RWANDA FDA
Rwanda Food and Drugs Authority

GUIDANCE ON COMPETENCY REQUIREMENTS AND TRAINING NEEDS FOR RWANDA FDA MEDICINAL PRODUCTS ASSESSORS

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) 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 medicinal products, medical devices and IVDs in order to protect public health by increasing their access and availability.

Considering the provisions of the Technical Regulations No CBD/TRG/010 governing the registration of human medicinal products, Rwanda FDA Guidelines for Good Review Practices N° DAR/GDL/045, the Authority issues the Guidance N° DAR/GDL053 on Competency Requirements and Training Needs for Rwanda FDA Medicinal Products Assessors

It is important that Rwanda FDA develop a training strategy to have a pool of competent assessors with expertise to effectively assess dossiers of medical products, before their issued market authorization.

It is in this regard, that the Authority has developed a Guidance on Competency Requirements and Training Needs for Rwanda FDA Medicinal Products Assessors to define the competence criteria for medicinal products assessors and also define the first and second assessor and their needs for subsequent training. The Authority believes that this guidance will be useful for its assessor's capacity building strategy.

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ABBREVIATIONS

EAC – MRH: East African Community – Medicines Regulatory Harmonization

CTD – Common Technical Document

WHO – World Health Organization

SRAs – Stringent Regulatory Agencies

ICH – The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

US FDA – United States Food and Drugs Administration

EMA – European Medicines Agency

IT – Information Technology

GMP – Good Manufacturing Practices

SmPC – Summary of Product Characteristics

PAT – Process Analytical Technology

Rwanda FDA – Rwanda Food and Drugs Authority

1.0 DEFINITIONS

Learning zone: Relates to the new entrant role. New entrants will initially be concentrating on gaining an understanding of the activities of the regulatory authority and becoming familiar with the key activities and responsibilities of the job.

Effective zone: refers to the majority of assessors, indicates that the assessor has gained sufficient experience and is competent to deliver on all the main aspects of the job.

Well-established NMRAs: These are NMRAs, which have system in place for assessment and registration of medicines.

Less-established NMRAs: These are NMRAs, which are still developing, or those with evolving systems for assessment and registration of medicines.

Orientation training program: These are training which are given to new medicine assessors (from less-established and well-established NMRAs) on the procedures for joint assessment.

Induction training program: These are training which are given to new medicine assessors (from less-established NMRAs) on the basic tools and guidance for joint assessment.

First reviewer: Is the first assessor of the medicine dossier irrespective of their levels.

Second reviewer: Is the second assessor of the medicine dossier irrespective of their levels.

Performance evaluation: Is the assessment to the determine the effectiveness of the training program.

2.0 INTRODUCTION

This document is part of the strategy of the Authority to ensure harmonized and high-quality performance standards of medicinal products assessment submitted for registration in Rwanda.

The document outlines a set of recommendations for the competence requirements of medicinal products assessors. The main objective is to define the competence criteria for medicinal products assessors in order to define the first and second assessor and identifying the training needs. These proposals aim at setting up the minimum requirements to be met by the assessors in the Authority to perform their work better and will serve as a useful tool for professional development of medicinal products assessors.

3.0 PURPOSE

The purpose of these guidelines is to define the criteria for defining the first and second assessor to assess the quality, safety and efficacy of medicinal products requesting Marketing Authorization.

These guidelines will also help to identify the training needs of the respective assessors according to their levels.

4.0 SCOPE OF APPLICATION

The guidance is applicable to assessors of medicinal products in the department of Drugs and Food assessment and registration.

5.0 CATEGORIZATION OF MEDICINAL PRODUCTS ASSESSORS

Medicinal products assessors shall be categorized into three levels i.e. level I, II and III for the purpose of assigning responsibilities or work, and also identifying their training needs.

The Head of Department and the Division Manager based on the criteria set in this document will do the categorization. The three levels are defined below:

5.1 Level I – Entry level

This is a career entry level. The individuals who operate at this level are at a junior or more established stage in their own professional career but he/she may be inexperienced in assessment work or new to the authority.

Assessors with limited experience require significant support and close supervision to attain the necessary skills. They also need to get specific trainings related to assessment of different parts of the dossier.

5.2 Level II – Experienced level

This is an experienced assessor. The assessor has demonstrated that he/she is competent to work independently and without supervision and that, he/she has the necessary technical and organizational skills to work on a broad range of active substances and dosage forms at national and regional level. Level II assessors shall continue to develop in the job skills to enable them to take on applications that are more complex as their training and competence develops. They shall continue to develop their competence through training and mentorship by level III assessors.

5.3 **Level III assessors – Expert level**

Level III consists of more experienced assessors who are expected to make an advanced contribution to the assessment and may be recognized as an expert in a particular field, based on increased breadth or depth of skills. The assessor should have knowledge and personal skills appropriate to mentoring and development of less experienced assessors. Level III assessors should be able to assess a wide range of applications, including those with novel or complex issues, to ensure product compliance with regulatory requirements. The assessor should have continuing knowledge of the broader regulatory environments and processes following the best international practices.

6.0 CRITERIA FOR CATEGORIZATION OF MEDICINAL PRODUCTS ASSESSORS

The following criteria will be used to categorize the assessors into different levels:

a) Scientific Knowledge and Skills – The knowledge and skills required to achieve the objectives for the various assessment levels, which are gained through education, training and experience.

b) Regulatory Knowledge and Experience – The regulatory knowledge and experience required to achieve the assessment objectives through training and experience.

c) Work complexity and consistency in assessment – The assessor shall have demonstrated attitude, ability and consistency in assessment including complying within the set timelines.

d) Social skills and attunement to internal and external content – The assessor shall be aware of assessment contents about the patients, pharmaceutical company, national and international situations.

e) Language requirements – Should have a command on writing a good English in order to make a clear and comprehensive report.

7.0 LEARNING CURVES OF MEDICINAL PRODUCTS ASSESSORS

The assessor shall demonstrate an increasing level of progression about regulatory knowledge and experience. The rate at which the assessor makes progress will depend on the aptitude for assessment, level of previous experience, and degree of support and training provided. The experienced and expert level assessors shall be monitoring the improvement of the entry-level assessors to determine their progression from learning zone to effective zone.

8.0 PROFILE MATRIX OF MEDICINAL ASSESSORS

The assessors will be categorized into the three levels as per the criteria defined in the table below:

Key Requirements	Level I (Entry level)	Level II (Experienced level)	Level III (Expert level)
Scientific Knowledge and Skills	Must hold a degree in pharmacy or other relevant scientific discipline. The individual may have limited relevant experience, however, must be able to demonstrate a general knowledge of the key scientific activities relevant to the role. The assessor may be new to the Authority but should have an understanding of its	Must hold a degree in pharmacy or other relevant scientific discipline. Significant relevant experience is required at this level. The assessor must demonstrate a broad knowledge across a range of scientific activities or may be starting to develop a specialist level of knowledge in one or more scientific areas.	Must hold a degree in pharmacy or other relevant scientific discipline. The individual should have an up-to-date knowledge of a broad range of scientific activities in addition to specialist knowledge in one or more relevant scientific areas. Is recognized both within the Authority and by peers outside as an expert/opinion leader.

	key activities.		
Regulatory Knowledge and Experience	The individual gained some knowledge of regulatory activities and is capable of demonstrating basic knowledge and understanding of medicines regulation in national and regional procedures. Should be familiar with CTD format and relevant guidelines and tools. The individual should have received an orientation training by experienced assessors. He/she should have assessed at least five (5) new applications and fifteen (15) query responses (additional data).	The individual must be able to demonstrate a good working knowledge and experience of one or more areas of regulatory activity. Demonstrated ability to mentor and train others. Attended at least one (1) basic training in assessment of medicine dossiers for short duration organized by the Authority and attained a certificate. Should have at least six (6) months of experience in assessment of medicine dossiers. Individuals should have assessed/audited at least twenty-five (25) new applications, twenty-five (25) query responses (additional data) and ten (10) variations. Should also have assessed at least three (3) formulation types.	Demonstrates a detailed working knowledge and experience of all relevant regulations in one or more areas of regulatory activity. May provide input into the development of key regulatory systems policies or definitive guidelines as a recognised expert (both within and outside the Authority). Provides authoritative leadership in dealing with the most difficult technical or regulatory issues and makes them accessible to others. Should have at least two (2) years of experience in assessment of medicine dossiers. Attended at least one (1) advanced training in assessment of medicine dossiers organized by EAC – MRH, Regional Centre of Excellence, WHO, SRAs or any recognized training institutions. Individuals should have

			assessed at least fifty (50) new applications, fifty (50) query responses (additional data) and twenty-five (25) variations. Should also have assessed at least three (3) formulation types.
Work complexity and consistency in assessment	Works in assessment of query responses (additional data) and generic applications of simple dosage forms. The assessor must meet quality targets and timelines; and demonstrate consistency in the quality of assessment work. The assessor would be the first reviewer of the dossier.	Works in assessment of complex dosage forms. The assessor must meet quality targets and timelines; and demonstrate consistency in quality of assessment work. Act as a second reviewer for entry level.	The assessor evaluates the most complex dosage forms. Require skills for research and newly assimilated knowledge. Provide creative and innovative regulatory solutions. They can be second reviewer of level II and also assist in quality assurance as lead assessor. To determine training needs, policy, materials and/or carry out the trainings for the assessment team.
Social skills and attunement to internal and external content	Individual should write an assessment report with guidance from experienced Assessor (Level II)	Individuals should write critical assessment reports. Make presentations on scientific regulatory issues. To be continuously aware of the existing regulatory situations with regards to the	Individual should make individual contributions to other professional or representational activities. Successfully transfers knowledge on highly complex matters. Influential in international networks, collects and critically

		patients, pharmaceutical company, national and international situations.	evaluates new and evolving information and influences standards and opinions. May represent the Agency on Scientific/Regulatory policy issues.
Language requirements	Good command of English	Very good command of English	Very good command of English

9.0 TRAINING FOR MEDICINAL PRODUCT ASSESSORS

The Authority from time to time shall identify the training needs for assessors in each level. The identified training needs will then be used to develop training programmes for different levels.

An orientation training program for level I assessors shall be provided in order to make them aware of the basic assessment tools. In addition to the orientation training program, the level I assessor should undergo an induction training program.

After conduction of the training, a performance evaluation will be conducted i.e. pre and post training assessment, that will be used to evaluate the knowledge and skills of the trainees with regards to understanding of the regulation and guidelines. The passing threshold for the training will be 60% and the individual improvement of the trainees will be monitored. A successful trainee will be confirmed if the individual meets the passing threshold and complies with the respective deadlines for any assigned work.

10.0 DATABASE OF MEDICINAL PRODUCTS ASSESSORS

The database of medicinal products assessors is necessary to be used for assigning dossier to assessors. This database will be developed as per the following steps:

a) The Head of Department and Division Manager will categorize their medicinal products assessors into different levels (i.e., I – III) as per the defined criteria;

b) The Division Manager will then make the list of categorized medicinal products assessors available to all assessors;

c) The database of medicinal products assessors will be annually reviewed by the Head of Department and Division Manager based on set criteria.

The format of the database of medicinal products assessors is illustrated in **Annex II.**

Annex I: Overview of knowledge and skills to be developed in relation to the criteria for categorization of medicine assessors

The sections below summarize the requirements in terms of skills, general and scientific knowledge for medicine assessors. It is intended to be used in connection with the profile matrix and can be used to define training needs for individual assessors.

General skills required from assessors: application of scientific skills

- Personal characteristics: self-dependency, efficiency, self-organization, ability to prioritize work, attention to detail, ability to estimate risk and identify correlations (logical thinking), ability to follow standardized procedures,
- Ability to actively apply the concepts of the General Quality, Safety and Efficacy related Guidelines,
- Ability to apply the concepts of the product specific Guidelines and officially recognized pharmacopoeia monographs if applicable for the specific products or techniques,
- The ability to evaluate suitability of data for assessments and to identify when to investigate/validate further,
- The ability to assess applications to ensure product compliance with regulatory requirements in accordance with required timescales,
- Understanding his/her shortcomings in knowledge and experience and knows when to ask for advice either from another assessor, or from a specific expert,
- Basic IT skills,
- Ability to write clear and comprehensive Assessment Reports,
- Ability to raise relevant and appropriate deficiency points and awareness of the impact of the questions asked to the applicants,
- Social skills (acceptable interactions with colleagues, etc.) and ability to attune to relevant internal and external context,
- Sufficient knowledge of written English to express themselves in a concise and clear way,

- Awareness of the impact of the proposed design and presentation of the product and instructions for use, on practical use by the patient and/or health care professional.

Regulatory knowledge requirements for quality assessors (B)

- To have working knowledge on Rwanda FDA registration guidelines, and other international guidelines (EAC, ICH, WHO, US FDA, EMA),
- Basic knowledge of the legislative system governing the process of approval of medicinal products in the respective NMRAs,
- Knowledge of the content of the national assessment policy (if applicable) and ability to apply this in the assessments,
- The assessors should have sufficient knowledge and understanding of GMP,
- Sufficient knowledge of CTD format and content of a dossier,
- Internal assessment templates.

Basic knowledge requirements relevant for Work complexity and consistency in assessment (C)

Training program on basic knowledge of regulatory and scientific guidelines relevant for pharmaceutical assessment should include, but not be limited to the following topics:

- General aspects of assessment,
- Active substance,
- Pharmaceutical Development,
- Manufacture of the medicinal product,
- Impurities,
- Specifications, analytical procedures and validation,
- Excipients,
- Container closure systems,
- Stability,
- Specific types of products,
- SmPC,
- Patient leaflet and labelling,
- Bioequivalence assessment, including bioanalytical methods used in the BE assessment,
- Dissolution testing,

- PAT/Quality by design,
- New analytical methods,
- Fermentation products and their specific requirements,
- Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products.

Annex II: Format of the database of medicinal products assessors

S/N	Assessors Name	Level of Assessor	Comment of the Division Manager
1			
2			
3			
4			
5			
6			
7			

11.0 DOCUMENT REVISION HISTORY

Date of Revision	Revision Number	Document Number	Change Made
23/08/2021	Rev_0	DAR/GDL/053	First Issue

End of document