SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

COMMUNICATION TO STAKEHOLDERS

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Regulatory Requirements for Veterinary Medical Devices (including *in-vitro* Diagnostic Veterinary Medical Devices)

INTRODUCTION

1. The Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, read in conjunction with the General Regulations on Medical Devices, published in Government Gazette Notice 40480, No.1515 of 9 December 2016, provides for the regulatory oversight of veterinary medical devices including *In-Vitro* Diagnostics (IVDs), in South Africa.

2. The General Regulations on Medical Devices, published in Government Gazette Notice 40480, No.1515 of 9 December 2016 Regulation 8 (Application for registration of a medical device) and Regulation 12 (License to manufacture, import or act as a wholesaler of a medical device) prescribe the requirements for medical devices including veterinary medical devices and IVDs, which are used in South Africa. No veterinary medical device, including an IVD, may be imported into the country without authorisation from the South African Health Products Regulatory Authority (SAHPRA).

3. The definition of a medical device according to the Medicines and Related Substances Act 101 of 1965, is as follows:

   "medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)—intended by the manufacturer to be used, alone or in combination, for humans or animals,

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for one or more of the following:

(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 purposes by means of in vitro examination of specimens derived from the human body; and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or **animal body**, but which may be assisted in its intended function by such means;*

4. A medical device, including an IVD, which acts in or on the animal body is referred to as a veterinary medical device or IVD medical device.

5. All veterinary medical devices, including IVDs, require authorisation from the Authority before they are placed on the South African market.

6. A person who intends to market, a single medical device including IVDs,, a medical device group, medical device family, or a medical device system must apply to the Authority for a medical device establishment license issued under Section 22C of the Medicines and Related Substances Act 101 of 1965, as amended, prior to importation, manufacture, distribution or wholesale of the medical device. This is applicable for all medical devices, including those for use on a human and / or animal body.

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REGULATORY REQUIREMENTS for VETERINARY MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTIC MEDICAL DEVICES (IVDs):

1. The South African risk classification must be used. There are four (4) classes of medical devices including IVDs, as provided in the medical device classification rules. Classification depends on the level of risk as per the SAHPRA classification guideline: SAHPGL-MD-04 (https://www.sahpra.org.za/document/guideline-for-classification-of-medical-devices-and-ivds/)
2. Manufacturers of all classes of veterinary medical devices including IVDs, are expected to demonstrate conformity to the Essential Principles of Safety and Performance as per SAHPRA guideline https://www.sahpra.org.za/document/medical-device-ivd-essential-principles/, through the preparation and holding of technical documentation that shows how each veterinary medical device was developed, designed, and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity.
3. The medical device including IVDs, must be manufactured in a facility that has been certified to comply with the requirements of the current standard ISO 13485 Medical Devices- Quality Management Systems - Requirements for Regulatory Purposes or ISO9001 Quality Management System.
4. For all medical devices, including IVDs, intended for animal use/animal healthcare, it shall be indicated and labelled "For Veterinary Use" or "Device for Veterinary Use Only/ For animal use only".
5. Where a GMDN code and descriptor does not exist, the applicant will indicate /write "VET" on the application form in place of the GMDN code.
6. A Medical Device not registered for veterinary use by the National Regulatory Authority (NRA) in a country recognised by SAHPRA but fits the definition a medical device for VETERINARY USE ONLY, should be listed. Approval from a recognised NRA may be exempted at the discretion of SAHPRA.

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7. Veterinary medical devices including IVDs, regulated under the Hazardous Substances Act 15 of 1973 (Act 15) should further ensure compliance with Act 15 and related regulations.

APPLICATION FOR A SAHPRA MEDICAL DEVICE ESTABLISHMENT LICENCE

1. Any legal person (individual or company) must submit an application to SAHPRA to be licensed as an importer, manufacturer, distributor or wholesaler of a veterinary medical device, including an *In-Vitro* Diagnostic medical device (IVD), as per Guideline SAHPGL-MD-06 (https://www.sahpra.org.za/document/guideline-for-a-license-to-manufacture-import-export-or-distribute-medical-devices-and-ivds/).
2. A Medical device establishment which already holds a medical device establishment licence to import, manufacture, distribute or wholesale a medical device for **human use**, and who wishes to **add veterinary medical devices**, including veterinary IVDs, must list all veterinary medical devices, including all veterinary medical devices; on an application for an amendment of a SAHPRA medical device establishment licence and on the application for a renewal of a SAHPRA medical device establishment licence, when relevant.
3. The holder of licence to import, manufacture, distribute or wholesale a medical device, including an IVD medical device, for human use may NOT import, manufacture, distribute or wholesale a veterinary medical device, including a veterinary IVD, unless the veterinary medical device, including a veterinary IVD, is listed on the licence application, licence amendment application or licence renewal application and approved by SAHPRA.

4. Refer to the guideline : Amendment of Medical Device Establishment Licence https://www.sahpra.org.za/document/communication-to-industry-licence-amendment/

ADDITIONAL DOCUMENTS TO BE SUBMITTED UPON APPLICATION FOR A VETERINARY MEDICAL DEVICE ESTABLISHMENT LICENCE

The following documents must be submitted upon application to SAHPRA for an application for a new, amended or renewal of a medical device establishment licence for VETERINARY medical devices, including veterinary IVDs:

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1. This application refers to a:
    - Class A veterinary medical device, including veterinary IVD, that has measuring properties/characteristics and /or is sterile;
    - Class B veterinary medical device, including veterinary IVD;
    - Class C veterinary medical device, including veterinary IVD; and
    - Class D veterinary medical device, including veterinary IVD.
2. The Instructions for use (IFU) of the veterinary medical device, including veterinary IVD, or a user manual.
3. Copies of the labels on the veterinary medical device, including veterinary IVD, and the labels on the primary and secondary levels of packaging.
4. A valid certificate of compliance of the veterinary manufacturer's quality management system to the current ISO13485 standard or ISO9001 standard.
5. For Class C and D veterinary medical device, including veterinary IVD, provide evidence of pre-market approval or registration for each listed veterinary medical device, including veterinary IVD, from at least one of the six jurisdictions recognised by SAHPRA (Australia, Brazil, Canada, Europe, Japan, United States of America) or pre-qualification by the World Health Organization.

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer (CEO)
SAHPRA