1.0 PURPOSE

The purpose of this Standard Operating Procedure is to provide guidance for full and abridged assessment of applications for registration of medical products.

2.0 SCOPE

This Standard Operating Procedure is 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 N° CBD/TRG/010 Governing Registration of medicinal products,
3.3 Regulation N° CBD/TRG/012 Governing Registration of Medical Devices,
3.4 Regulation N° CBD/TRG/011 Governing Control of Medicated Cosmetics,
3.5 Regulation N° CBD/TRG/013 Governing the Registration of Pesticides, Laboratory and cleaning chemicals.

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 **Peer review committee:** it is evaluation
4.1.3 **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

4.1.4 **Medical Products** refers to medicinal products, medical devices and IVDs, cosmetics, pesticides, laboratory and cleaning chemicals

4.2 **Abbreviations**

4.2.1 **API:** Active Pharmaceutical Ingredient

4.2.2 **BTIF:** Bioequivalence Trial Information Form

4.2.3 EAC: East African Community

4.2.4 **FPP:** Finished Pharmaceutical Product

4.2.5 **PIL:** Patient Information Leaflet

4.2.6 **SmPC:** Summary of Product Characteristics

4.2.7 **SRAs:** Stringent Regulatory Authorities

4.2.8 **WHO:** World Health Organization

4.2.9 **WLAs:** WHO Listed Authorities

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 assessing medical products applications for registration.

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

5.3 Assessors adhere to the provisions of this SOP whenever carrying out assessment for product applications for 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 to ensure that this SOP is updated.

6.0 DISTRIBUTION

6.1 Director General

6.2 The Head of Department of Food and Drugs assessment

6.3 Division Manager

6.4 Assessors

6.5 Head of central secretariat

6.6 Person in charge of Quality Management System.

7.0 REFERENCE

Guidelines related to medicinal products, medical devices and IVDs, cosmetics, pesticides, laboratory and cleaning chemicals assessment and registration

8.0 SAFETY PRECAUTIONS

N/A

9.0 MATERIALS AND EQUIPMENT

9.1 Copy of electronic dossiers
9.2 Medical Devices and IVDs Assessment Template No.: DAR/FMT/057
9.3 QMS approved assessment Templates No: DAR/FMT/058
9.4 Additional Data Assessment Template No.: DAR/FMT/059
9.5 Abridged Procedure Assessment Template No.: DAR/FMT/046
9.6 Assessment of New Medical Cosmetics Template No.: DAR/FMT/060
9.7 Assessment of new Household Pesticides and Vector Control Products Template No.: DAR/FMT/61
9.8 Assessment of New Antiseptic and Disinfectant Products Template No.: DAR/FMT/062
9.9 Guidelines for registration of Medical products
9.10 Recognized Pharmacopeia and other recognized standards
9.11 Registration samples
9.12 Computers with access to the Rwanda FDA server
9.13 WHO/SRAs/WLAs assessment report for abridged
9.14 EAC joint assessment report

10.0 ASSESSMENT PROCEDURES

10.1 The Division Manager assigns available product dossier applications to assessors according to First In First Out (FIFO) rules and the lead assessor ensures the proper implementation of the work distribution.

10.2 First assessment report writing from Rwanda FDA server, the 1st assessor opens the electronic dossier allocated to him/her which contains a registration application (dossier) in PDF. In addition, it contains templates (Quality Information Summary (QIS), Quality Overall Summary (QOS) and/or bioequivalence trial information (BTIF)/ biowaiver application form) in word format where applicable. The product sample is obtained from the Sample Repository Office. The 1st assessor is responsible of the assessment report.

10.2.1 The assessor opens a folder on the Laptop/PC and rename corresponding to the dossier file number, e.g. for **0001-2021**

10.2.2 Copy the *Product Assessment Report Template,* rename and save as **R1 (First assessment Report). e.g. 0001-2021-R1** in the assessment report folder **e.g. 0001-2021-R.**

10.2.3 Copy the QOS (word format) from the dossier and paste it at the end of the report template stated above. If applicable, copy the BTIF or biowaiver application form and paste in the above template after the QOS.

10.2.4 The assessment report should be written in "Times New Roman 12" font.

10.2.5 The first assessor's comments are written in each section of the template using RED COLOR and points to be communicated to the applicant are highlighted in YELLOW.

10.2.6 The first assessor ensures that points to be communicated to the applicant (queries) are properly phrased so as to be easily understood to facilitate proper responses. A good communication to the applicant has three components:

a) State the problem that you have identified;
b) Identify the section of the relevant guideline that has not been complied with; and
c) State what information the applicant shall submit to the Rwanda FDA.

10.2.7 The first assessor copies and pastes the API and FPP Specifications, PIL, SmPC, mockups, application cover letter and proof of payment at the end of the Assessment Report where applicable. In case one of the above documents is queried, this is mentioned **e.g. SmPC-queried**. If it not possible to copy the aforesaid documents, the assessor saves them in the assessment report folder.

10.2.8 After the completion of first assessment of product dossier, the first assessor signs and saves the assessment report to the server and notifies the lead assessor via e-mail.

10.3 **Second Assessment Report Writing**

The 2nd Assessor is responsible for quality assurance of the assessment report

10.3.1 Obtain from the server a folder containing the first assessor's report and rename the first assessor's report as **R2** e.g.: **0001-2021-R2**

10.3.2 The second assessor reviews the first assessor's report and enters comment notes in the report using **BLUE color**. The points to be communicated with the applicant are highlighted in Yellow

10.3.3 The Second assessor shall not delete any information previously entered by the first assessor. Striking through the first assessor's notes is acceptable but shall be accompanied by the second assessor's comments.

10.3.4 The second assessor discusses with the first assessor any areas of contention and arrives at a common position. The assessment lead assessor is contacted if necessary, for resolution of contentious matters and edit the agreed points to be communicated to the applicant.

10.3.5 The second assessor transfers all points to be communicated to the applicant to the top of the template under the section: "POINTS TO BE COMMUNICATED TO THE APPLICANT"

10.3.6 After the completion of second assessment of product dossier, the second assessor signs and saves the assessment report to the server.

10.3.7 The second assessor prepares the feedback letter using the appropriate format and saves it in the assessment report folder (e.g. 0001-2021-R) to Rwanda FDA server and notifies the lead assessor via email.

10.4 **Assessment of additional data**

10.4.1 The assessment of additional data follows the same procedures as described above.

10.4.2 In addition, the first assessor copies additional data assessment report template, rename and save as **R1 ADD DATA (First assessment Report of additional data). e.g. 0001-2021-R1 ADD DATA** in the assessment report folder **e.g. 0001-2021-R ADD DATA**

10.4.3 The first assessor copies the query (ies) as they were communicated in the feedback letter without changing the query.

10.4.4 The first assessor takes snapshots of the query response (s) as received from the applicant.

10.4.5 The first assessor puts his/her comments after the query response from the applicant based on analysis using references to regulatory requirements (ICH Guidelines and other international standards).

10.4.6 Query that are unsatisfactorily addressed in the current submission are reconsidered in new feedback to the applicant

10.5 **Submission of completed assessment reports**

10.5.1 After completion of the assessment report (first and second), the lead assessor notifies the Division Manager via routing slip and feedback letters.

10.5.2 If an electronic device was used, return it to the responsible person.

10.5.3 Return the product sample to the Sample Repository office, ensuring it is logged back in by the responsible person.

10.6 **Feedback communication to the applicant**

10.6.1 If the feedback requests additional data, the Division Manager reviews and approves the feedback letter and submits it with application cover letter to the Central Secretariat.

10.6.2 If the feedback recommends the approval of Marketing Authorization, after the peer review committee meeting, the Division Manager reviews and submits the draft Registration Certificate and peer review minutes with the zipped assessment report folder (**e.g. 0001-2021-R**, also containing summary report together with the application letter and copy of proof of payment) to Director General Office through Head of department of Food and Drugs Assessment and Registration.

10.6.3 If the feedback recommends the rejection of application, after the peer review meeting, the Division Manager reviews and submits the rejection letter and peer review minutes with the

zipped assessment report folder (**e.g. 0001-2021-R**) to Director General Office through Head of department of Food and Drugs Assessment and Registration

10.6.4 After the DG's approval of the registration Certificate or rejection letter, the documents are sent to the Central Secretariat for communication to the applicant.

10.6.5 The Central Secretariat dispatches the signed Registration Certificate or rejection letter via email or post to the local appointed technical representative who may also collect it in person.

11.0 UPDATES OF THE REGISTER

Once the Marketing Authorization is granted, the register is updated according to the SOP Number DAR/SOP/043

12.0 APPENDICES

Assessment report templates (full, abridged and additional data)

13.0 DOCUMENT REVISION HISTORY

Date of revision	Revision Number	Document Number	Summary of Changes	Reason(s) for Revision
26th April 2021	0	DAR/SOP/042	NA	N/A

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