Botswana Medicines Regulatory Authority

Approved By: _____ _____

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Director - Product Evaluations and Registration

Date of approval (DD/MM/YY)

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Revision status sheet

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1 Purpose

1.1 The purpose of this policy is to outline the criteria for recognition and/or reliance on information regarding medical devices including In Vitro Diagnostics (IVDs) from other regional and international regulatory authorities.

1.2 This policy is subject to future amendments by the Chief Executive Officer (CEO) and Director of Product Evaluation and Registration, depending on the prevailing operational developments at the Authority.

2 Scope

This policy is applicable to information related to medical devices market authorization activities.

3 Definitions and Abbreviations

3.1 Definitions

3.1.1 In Vitro Diagnostic

Means 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.

3.1.2 Medical Device

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

3.1.3 Recognition- The acceptance of the regulatory decision of another regulator or trusted institution. Recognition is based on evidence of conformity that the regulatory requirements of the reference regulatory authority is sufficient to meet the regulatory requirements of BOMRA.

3.1.4 Reliance - The act whereby the NRA in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

3.1.5 Stringent Regulatory Authority- A National Medicines Regulatory Authority which is strict, precise, exact with effective and well-functioning systems as defined by WHO.

3.2 Abbreviations

3.2.1 **AMDF –** African Medical Device Forum

3.2.2 **ARSO** – African Organisation for Standardization

3.2.3 **BOMRA** - Botswana Medicines Regulatory Authority

3.2.4 **CEO** – Chief Executive Officer

3.2.5 **GMP** – Good Manufacturing Practices

3.2.6 **IMDRF -** International Medical Device Regulators Forum

3.2.7 **IVD** - In Vitro Diagnostics

3.2.8 **NRA** - National Regulatory Authority

3.2.9 **SADC** - Southern African Development Community

3.2.10 **SRA** – Stringent Regulatory Authority

3.2.11 **WHO** – World Health Organization

4 Criteria for Recognition and/or Reliance

4.1 General

4.1.1 One of the goals of medical devices regulations is to ensure access to safe, efficacious, and good quality medical devices and IVDs to the population of Botswana for the diagnosis, prevention, treatment, and control of diseases. In order to reduce duplication of work and

to ensure efficient utilisation of the limited resources for the facilitation of access to medical devices, BoMRA shall recognise and rely where applicable on the assessments done by other regulatory agencies to make risk-based informed regulatory decisions.

4.1.2 The African Union and at a regional level, the SADC, have shown commitment to the regulatory harmonization through the IMDRF, AMDF, WHO, ARSO and SADC initiative and has promoted regulatory recognition and reliance on the work of other regulators. This work is now at an infant stage for the medical devices' regulation.

4.2 Recognition

4.2.1 Recognition of Quality and/or technical document assessment

BOMRA unilaterally recognizes registration assessments done by the following regional and international bodies:

a) Stringent Regulatory Agencies as defined by the World Health Organization: A regulatory authority that is:

1. a member of ICH prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or

2. an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or

3. a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein, and Norway

b) World Health Organization Prequalification and,

c) The following African Countries for low to moderate risk medical devices including IVDs

1. Ethiopia 2. Ghana 3 Tanzania

4. South Africa 5. Kenya

d) NRAs of IMDRF management committee

4.2.2 Recognition of medical devices registration assessments conducted through WHO pre-qualification, SRA, SADC and other agencies to be recognized by BOMRA collaborative initiatives.

BOMRA recognizes decisions taken through assessments' reviews conducted under SRA, WHO, and other recognised medical devices regulatory agencies as stated in 4.2.1. Since BoMRA will participate in the final decision making of approval of applications and desk reviews assessed through SADC collaborative initiative, the assessments done by SADC may not be repeated by BOMRA. The approved applications shall be added to BOMRA approved lists.

4.3 Abridged Review

4.3.1 Based on information received on 4.2.2 above, an abridged review of the application information received may be conducted by BOMRA.

4.3.2 BOMRA still reserves the right to request more information and make an independent decision after consideration of all the information provided.

5 Review of the Policy

5.1 The policy will be reviewed as stated in the Control of Documents **BOMRA/QM/P01**.