1.0 PURPOSE

This Standard Operating Procedure is to provide guidance for assessment of variation application to registered medical products

2.0 SCOPE

This Standard Operating Procedure applies to all applications for variation to registered medicinal products, medical devices and IVDs, cosmetics, pesticides, laboratory and cleaning chemicals, submitted to Rwanda FDA.

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 Registration of Pesticides, Laboratory and cleaning chemicals.

3.6 Regulation No. CBD/TRG/004 related to regulatory services tariffs/fees and fines

4.0 DEFINITIONS AND ABBREVIATIONS

4.1 **"Variation":** Any change to the original information for a product registered in Rwanda. This applies to any information submitted with the application for registration or set as conditions for registration.

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

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 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 The Director General of Rwanda FDA

6.2 The Head of Department of Food and Drugs assessment

6.3 Division Manager

6.4 Assessors

6.5 Person in charge of Quality Management System.

7.0 REFERENCES

7.1 Rwanda FDA guidelines for variations to the registered medicinal products

7.2 Rwanda FDA guidelines for variation to the registered medical devices

8.0 SAFETY PRECAUTIONS

Not applicable to this SOP

9.0 MATERIAL AND EQUIPMENT

9.1 Copy of electronic applications for variation

9.2 Shared folder of the previous assessment report on the Rwanda FDA Server

9.3 QMS approved for Variation Assessment Templates No. DAR/FMT/062

9.4 Relevant Guidelines for variation to the registered products

9.5 Recognized Pharmacopeia or relevant recognized standards

9.6 Computers with access to the Rwanda FDA server

9.7 WHO/SRAs/WLAs variation assessment report for abridged procedure

9.8 EAC joint assessment reports for variation

10.0 PROCEDURES

10.1 **Variation assessment**

10.1.1 **The Division Manager assigns** available variation applications to assessors and the lead assessor ensures the proper implementation of the work distribution.

10.1.2 The assessor opens a folder on the Laptop/PC and rename corresponding to the dossier file **e.g. 0001-2021-V**

10.1.3 Copy the variation Assessment Report Template, rename and save as V1 (First assessment Report). **e.g. 0001-2021-V1** in the assessment report folder e.g. **0001-2021-V** at the server

10.1.4 The first assessor's comments are written in Times New Roman font, 12, using RED COLOR and points to be communicated to the applicant shall be highlighted in YELLOW

10.1.5 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 shall have 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 Rwanda FDA.

10.1.6 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.

10.1.7 The second assessor obtains from the server a folder containing the first assessor's report and rename the first assessor's report as **V2** e.g.: **0001-2021-V2**

10.1.8 The second assessor reviews the first assessor's report and comments are written in Times New Roman font, 12, using **BLUE color**. The points to be communicated with the applicant shall be highlighted in Yellow.

10.1.9 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.

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

10.1.11 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"

10.1.12 After the completion of second assessment, the second assessor signs the assessment report and prepares the feedback letter using the appropriate format and saves all in the assessment report folder **(e.g. 0001-2021-V)** to Rwanda FDA server and notifies the lead assessor via e-mail.

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

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

10.1.15 Where applicable, return the product sample to the Sample Repository office, ensuring it is logged back in by the responsible person.

10.2 **Assessment of additional data**

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

10.2.2 In addition, the first assessor copies additional data assessment report template, rename and save as **V1 ADD DATA (First assessment Report of additional data). e.g. 0001-2021-V1 ADD DATA** in the assessment report folder **e.g. 0001-2021-V ADD DATA**

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

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

10.2.5 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).

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

10.3 Feedback communication to the applicant

10.3.1 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.

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

10.3.3 If the feedback recommends the rejection of variation 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-V**) to the office of Director General, through Head of department of Food and Drugs Assessment and Registration

10.3.4 After the DG's approval of the variation or rejection, the feedback is sent to the Central Secretariat for communication to the applicant.

10.3.5 The Central Secretariat dispatches the approved feedback or rejection letter via email or post to the local appointed technical representative who may also collect it in person.

11.0 UPDATE OF THE REGISTER

Once the variation is approved, where applicable, the register may be updated according to the SOP number DAR/SOP/043

12.0 APPENDICES

12.1 Assessment Report Template for Variation on Registered Human Medicinal Products

12.2 Assessment Report Template for Variation on Registered Medical Devices

13.0 DOCUMENT REVISION HISTORY

Date of revision	Revision Number	Document Number	Summary of Changes	Reason(s) for Revision
04 May 2021	0	DAR/SOP/045	NA	N/A

End of Document