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Document Type: **Standard Operating Procedure**		Doc. Number	:**DAR/SOP/039**
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Handling Of Dossier Applications And Samples For Medical Product Registration**	Revision Number	: 0
		Revision Date:	: **26 April 2021**
		Effective Date	: **04 May 2021**
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1.0 PURPOSE

The purpose of this Standard Operating Procedure is to provide guidance for handling of dossier applications and samples for medical product registration

2.0 SCOPE

This Standard Operating Procedure shall be applicable to all new applications, additional data provided in response to deficiencies for medicinal products, medical devices and IVDs, cosmetics, pesticides, laboratory and cleaning chemicals, submitted to Rwanda FDA 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.

4.0 DEFINITIONS

4.1 Definitions

4.1.1. 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

4.1.2. Medical product refers to medicinal products, medical devices and IVDs, cosmetics, pesticides, laboratory and cleaning chemicals.

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 handling dossier applications for medical product registration

	Author	Checked by	Authorized by	
Title/	DM/ DHT	QMS Specialist	HoD/ FDAR	Page 1 of 3
Signature & Date				

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

5.3 Assessors, Head of Central Secretariat and Archivist adhere to the provisions of this SOP whenever handling dossier applications for medical product registration

5.4 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, Head of Central Secretariat and Archivist 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 Head of Central Secretariat

6.5 Archivist

6.6 Person in charge of Quality Management System.

7.0 REFERENCE

NA

8.0 N/ASAFETY PRECAUTIONS

8.1 Submitted dossier applications both hard and electronic copies must be properly kept.

8.2 The person handling samples needs Personal Protective Equipment for safe protection

8.3 Expired samples should be removed from Sample Repository Office according to Best Disposal Practices.

9.0 MATERIALS AND EQUIPMENT

9.1 Shelves, lockable cupboards and drawers, Pallets;

9.2 Fridges;

9.3 Computers with access to the Rwanda FDA server;

9.4 Personal Protective Equipment, Registers, wall thermometers.

10.0 HANDLING PROCEDURES

10.1 The Central Secretariat receives the dossier application and assigns the with Rwanda FDA reference number (e.g. 0001/2021) to it and mention the dates of reception.

10.2 The received application dossier is transmitted to the Food and Drugs Assessment and Registration department.

10.3 The HoD assigns the product dossier application to the responsible Division Manager

10.4 The Division Manager updates the cumulative list of all applications

10.5 The Division Manager distributes the dossier applications to the Assessors for screening using the screening SOP (Number).

10.6 After Screening, the cover letter, external drivers and samples are handed to the responsible person at the sample repository office

10.7 The cover letters and external drives are kept in a separate place with the samples in easily retrievable manner

10.1 Sample storage room conditions are regularly monitored according to the individual sample storage conditions

10.2 The person in charge of the sample repository office hands the cover letter, external drives and samples to the assessors when requested and ensures they are returned after use.

10.3 The person in charge of the sample repository office monitors the shelf life of sample and ensure their safe disposal after the expiration of the marketing authorization.

10.4 One sample in the submitted samples is used during the assessment and the other one is transmitted to the Quality Control Laboratory.

10.5 After the marketing authorization is granted, the product dossier, the assessment reports and a copy of the registration certificate are handed to the responsible person of the archive.

11.0 APPENDICES

Template of cumulative list of all applications

12.0 DOCUMENT REVISION HISTORY

Date of revision	Revision Number	Document Number	Summary of Changes	Reason(s) for Revision
27 /04/2021	0	DAR/SOP/039	NA	N/A