Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

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Revision status sheet

Page	Changes made	Issue No	Process owner (Title)	Reviewer's Name	Date

1. Purpose

These guidelines are intended to provide guidance to all stakeholders on the requirements for retention of registered and/or listed medical devices including In Vitro Diagnostics in the **Listed Medical Devices Register *BOMRA/ER/MED/P02/F06*** and **Medical Devices Register *BOMRA/ER/MED/P04/F11***.

2. Scope

This guideline is applicable to all medical devices in the **Listed Medical Devices Register BOMRA/ER/MED/P02/F06** and the **Medical Devices Register BOMRA/ER/MED/P04/F11**. It will not be applicable to medical devices that have been removed from the register(s) for quality, safety or efficacy reasons. For the purposes of this guideline, the medical devices term will include both general medical devices and IVDs.

3. Abbreviations and Definitions

3.1 Abbreviations

The following abbreviations shall apply.

3.1.1 **BOMRA –** Botswana Medicines Regulatory Authority

3.1.2 **BRIMS –** Botswana Medicines Regulatory Authority Regulatory Information Management System

3.1.3 **IVD** – In Vitro Diagnostic

3.2 Definitions

The following definitions shall apply.

3.2.1 **Retention** – For the purposes of this guideline, retention is the process of maintaining a listed and/or registered medical device on the respective register. This process shall be done annually and involves the payment of an applicable annual fee and submission of any additional product information as prescribed by the Authority from time to time.

3.2.2 **In vitro Diagnostic-** a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimen derived from the human or animal; solely or principally to provide information for diagnostic, monitoring or compatibility purposes which includes but not limited to – reagents used for IVD purposes, calibrators, control chemicals, specimen receptacles, software and related instruments or apparatus or other articles and are used for the following test purposes; diagnosis; aid to diagnosis; screening; monitoring; predisposition; prognosis; prediction; determination of physiological status.

3.2.3 **Medical devices** - any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article -

a) intended by the manufacturer to be used, alone or in combination, for humans or animals for-
   i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
   ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
   iii. investigation, replacement, modification or support of the anatomy or of a physiological process;
   iv. supporting or sustaining life;
   v. control of conception;
   vi. cleaning, disinfection or sterilization of medical devices; or
   vii. providing information for medical or diagnostic purpose by means of in vitro examination of specimens derived from the human body; and

b) which do not achieve its primary intended action in or on human or animal body by pharmacological, immunological or metabolic

3.2.4 **Withdrawal** - For the purpose of this guideline, withdrawal shall be as per the withdrawal guideline "**Withdrawal of market authorization and or registered listed medical devices including IVDs – *BOMRA/ER/MD/P08/G01***" in which medical devices will be removed from the **Listed Medical Devices Register – *BOMRA/ER/MED/P02/F06*** and/or the **Medical Devices Register – *BOMRA/ER/MED/P04/F11***.

4 General Principles

4.1 As per the provisions set out in the Medicines and Related Substances Act (MRSA) 2013, the stakeholders shall submit information to the Authority annually, in the prescribed manner, and accompanied by a retention fee to retain the medical devices on the register.

5 Retention of listed medical devices in the Listed Medical Devices Register

5.1 The retention process shall be carried out on the BRIMS self-service portal (https://brims.bomra.co.bw/#/public/app-home). The process shall involve the steps listed below:

5.1.1 The applicant shall compile a list of medical devices they wish to retain in the Listed Medical Devices Register using **Annexure I of Retentions of Medical Devices- *BOMRA/ER/MED/P10/F01*** every year (between January and March).

5.1.2 Medical devices can be retained as a group following the **Guideline for Grouping of Medical Devices – *BOMRA/ER/MED/P04/G07*** or as a single medical device and submitted in one product application.

5.1.3 Retention shall be done by the product owner/manufacturer. If retention is not done by the product owner/manufacturer then the authorization letter from the product owner is required.

5.1.4 Upon submission of the retention application, the Authority will assess the application, verify the accuracy of the grouping and information provided, including the quoted fees, and, if necessary, raise any queries with the applicant within 10 working days.

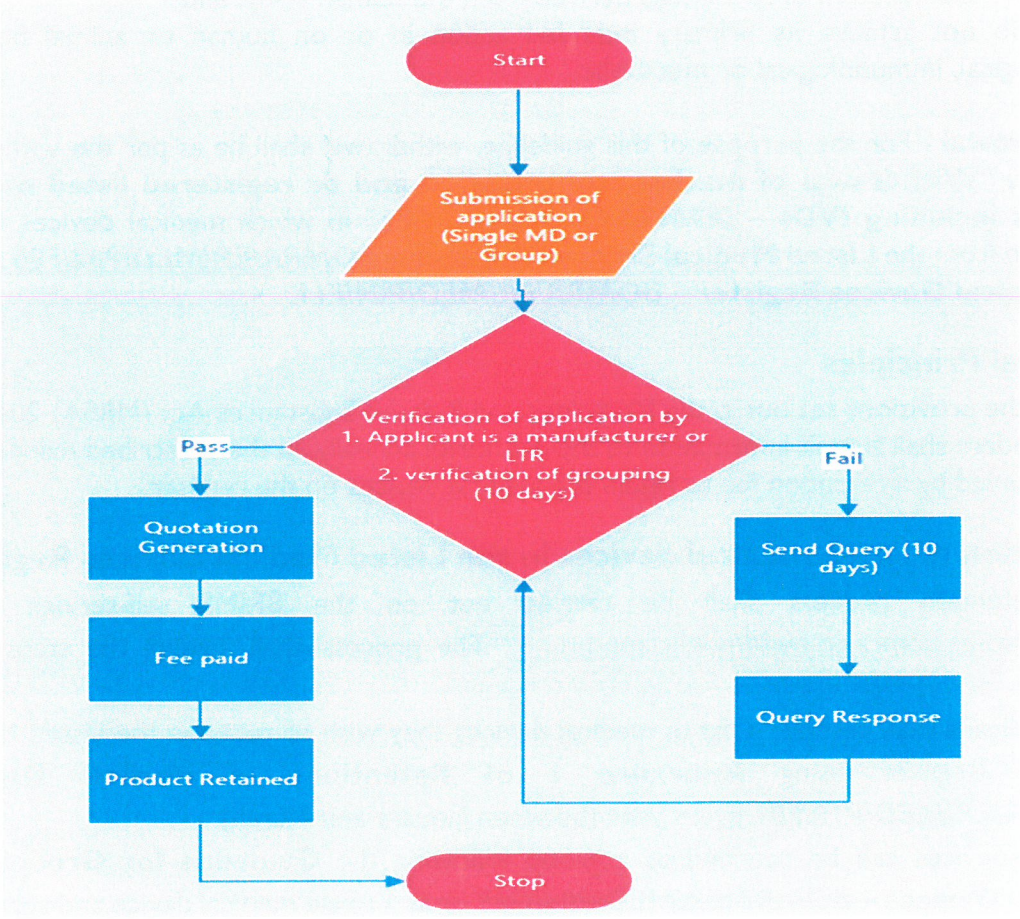
5.1.5 The applicant will then have 10 working days to respond to any queries raised

5.1.6 After verification by the Authority, the applicant shall proceed to accept the quotation generated and make payment.

5.1.7 The applicant shall provide additional information to the Authority as may be required.

5.1.8 The Authority shall then update the register accordingly.

5.1.9 The updated Listed Medical Devices Register shall be published on the website and/or shared with the stakeholders through other media periodically.



6 Retention of registered medical devices in the Medical Devices Register

6.1 The retention process shall be carried out on the BRIMS self-service portal (https://brims.bomra.co.bw/#/public/app-home). The process shall involve the steps listed below:

6.1.1 The applicant shall compile a list of medical devices they wish to retain in the Medical Devices Register using **Annexure I of Retentions of Medical Devices *BOMRA/ER/MED/P10/F01*** every year submitting the application before the anniversary of the product's registration date

6.1.2 Medical devices will be retained as they appear in the **Medical Devices Register *BOMRA/ER/MED/P04/F11***.

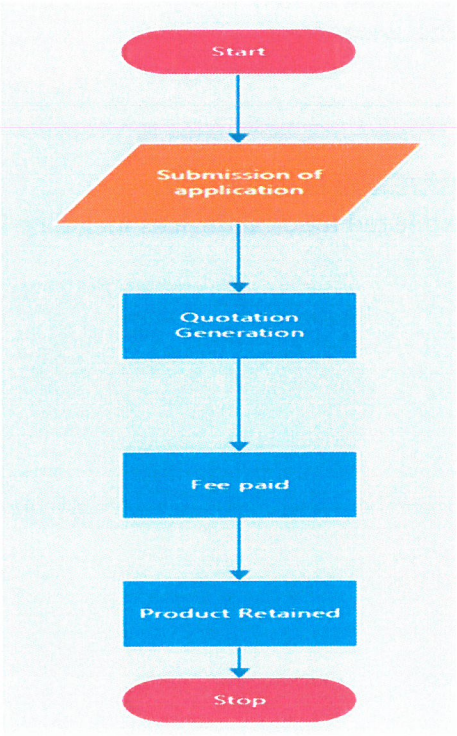
6.1.3 Retentions shall be done by the Market Authorization Holder (MAH).

6.1.4 After the retention application has been submitted, the applicant shall proceed to verify and accept quotation and make payment.

6.1.5 The applicant shall provide additional information to the Authority as may be required.

6.1.6 The Authority shall then update the register accordingly.

6.1.7 The updated **Medical Devices Register – *BOMRA/ER/MED/P04/F11*** shall be published on the website and/or shared with the stakeholders through other media periodically.



7 In the event of failure to retain the medical device as per clause 5.1

7.1 All listed medical devices not retained by the 31st of March of every year shall be removed from the Listed Medical Devices Register and these products will not be allowed access into the Botswana market unless they are registered or exempted from registration.

7.2 All registered medical devices after the due date shall be suspended from the Medical Devices Register. If still not retained a month (one) after the due date, registration will be cancelled and they shall be removed from the medical devices register and not allowed access to Botswana market unless they are exempted.

8 Reinstatement of products into the Listed Medical Devices Register and Medical Devices Register

8.1 Reinstatements shall not be applicable to products that were previously removed from the listed medical devices register and medical devices register. Such products will have to undergo registration if they are part of the priority list or follow the exemption procedure if otherwise.

9 Reinstatements resulting from suspension due to failure to renew, retain or voluntary withdrawal of the product for commercial reasons.

9.1 Reinstatements shall not be applicable to products that were previously removed from the registers. Such products will have to undergo registration if they are part of the current priority list or follow the exemption procedure if otherwise.

10. References

10.1. Guideline for Grouping of Medical Devices – ***BOMRA/ER/MED/P04/G07***

10.2. Withdrawal of market authorization and or registered listed medical devices including IVDs – ***BOMRA/ER/MD/P08/G01***