data and information on medical product applications filed with Rwanda FDA for marketing authorization.

Although this document was written to provide guidance on pharmaceutical products, biologicals and higher risk medical devices used in humans, the concepts may be applied to other types of medical products. Similarly, the concepts could also be applied to the entire product life cycle from investigational testing to new product applications, updates or variations to existing marketing authorizations and maintenance of the product.

3. GLOSSARY

The definitions given below apply to the terms used in this document. They may have different meanings in other contexts.

Applicant

The person or company who submits an application for marketing authorization of a new medical product, an update to an existing marketing authorization or a variation to an existing marketing authorization.

Application The information provided by the applicant to the Authority for evidence based review and marketing authorization decision.

Good Review Practices (GRevP)
Documented best practices for any aspect related to the process, format, content and management of a medical product review.

Marketing authorization
Also referred to as product license or registration certificate. A legal document issued by the Rwanda FDA that authorizes the marketing or free distribution of a medical product in the respective country after evaluation of safety, efficacy and quality. In terms of quality it establishes the detailed composition and formulation of the medical product and the quality requirements for the product and its ingredients. It also includes details of the packaging, labelling, storage conditions, shelf life and approved conditions of use.

Principles (of a good review)
The important GRevP elements for authority to implement in order to achieve successful review outcomes.

Project management (for the review process)
The planning, organization and resources to achieve a complete and high quality review of an application within a specified time frame.

Quality Management (QM)
The coordinated activities that direct and control an organization with regard to quality.

Quality management system (QMS)
An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.

Regulatory Authority (RA)
The Authority responsible for the registration of and other regulatory activities concerning medical products.

Regulatory convergence
The process whereby regulatory requirements, approaches and systems become more similar or aligned over time as a result of the adoption of internationally recognized technical guidance, standards and best practices.

Review
A highly complex, multidisciplinary assessment of medical product applications to assess whether they meet scientific and evidentiary standards for safety, efficacy and quality. It forms the scientific foundation for regulatory decisions. The first stage of the review process, validation (sometimes referred to as screening), occurs before the scientific review with the aim of ensuring completeness of the application in order to subsequently facilitate the scientific review.

Review strategy
The approach or plan of action that a reviewer or review team uses to review a medical product application.

Standard Operating Procedure (SOP)
An authorized written procedure giving instructions for performing operations (both general and specific).

Stringent Regulatory Authority (SRA)
The national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Transparency
Defining policies and procedures in writing and publishing the written documentation and giving reasons for decisions to the public.

4. PRINCIPLES OF GOOD REVIEW

GRevPs are documented best practices for any aspect related to the process, format, content and management of a medical product review. GRevPs help any National Regulatory Authority to achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality in both the content and management of reviews.
The following are the principles of good review:

a) **Balanced:** A good review is objective and unbiased. Decisions are made based on clear scientific evidence.
b) **Considers context:** A good review considers the data and the conclusions of the applicant in the context of the proposed conditions of use and storage, and may include perspectives from patients, health-care professionals and other RAs' analysis and decisions.
c) **Evidence-based:** A good review is evidence-based and reflects both the scientific and regulatory state of the art. It integrates legislative, regulatory and policy frameworks

with emerging science. It provides reassurance to other parties that regulations are in the public interest, and facilitates a common understanding that initiatives should be supported by evidence.

d) **Identifies signals:** A good review comprehensively highlights potential areas of concern identified by the applicant and the reviewers. It makes recommendations for improvements throughout the life cycle.

e) **Investigates and solves problems:** A good review provides both the applicant's and the reviewers' in-depth analyses and findings of key scientific data and uses problem-solving, regulatory flexibility, risk-based analyses and synthesis skills to devise and recommend solutions and alternatives where needed.

f) **Makes linkages:** A good review provides integrated analysis across all aspects of the application: preclinical; nonclinical; clinical; chemistry/biocompatibility; manufacturing; and risk management plan. It includes timely communication and consultation with applicants, internal stakeholders and, as needed, with external stakeholders who have expertise relevant to the various aspects of the application.

g) **Thorough:** A good review reflects adequate follow-through of all the issues by the reviewers. May take several rounds for issues to be resolved.

h) **Utilizes critical analyses:** A good review assesses the scientific integrity, relevance and completeness of the data and proposed labelling, as well as the interpretation thereof, presented in the application.

i) **Well-documented:** A good review provides a well-written and thorough report of the evidence-based findings and conclusions provided by the applicant in the dossier, and the reviewers' assessment of the conclusions and rationale for reaching a decision. It contains clear, succinct recommendations that can stand up to scrutiny by all the parties involved and could be leveraged by others.

j) **Well-managed:** A good review applies project and quality management processes, including clearly defined steps with specific activities and targets.

k) **Transparency and engagement:** Builds confidence that evidence was considered, and due process was followed. It enables information sharing and stakeholder engagement.

5. MANAGING THE REVIEW

The process of reviewing medical product applications should be actively managed in order to maximize both the potential for a positive public health impact and the effective and efficient use of review resources. The separate steps in the process, each with specific activities and targets, should be clearly defined.

The principles of project management and quality management are very critical to the Authority. The practices of planning and monitoring review activities coupled with timely, informative communications within Rwanda FDA and clearly-defined work instructions for the reviewers, can maximize the efficiency and effectiveness of the review.

5.1 Project Management

Project management for the review process refers to the planning, organizing and setting adequate resources necessary to achieve a complete and high-quality review of an application within a specified time frame. Techniques should be developed to monitor the progress of applications under review and these may include a simple table or spreadsheet, or computer software to monitor many applications at one time. These techniques should have a written procedure that is documented appropriately. Data should be periodically collected and interpreted to assess the effectiveness of the review strategy for completing reviews within the specified time frame. The technique most suitable will be one that enables:

- Interpretation of the data to show the progress of one application as well as that of many applications under review at any time;
- Interpretation of the data to help in decision-making with respect to balancing workload against resources;
- Monitoring that can be performed and/or interpreted by the relevant people.

As the conditions, resources and workload evolve, the techniques and complexity of project management should also be adapted.
The Project manager is an individual or group of individuals assigned to manage review projects or application within Rwanda FDA. Where many applications are involved, different timelines may be applied for each application depending on complexity and immediate need. Tasks performed by regulatory officers or assessors with necessary skills can suffice.

5.2 Quality Management System (QMS)

Quality Management (QM) is defined as the coordinated activities that direct and control an organization with regards to quality. A Quality Management System (QMS) refers to the appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.
QM includes standardized procedures to ensure that GRevPs are in place, regularly monitored and subject to continuous improvement. Beyond standardized processes and procedures that provide consistency and predictability, QM has the ultimate goal of supporting robust regulatory decisions and actions. QMS will be influenced by several factors including:

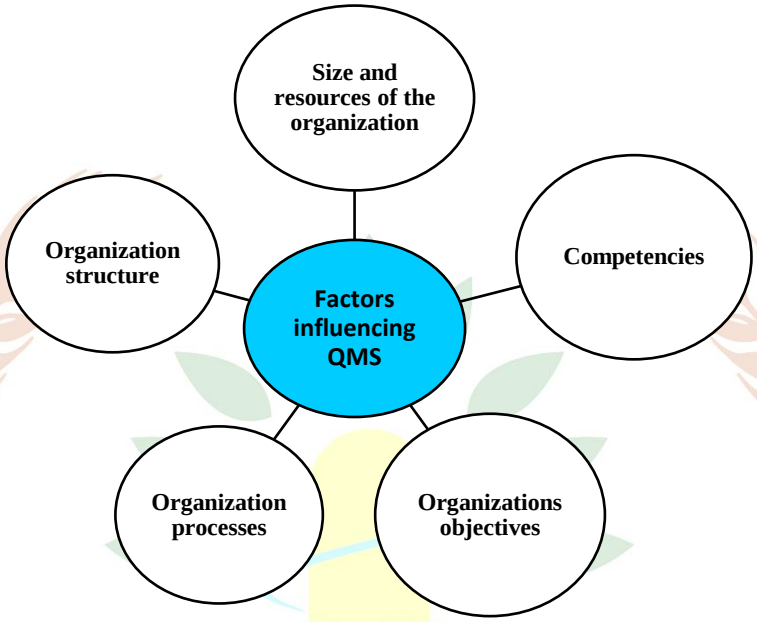

Figure 1: QMS influencing factors

Successful QM implementation requires the commitment of senior management but is ultimately the responsibility of everyone in the organization. The quality management cycle is made up of four key components:

Figure 2: Quality management cycle

This cycle ensures that GRevPs are not just esoteric guidelines (say what you do) but become embedded in the daily practice of an Authority (do what you say). Quality management is also important as it can help an Authority review its practice (prove it) and evolve where necessary, either in response to evolving regulatory science or through the adoption of a new review process and procedures (improve it).

Figure 3: Quality management approach to GRevP

Say what you do

- Provide key documents, such as SOPs and assessment templates.
- Define processes for decision making, such as decision frameworks, time frames for completion and communication of reviews, use of external experts, public meetings and peer review.

Do what you say

- Implement processes defined in key documents and adhere to specified time frames.
- Offer professional development, mentoring and regular on the job training.
- Record and collect key documents, such as minutes of meetings and teleconferences, memoranda, letters and reports.

Prove it

- Ensure that review procedures and templates are being consistently interpreted and applied through the assessment of various inputs, such as internal and external feedback and periodic evaluation of practices by internal and external experts.
- Assess public health impacts of regulatory decisions, such as through a lessons learned session that could include assessing the impact on disease, the health-care system and any unintended consequences.

Improve it

- Review documentation and decision-making processes regularly.
- Consider introducing improvements to the review and decision-making process, such as: internal assessment of a review; peer review; internal quality audits; self-assessments; analyses of feedback from stakeholders; post approval analysis of the decision in

collaboration with other authorities; the public and applicants; and analysis of impact on public health.

- Implement new and improved work practices, the latest evaluation techniques, and scientific and technological advancements.

Implementing QM is an iterative process that incorporates lessons learned with regards to improved processes and decision making.

5.3 Standard Operating Procedure

Creating and adopting a set of SOPs enables the Authority to:

- Outline the workflow processes that facilitate project management when multiple reviewers assess different parts of the same application and when there are multiple applications to review;
- Handle and review product applications in a consistent manner;
- Facilitate staff training.

SOPs are authorized written procedures giving instructions for performing operations (both general and specific). They describe procedures (or processes) in a step-by-step manner. They should be brief, but should describe the overall procedure from start to finish. SOPs should be written clearly to provide both instruction and consistency related to the work being performed.
SOPs may be structured to contain additional tools that will assist in performing the procedure. Alternatively, companion documents can be created to give more detailed instruction and structure in support of an SOP. These companion documents (for example, guidelines for reviewers, templates and checklists) can describe in detail how a particular procedure is performed or give advice on handling a specific situation when performing the procedure.
Templates and checklists present information in a structured manner to facilitate understanding of the information submitted for review. Templates prompt the user to provide specific information, while checklists prompt the user to ensure either that information has been provided or that a particular task has been completed. Templates and checklists have the added benefit of training reviewers and review teams on how to provide information in a structured, consistent manner.
While SOPs have often been kept internal within Rwanda FDA, making templates and checklists available to applicants can be beneficial in ensuring mutual understanding of the information to be submitted for review. SOPs can be further complemented by guidelines for applicants, in order to promote transparency and guide applicants on how to submit high-quality marketing authorization applications. Guidelines for applicants can be made available using a step-wise approach, usually involving informing applicants of the guidelines before making them publicly accessible.

SOPs, guidelines, templates and checklists will require updating (or in some cases even cancellation) as technological advances occur or scientific and regulatory thinking evolves. This evolution could be related to influences including scientific progress, international harmonization of guidelines, changes in review strategy, available resources, increased volume of applications, collaborative work-sharing and national laws and regulations, among others.

5.4 Review Process Stages

Two key stages in the process of reviewing medical product applications are validation (screening) and scientific review.
The validation stage, commonly referred to as screening, occurs first, with the aim of ensuring completeness of the application in order to facilitate the subsequent scientific review. Validation involves an examination of the application to ensure that it is well-organized and that all the required forms and relevant documents have been submitted. Identifying missing information in the application prior to scientific review enables the Authority to avoid spending time and review resources on an application that does not allow critical analysis, signal identification or regulatory decision making.

Scientific review will be discussed further in section 7. It is essential that applicants are made aware of the Authority expectations at both stages, including the target time frames, guidelines, requirements, templates and checklists. This results in a more predictable and clear process for applicants. In turn, the Authority benefits when applicants submit complete applications at the outset.

6. COMMUNICATIONS

Communication is the act of conveying information for the purpose of creating a shared understanding. Communication can also be described as the activity of conveying information through the exchange of thoughts, messages, or information, as by speech, visuals, signals, writing, or behaviour.
Good communication is critical and has many advantages for the Authority, applicants and the public. It can improve the efficiency of the development and review process, allowing patients faster access to important medical products. It can also improve the quality of the review by providing access to additional expertise. Communications can take many active forms such as providing information on the websites, sending e-mails, sending short text messages (SMS), sending letters via the ordinary postal system (‘snail mail’), stakeholder engagements, etc.

Regulatory communication: A communication that contains regulatory information, including correspondence generated by the regulatory authority.

Regulatory Information: Information related to products regulated by the Authority, including product, manufacturing, and facility or company information, adverse events, compliance actions and correspondence generated by the regulatory authority.

The communication process is made up of various elements. These elements are communicators (senders), messages, receivers, channels (e.g. written words, sound, sight, radio, and television), feedback, noise, and setting.

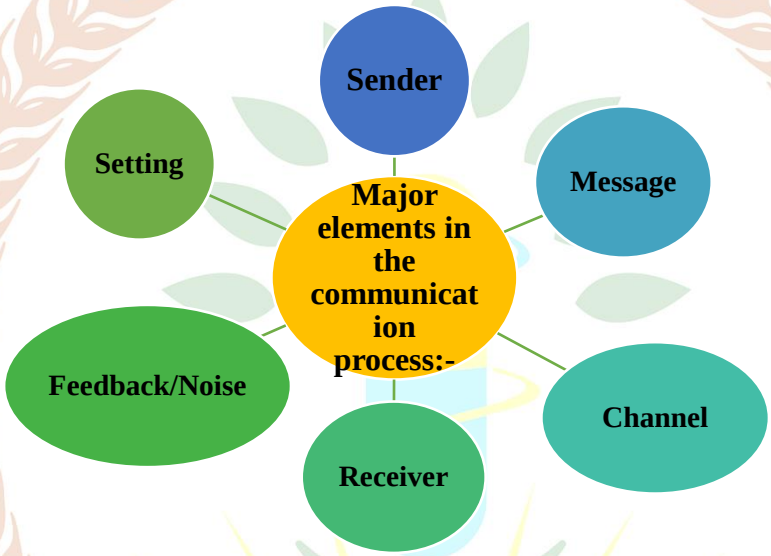

Figure 5 Elements of communication

Active communication is a technique that enables you to verbally and nonverbally communicate in a way that makes you agreeable and easily understood. Active forms of Regulatory communications can be used to the advantage of others, including other regulatory authorities.

6.1 Intra-Agency

Product reviews are conducted in a collaborative environment. They often require expertise from and coordination with different organizational units within the RA, such as pre- and post-marketing scientific disciplines, pharmacovigilance, inspection and others.

Therefore, good communication will improve efficiency. Open, clear, constructive and timely communications regarding the progress of the review, review findings, differing data interpretations and discussion of possible solutions and actions within the Authority are desirable. In addition to establishing meetings, forums and other vehicles for exchange of ideas among reviewers, a checklist of personnel or departments involved on specific issues or actions should be developed. Information management systems should be process centric rather than organizational structure centric to ensure appropriate and efficient information flow.

6.2 Inter-Agency

RA to RA communications have become more frequent and, in many cases, normative especially with SRAs. As a means of peer collaboration and cooperation, interagency communications can facilitate greater regulatory convergence and reliance. This, in turn, can increase the efficiency and quality of medical product development and review processes and improve patient access. Types of interagency communication that Rwanda FDA should use include:

- Accessing information from other RAs' public websites, such as guidelines, application decisions and product recalls;
- Using information from other RAs, such as review reports and certificates of pharmaceutical product;
- Actively sharing information between RAs, such as nonclinical, clinical and inspection findings during an application review;
- Actively working with other RAs, for example, on joint reviews of applications and development of new guidelines.

Interagency communication may evolve from sharing and awareness of information, to consideration of findings from one RA by another in its decision making, to using and relying on those findings to make the best use of resources. Information sharing arrangements and procedures, such as memoranda of understanding, confidentiality arrangements, consent from the applicant, redaction and non-disclosure of specific information, as well as other arrangements and actions, have been used to ensure confidentiality of commercial data, trade secrets and personal information.

6.3 With Applicants

Public availability of guidelines, notices, questions and answers, and presentations, as well as finalized review reports and decision summaries (redacted as needed), provide insight into our current thinking and expectations. These communications allow applicants to provide better quality applications.

Communication between the Rwanda FDA and individual applicants on specific applications before, during and after the review process is also important as it can:

- Foster efficient medical product development through the provision of scientific advice;
- Increase applicants' understanding of evolving regulatory expectations in a changing medical and scientific environment;
- Increase the Authority's understanding of challenges and trade-offs with various requirements;
- Foster applicants' compliance with requirements;
- Inform applicants about the progress and status of the review of their applications.

Procedures allowing applicants and the Authority to engage with each other can facilitate the development, review and availability of medical products. Topics for dialogue can relate to product development requirements (including feedback on guideline development and implementation), as well as issues identified during the application review or post marketing.

6.4 With External Experts

Expertise in the scientific assessment of the safety, efficacy and quality of medical products is not limited to the Authority. Academic institutions, industry associations, patient organizations and medical and scientific organizations all have extensive expertise that may be useful to the review. Asking for the input of external experts into decision-making improves public confidence, provides additional perspectives for the Authority to consider and provides expertise that otherwise may be lacking. Ensuring both confidentiality and absence of conflict of interest is important and can be achieved through transparent processes for management of confidential information and screening for potential conflicts.

6.5 With the Public

Communication with the public about the mission and accomplishments of the Authority can foster greater public awareness, understanding of and confidence in the Rwanda FDA.

Transparency refers to defining policies and procedures in writing, publishing the written documentation, and giving reasons for decisions to the public. Transparency initiatives usually involve web-based information about how it is organized and operates, its decision-making processes and criteria and its actions, such as application approvals and product recalls. Additionally, there should be mechanisms whereby the public can provide input on medical needs, efficacy expectations and risk tolerances, such as through emails, snail mail, public meetings and engagement meetings.

Providing the public with the opportunity to comment permits enhanced content and feasibility of proposed guidelines and regulations. Use of plain language will ensure communications are properly understood.

The public may also be consulted on specific applications under review by the Authority.

7. REVIEW PERSONNEL

The quality, timeliness and success of medical product application reviews are dependent on adequate review capacity. In addition to having a sufficient number of reviewers, capacity relates to many personnel factors including the qualifications, knowledge, skills, abilities and attitudes of reviewers. Together, these considerations define the core competencies for personnel involved in the various aspects of managing and conducting reviews. Reviewers may be staff, external experts or both. To ensure the integrity of product reviews and recommendations, reviewers should be free of actual or perceived conflicts of interests. To be free of any conflict of interest means the review

decision or recommendation is not likely to be influenced by personal, family, financial or professional motives.

7.1 Reviewer expertise, competency and training

The use of core competencies can contribute to improved application review by encouraging evidence based, population focused, ethical decision making. Core competency starts with reviewers who are scientifically trained. Reviewers should have professional qualifications, training and expertise in scientific or medical fields that relate to the assessment of medical product safety, efficacy and/or quality. Both practical and theoretical knowledge is desirable in order to achieve a good understanding of the issues likely to be associated with the product under review.

Reviewer competencies depend on the duties and scope of review work. Scientific writing, presentation of data, data analysis, inferential and deductive reasoning, risk-based analyses and problem solving are important skills for reviewing a medical product application. Review staff should also follow sound ethical practices.

General competencies required to conduct review work include:

- Knowledge of statutes, regulations, guidelines and precedents, including international guidelines and precedents, and their applicability;
- Knowledge of the process of medical product development from early development phases to post-marketing surveillance and risk management;
- Scientific communication skills for written evaluations, public presentations and negotiation and consensus building with applicants and stakeholders.

Reviewers should keep their scientific expertise up to date. Increasingly, regulatory science curricula from universities and international regulatory initiatives and organizations are available. Reviewers should have the opportunity to attend relevant conferences, courses and international meetings. Reviewers should also be encouraged to read scientific journals and to be members of professional societies or relevant organizations.

For on the job training, a site visit program that allows reviewers to visit sites such as laboratories, manufacturing facilities and clinical settings may be considered. In addition, experienced reviewers should be encouraged to mentor and train junior reviewers. The establishment of a capacity building policy and a structured training program within Rwanda FDA to facilitate the professional development of review staff should be encouraged.

7.2 Critical thinking

Critical thinking requires an objective and systematic approach to analysing information and to problem solving. It relies on the collection of data and evidence-based decision making instead of

generalizing from one's own experience, intuition or trial and error. Decisions should be reproducible and clearly understood by others.

Nevertheless, every regulatory decision involves judgment. Therefore, core competence in public health and bioethics, and the ability to integrate up to date scientific knowledge with an understanding of the evidentiary standards for regulatory action (including the flexibility inherent in those standards and regulations), can guide decisions.

Beyond their professional qualifications, reviewers should have the ability to critically appraise the information presented in an application and not just accept it as presented. This skill may often be developed or strengthened during the training process, for instance, by evaluating the responses to questions raised by a senior reviewer so that the questioning process becomes a learning tool.

Discussion among reviewers and external experts on application specific issues can promote critical regulatory thinking and problem solving. Good judgement is required to come to a balanced decision. This involves focusing on the important issues in the application, rather than on data that provide more information, but will not ultimately affect the outcome of an application. Good judgment includes, where applicable, using international harmonized regulatory requirements and adopting regulatory approaches that show flexibility to maximize public health benefits while minimizing adverse, unintended consequences.

Regulatory decision making or recommendations from reviewers should be based on the best current science. The public health needs of the country and its healthcare system provide context for this decision making. In decisions to grant authorization the benefits must, on balance, outweigh the risks, based on sound scientific evidence. Documentation of scientific rationale for decision making, taking into account regulatory requirements, provides a record to ensure the integrity of the review process. The decision making document should address dissenting, evidence based views and clearly identify the information that was considered. Decision making should be independent of influences beyond public health.

8. CONDUCTING THE REVIEW

Conducting the review means executing an assessment of medical product applications to assess whether they meet scientific and evidentiary standards for safety, efficacy and quality. Defining and then following an application specific review strategy that is amended only as needed when new information comes to light, ensures soundness of the review process, the quality of the report and the efficient use of resources.

8.1 Key elements in defining a review strategy

A review strategy is the approach or plan of action that a reviewer or review team uses to review a medical product application. The strategy employed may be shaped by the following.

- Public health priority of the medical product application
- Understanding other RAs' action on the application, especially SRAs
- Understanding specific intrinsic and extrinsic factors that are clinically relevant to the Rwandan population
- Identification of major scientific questions and their possible resolution.

8.2 Applying the review strategy

The way a review is conducted will depend on the resources available. While a multidisciplinary team will provide broader expertise, in some cases an application may be assigned to a single reviewer. The review should be evidence based, taking into account national laws and regulations, regional and international guidelines, and, where applicable, monographs and standards. The reviewer should determine the information necessary to approve the product application and consider whether further information can be obtained in post approval studies without compromising safety. The model adopted for review may allow for questions to be asked during the review to supplement or clarify information supplied, until the reviewer is satisfied that enough information has been provided to allow a conclusion to be reached.

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;
- The involvement of senior management.

The review strategy should ultimately enable the reviewer or review team to understand the benefit-risk profile of the medical product, given the indication and context of use. The nature of the benefits and types of risks should be described as part of the review. Benefits and risks can be quantified or qualitatively characterized, and the levels of certainty surrounding the benefits and risks should be stated. The review should address generalizability of the data, the clinical significance of findings and what (if any) additional information may be needed to clarify benefits and risks.

Various methodologies can be used to quantify benefits and risks. The choice depends on circumstances such as complexity of issues and relevance. The acceptability of benefits and risks will depend on public health priorities, presence of available alternative therapies, size and certainty of the treatment effect versus that of the adverse reactions and possible risk mitigation or benefit enhancement that can be implemented (such as conducting responder analyses to identify a population more likely to experience benefits).

The findings and conclusions of the review must be described in a well-documented review report. Once the final decision is made it should be conveyed to the applicant. If the Authority decides not to grant authorization, a statement of reasons should be provided, which details the documents, information and applicable regulatory requirements taken into account in reaching the decision. A post-action discussion with the applicant may be done to help improve the quality of future applications. The Authority should have mechanisms for communication with the public on the approval of the product and/or action taken in relation to the application. This communication is preferable by email. Publication of information on the approval of products increases transparency of regulatory actions.

9. REFERENCES

1. Canada Therapeutic Products Directorate: Good review practices, 2011
2. **Fred C. Lunenburg, 2010;** Communication: The Process, Barriers, And Improving Effectiveness http://www.nationalforum.com/Electronic%20Journal%20Volumes/Lunenburg,%20Fred%20C,%20Communication%20Schooling%20V1%20N1%202010.pdf
3. Good review practices: guidelines for national and regional regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-ninth report. Geneva: World Health Organization; 2013: Annex 9 (WHO Technical Report Series, No. 992).
4. **John Velentzas and Georgia** Broni; Communication cycle: Definition, process, models and examples https://pdfs.semanticscholar.org/da4e/69265653057d6f03fdc4ce3692b4e6923a0f.pdf?_ga=2.120742987.2123808975.1591442676-1042230176.1581878685

10. REVISION HISTORY

Date of Revision	Revision Number	Document Number	Change made
11/06/2021	Rev_0	DAR/GDL/045	First Issue

	Author	Authorized by	Approved by
Title	Division Manager of Human Medicines, and Devices Assessment & registration	Head of Drugs & Food Assessment and Registration Department	Director General
Names	**Dr. Eric NYIRIMIGABO**	**Mr. Joseph KABATENDE**	**Dr. Charles KARANGWA**
Signature			
Date	11/06/2021	11/06/2021	11/06/2021