Botswana Medicines Regulatory Authority

Approved By:

Mr. Bathusi Kgosietsile
Director – Product Evaluations and Registration

Date of Approval (DD/MM//YY)

Revision status sheet

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

TABLE OF CONTENTS

Table Of Contents

1 Purpose

This guideline provides guidance that will enable applicants to submit requests for withdrawal of market authorization and/or registered/listed Medical Devices including In Vitro Diagnostics (IVDs).

2 Scope

The guideline applies to all withdrawals of market authorization of all medical devices including IVDs at the various stages of registration, submitted or undertaken by the Authority. This also applies to all removals of market authorization of all medical devices including IVDs.

3 Abbreviations and Definitions

3.1 Abbreviations

For the purpose of these guidelines, the following abbreviations shall apply:

3.1.1 **BOMRA** - Botswana Medicines Regulatory Authority

3.1.2 **BRIMS-** BoMRA Regulatory Information Management System

3.1.3 **IVD** - In-vitro Diagnostics

3.1.4 **MA-** Market Authorization

3.1.5 **MAH-** Market Authorization Holder

3.1.3 **WHO** - World Health Organization

3.2 Definitions

For the purpose of these guidelines, the following definitions shall apply:

3.2.1 **Applicant –** The applicant shall be a legal manufacturer or registered company or entity in term of Companies Act requesting for service and taking responsibility for ensuring the medical devices and IVDs' requirements are in compliance with the laws and regulation in force in Botswana. If the applicant is not a resident in Botswana, then he/she shall appoint a Local Technical Representative (LTR) also referred to as Authorized Representative who must be residing in Botswana or company incorporated in Botswana.

3.2.3 **Marketing authorization (MA)**-Means a legal document issued by the Authority for the purpose of marketing or free distribution medical devices including IVDs, which has been approved after evaluation for quality, safety, efficacy, or performance.

3.2.4 **Market Authorization Holder** - the applicant to whom the market authorisation is issued.

3.2.5 **Medical Device -** 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,

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 means but which may be assisted in its intended function by such means.

3.2.6 **Withdrawal**- Any measure aimed at preventing a medical device in the supply chain from being further made available on the market. This also applies to all removals of market authorization of all medical devices including IVDs.

4.0 Withdrawal of marketing authorization holder

4.1 A marketing authorization holder who wishes to withdrawn from their position as an MAH, shall provide the Authority on their letter head and in English with;

a. information on the decision to withdraw
b. the effective date of withdrawal
c. reasons for withdrawal
d. the plan of communication to all consignees
e. the plan of the medical device(s) in the market

5.0 Withdrawal of on-going applications

5.1 An applicant who wishes to withdraw on-going applications shall provide the Authority on their letter head and in English with;

a. information on the decision to withdraw
b. the effective date of withdrawal
c. reasons for withdrawal

6.0 Withdrawal of registered/listed Medical Devices including IVDs

6.1 A marketing authorization holder who wishes to withdraw his or her medical device from the market shall provide the Authority on their letter head and in English with;

a. information on the decision to withdraw
b. the effective date of withdrawal
c. reasons for withdrawal
d. the plan of communication to all consignees
e. the withdrawal plan of the medical device(s) from the market

After the intent to withdraw the medical device or MAH has been logged, the Authority shall then update the register to indicate withdrawal if the request has been approved. Any other decisions or queries shall be communicated with the applicant. The updated medical devices register will be published on the BoMRA website or any media as may be communicated as and when required.