1.0 PURPOSE

The purpose of this Standard Operating Procedure is to provide guidance for screening of dossier application for registration of medical products and ensure that submitted dossier application meet the minimum requirements for processing.

2.0 SCOPE

This Standard Operating Procedure applies to all new applications for medicinal products, medical devices and IVDs, cosmetics, pesticides, laboratory and cleaning chemicals, submitted to the authority for registration.

3.0 POLICY

3.1 Law N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning,
3.2 Regulation No CBD/TRG/010 Governing Registration of medicinal products,
3.3 Regulation No. CBD/TRG/012 Governing Registration of Medical Devices,
3.4 Regulation No CBD/TRG/011 Governing Control of Medicated Cosmetics,
3.5 Regulation No CBD/TRG/013 Governing the Registration of Pesticides, Laboratory and cleaning chemicals.
3.6 Regulation No CBD/TRG/004 Related to regulatory service tariff/fees and fines.

4.0 DEFINITIONS AND ABBREVIATIONS

4.1 **Definitions**

4.1.1. **Lead assessor:** is the assessor who is assigned by the Division Manager to coordinate the assessment activity

4.1.2. **Division Manager (DM):** refers to DM for Human Medicines & Medical Devices assessment and registration, DM for Veterinary Medicines Devices and assessment &registration, DM for Cosmetics & household chemicals assessment and registration

4.2 **Abbreviations**

- **IVDs:** In Vitro Diagnostic

5.0 RESPONSIBILITY

5.1 The Head of Department of Food and Drugs assessment approves this SOP and ensures that it is correctly implemented and consistently used during the process of screening of submitted dossier applications for registration

5.2 Division Manager ensures the compliance of staff to this SOP.

5.3 Assessors become fully familiar with provisions of screening SOP for product dossier applications

5.4 Assessors adhere to the provisions of this SOP whenever carrying out screening of submitted dossier applications for registration.

5.5 It is the joint responsibility of the person in charge of Quality Management System, Head of Food and drugs Assessment and Registration Department, Division Manager and Assessors to ensure that this SOP is updated.

6.0 DISTRIBUTION

6.1 The Head of Department of Food and Drugs assessment

6.2 Division Manager

6.3 Assessors

6.4 Person in charge of Quality Management System.

7.0 REFERENCE

N/A

8.0 SAFETY PRECAUTIONS

N/A

9.0 MATERIALS AND EQUIPMENT

9.1 Copy of electronic dossiers
9.2 QMS approved screening Templates and Checklist
9.3 Guidelines for registration
9.4 Registration samples
9.5 Computers with access to the Rwanda FDA server

10.0 SCREENING PROCEDURES

10.1 The Division Manager assigns newly submitted product dossier applications to assessors for screening according to the First in First out rules (FIFO).
10.2 The assigned assessor retrieves the Product Dossier application from the server.
10.3 The assessor saves the dossier on laptop/PC and gives it a name corresponding to application number, e.g. for **0001-2021**
10.4 Open the dossier to begin the administrative and technical screening for completeness using screening checklist No DAR/CKL/001
10.5 The assessor's comments are written in Times New Roman font, 12, in a RED color and the points to be communicated to the applicant are highlighted in YELLOW.
10.6 The assessor copies the list of deficiencies/points to be communicated to the applicant and types the conclusion of the screening report in designated section of the checking list.
10.7 After screening, the assessor prepares a screening feedback (deficiencies/acknowledgement) letter to applicant indicating information required to complete the dossier for assessment.
10.8 The assessor creates a sub-folder in the original product dossier and renames it "**Screening report 0001-2021-S**".
10.9 The assessor saves the screening report, application cover letter, proof of payment, and (deficiencies or acknowledgement) feedback letter in the created subfolder and notifies the lead assessor via email.
10.10 The lead assessor informs the Division Manager about the completion of screening process via routing slip accompanied with feedback letter
10.11 After review, the Division Manager updates the screening report and acknowledgement letter in Rwanda FDA server if any change has been made.
10.12 The Division Manager communicates to the applicant the screening outcome through acknowledgement letter with deficiency (ies) if any.

11.0 UPDATES OF CUMULATIVE LIST OF APPLICATIONS

11.1 Once the screening process is completed, the Division Manager updates the status of the product dossier application in cumulative list of application based on the outcome of screening.

11.2 The Division Manager schedules the product dossier for full or abridged assessment according to the SOP No DAR/DAR/047 of scheduling for Product Dossier assessment.

12.0 APPENDICES

12.1 Approved administrative information template

12.2 Approved screening checklist template

12.3 Approved Feedback letter template

13.0 DOCUMENTS REVISION HISTORY

Date of revision	Revision Number	Document Number	nmary of Changes	Reason(s) for Revision
28 April 2021	0	DAR/SOP/044	NA	First Version

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