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Expression of Interest for Medical Device Registration Voluntary Feasibility Study

Document History

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First publication	

This document sets out the requirements for interested parties to submit an Expression of Interest (EOI) to participate in the SAHPRA medical device registration feasibility study.

SAHPRA intends to conduct a voluntary feasibility study for medical device registration to validate the proposed process for registration of medical devices.

The purpose of registration of medical devices is to ensure medical devices available in South Africa are safe for use, perform as intended and are of acceptable quality.
As per the Medicines and Related Substances Act 101 as amended and supporting medical device regulations[1] SAHPRA is responsible to conduct registration of medical devices.

This is a "living document" and will be updated as required.

Following completion of the medical device voluntary registration feasibility study, participants (including SAHPRA evaluators and administrators) will be engaging to determine their learnings and opportunities for improvement to the process. For this reason, published technical requirements for registration and guidelines may be amended by SAHPRA.

1. INTRODUCTION

The medical device registration feasibility study is only for medical devices intended for human use and aims to provide an approach to benefit stakeholders, enabling the registration of medical devices which are currently either legally imported into South Africa or manufactured in South Africa.
Furthermore, the registration feasibility study will align to a risk based approach which recognises the high

[1] Regulations Relating to Medical Devices and *In-vitro* diagnostic Medical Devices (IVDs) Government Gazette 9 December 2016 No 40480.

burden of communicable disease in South Africa, and it will utilise a reliance regulatory framework where possible.

The high burden of disease in South Africa centers around both communicable diseases and non-communicable diseases. Medical devices are frequently used as a vital tool for diagnosing these diseases. Hence medical devices (IVDs and non-IVDs) which perform as intended in a consistent manner are imperative to facilitate correct diagnosis, treatment and monitoring of patients.-

Medical devices to test, diagnose and monitor communicable diseases such as HIV and TB are considered priorities for registration and applicable for this medical device voluntary registration feasibility study.The medical device voluntary feasibility study will include both IVD and non-IVD medical devices.

3.1. Voluntary Registration feasibility study – Medical Device establishment licence holders

The Authority invites application for participation in the registration of a medical device voluntary feasibility study, from holders of a medical device establishment licence where the licensed activity in South Africa includes importation of a medical device into South Africa (with or without labelling in South Africa), or manufacture of a medical device in South Africa, or both of the above scenarios.

Only one medical device will be considered for the medical device registration feasibility study from each holder of a medical device establishment licence.

This medical device registration feasibility study is only for medical devices intended for human use and it aims to provide an approach to benefit all stakeholders, to enable the registration of medical devices which are currently either legally imported into South Africa or manufactured in South Africa.

The Authority aims to include a range of IVDs and non-IVDs used to diagnose and monitor HIV and TB into the medical device voluntary feasibility study and will ideally include both medical devices manufactured in South Africa and imported class C and D medical devices into the medical device voluntary feasibility study

An overview of the type and range of medical devices for consideration are noted in diagram 1 below.

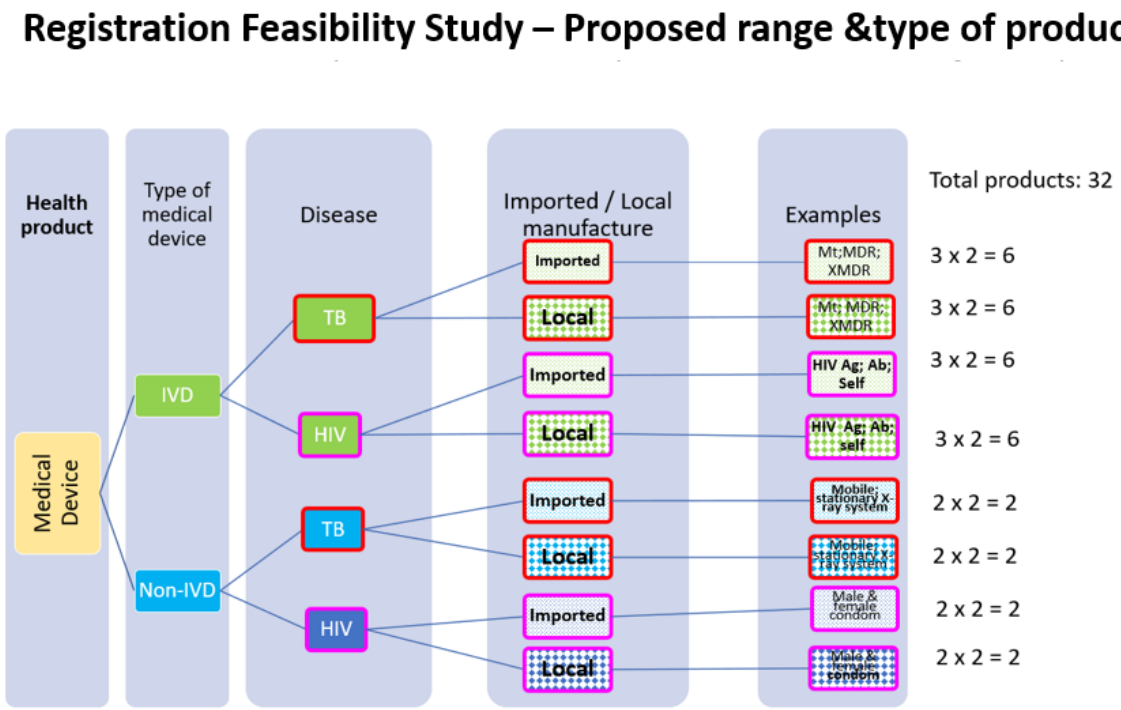

Diagram 1. Range and type of medical devices proposed for medical device registration feasibility study

3.2. Medical device registration voluntary feasibility study – overview

A qualification decision tree for the medical device registration feasibility study and the two medical device voluntary feasibility study registration pathways (for an imported medical device and for a locally manufactured medical device) are provided in Annexure C.
Following completion of the medical device voluntary registration feasibility study, participants (including SAHPRA verifiers, evaluators and administrators) will be engaged to determine their learnings and opportunities for improvement to the process. For this reason, published technical requirements and guidelines may be amended by SAHPRA.

3.3. Technical Requirements for medical device registration feasibility study

Act 101 empowers SAHPRA to call-up both medical devices (IVDs and non-IVDs) currently on the market and those yet to be brought to the South African market (i.e. new medical devices) for registration.

The global harmonised approach to regulatory control of medical devices is premised on a risk based approach – where the patient, user and public health are considered.
The regulatory framework uses a four-class risk system to classify medical devices and the fundamental premise is where there is higher risk of use or non-performance of the medical device then there are greater requirements to substantiate safety, quality and performance prior to authorisation to market.

The regulatory authority utilises a process whereby an accredited third party (i.e. a Conformity Assessment

Body accredited to ISO17021 by SANAS and recognised by SAHPRA) assesses and certifies when relevant standards and specifications are met as evidence that the medical device to be registered meets the **Essential Principles of Safety and Performance.**[2]
The third-party conformity assessment approach is aligned to that of multiple regulatory authorities, which recognises the work of external technical experts and helps to improve efficiency. This aligns to

a) the principles of global harmonisation where quality standards for accreditation of third party conformity assessment bodies (such as certification bodies and testing bodies) are recognised; and
b) the South African National Accreditation Standards Act (SANAS), implemented by the Department of Trade and Industry (DTI).

The South African regulatory framework for medical devices is based on the principles of assessment of conformity of a medical device to specified requirements by an independent and qualified expert. The extent of assessment is dependent on the risk class of the medical device.[3]

It is a requirement of the South African Authorised Representative [AR] to make a legal declaration that the technical documentation submitted to SAHPRA for registration of a medical device does conform to all the standards as identified by SAHPRA for the type and risk class of medical device, and that all required evidence to substantiate that the relevant Essential Principles of Safety and Performance are met.

It is for SAHPRA to verify and review the documentation submitted for relevance and quality prior to adding the specific medical devices to either the IVD medical device register or non-IVD medical device register.

Where a reliance regulatory model is used, the Authority will review the technical documentation submitted. Such a review will include verification of certificates, publications and references included in the technical file submitted by the Applicant.

The technical requirements and a guideline for application for registration of an IVD and a non-IVD respectively are published on the SAHPRA website.[4] [5]

The Medical Device unit of SAHPRA will appoint personnel to conduct verification of technical documentation submitted for registration. Such personnel will understand medical devices and specifically the type of medical device (IVD or non-IVD) under review.
The SAHPRA personnel will be trained to understand the conformity assessment requirements[6], the principles of the accreditation of conformity assessment bodies within a conformity assessment framework and the relevant regulatory science for medical devices.

3.4. Medical device registration voluntary feasibility study – product categories

The Authority invites application from holders of a medical device establishment licence (i.e. to manufacture and distribute a medical device), to participate in the medical device registration feasibility study , for the following medical device product categories, as listed within the GMDN database:

[2] SAHPGLMD01 Essential Principles of Safety & Performance
[3] SAHPGLMD11 Conformity assessment Procedures for Medical devices Guideline (MCC8.03)
[4] SAHPGLMD09v2 Registration of an IVD Technical Dossier
[5] SAHPGLMD10v2 Registration of a non-IVD Technical Dossier
[6] SAHPGLMD11 Conformity assessment Procedures for Medical devices Guideline (MCC8.03)

CT701 Infectious disease IVDs

3.6.1 HIV in-vitro diagnostic tests (IVDs) which are within the following GMDN term names:

term.termCode	term.termName
30768	HIV1 nucleic acid IVD, kit, nucleic acid technique (NAT)
48190	HIV1/HIV2/Mycobacterium tuberculosis antibody IVD, kit, rapid ICT, clinical
48212	HIV1/Hepatitis C virus nucleic acid IVD, kit, nucleic acid technique (NAT)
48216	HIV1/Hepatitis C virus/Hepatitis B virus nucleic acid IVD, kit, nucleic acid technique (NAT)
48430	HIV1/HIV2 antigen IVD, kit, enzyme immunoassay (EIA)
48431	HIV1/HIV2 antigen IVD, kit, chemiluminescent immunoassay
48432	HIV1/HIV2 antigen IVD, kit, rapid ICT, clinical
48436	HIV1/HIV2 antigen neutralization IVD, kit, enzyme immunoassay (EIA)
48437	HIV1/HIV2 antigen neutralization IVD, kit, chemiluminescent immunoassay
48441	HIV1/HIV2 nucleic acid IVD, kit, nucleic acid technique (NAT)
48445	HIV1/HIV2 antigen/antibody IVD, kit, enzyme immunoassay (EIA)
48446	HIV1/HIV2 antigen/antibody IVD, kit, chemiluminescent immunoassay
48447	HIV1/HIV2 antigen/antibody IVD, kit, rapid ICT, clinical
48451	HIV1/HIV2 antibody IVD, kit, enzyme immunoassay (EIA)
48452	HIV1/HIV2 antibody IVD, kit, chemiluminescent immunoassay
48453	HIV1/HIV2 antibody IVD, kit, immunoblot
48458	HIV1 antigen IVD, kit, enzyme immunoassay (EIA)
48459	HIV1 antigen IVD, kit, enzyme immunohistochemistry
48460	HIV1 antigen IVD, kit, chemiluminescent immunoassay
48462	HIV1 antigen neutralization IVD, kit, enzyme immunoassay (EIA)
48463	HIV1 antigen neutralization IVD, kit, chemiluminescent immunoassay
48468	HIV1 genotyping IVD, kit, nucleic acid technique (NAT)
48472	HIV1 antigen/antibody IVD, kit, enzyme immunoassay (EIA)
48473	HIV1 antigen/antibody IVD, kit, chemiluminescent immunoassay
48477	HIV1 immunoglobulin G (IgG) avidity IVD, kit, enzyme immunoassay (EIA)
48478	HIV1 immunoglobulin G (IgG) avidity IVD, kit, chemiluminescent immunoassay
48480	HIV1 antibody IVD, kit, enzyme immunoassay (EIA)
48481	HIV1 antibody IVD, kit, chemiluminescent immunoassay
48482	HIV1 antibody IVD, kit, immunoblot
48483	HIV1 antibody IVD, kit, rapid ICT, clinical
48487	HIV2 antigen IVD, kit, enzyme immunoassay (EIA)
48488	HIV2 antigen IVD, kit, chemiluminescent immunoassay
48492	HIV2 antigen neutralization IVD, kit, enzyme immunoassay (EIA)
48493	HIV2 antigen neutralization IVD, kit, chemiluminescent immunoassay
48497	HIV2 nucleic acid IVD, kit, nucleic acid technique (NAT)
48501	HIV2 antigen/antibody IVD, kit, enzyme immunoassay (EIA)
48502	HIV2 antigen/antibody IVD, kit, chemiluminescent immunoassay
48506	HIV2 antigen/antibody avidity index IVD, kit, enzyme immunoassay (EIA)

48507	HIV2 antigen/antibody avidity index IVD, kit, chemiluminescent immunoassay
48511	HIV2 antibody IVD, kit, enzyme immunoassay (EIA)
48512	HIV2 antibody IVD, kit, chemiluminescent immunoassay
48513	HIV2 antibody IVD, kit, immunoblot
48514	HIV2 antibody IVD, kit, rapid ICT, clinical
60809	HIV1 antigen neutralization IVD, kit, fluorescent immunoassay
60810	HIV1 antigen IVD, kit, fluorescent immunoassay
60868	HIV1/Hepatitis C virus/Hepatitis B virus nucleic acid extraction/isolation and control kit IVD
62052	HIV1/HIV2/Hepatitis C virus/Hepatitis B virus nucleic acid IVD, kit, nucleic acid technique (NAT)
63079	HIV/AIDS therapy-associated genotyping IVD, kit, nucleic acid technique (NAT)
63667	HIV1/HIV2/Treponema pallidum antibody IVD, kit, rapid ICT, clinical
65847	HIV1/HIV2 antibody IVD, kit, rapid ICT, clinical
65848	HIV1/HIV2 antibody IVD, kit, rapid ICT, self-testing

IVDs which include testing for HIV and hepatitis (or another infectious disease) are also included. (CT923 Multiple type infectious microorganism IVDs) e.g., HIV1/Hepatitis C virus/Hepatitis B virus nucleic acid IVD, nucleic acid technique (NAT)
HIV1/HIV2/Mycobacterium tuberculosis antibody IVD, rapid ICT, clinical

3.6.2 Mycobacterium *in-vitro* diagnostic tests (IVDs) which are within the GMDN term name CT791 **Mycobacterium IVD** and includes CT923 Multiple type infectious microorganism IVDs such as HIV1/HIV2/Mycobacterium tuberculosis antibody IVD, rapid ICT, clinical.
IVDs for multi-drug resistant tuberculosis (MDR-TB) or extensively drug-resistant tuberculosis (XDR-TB) using nucleic acid technique (NAT) are also included

30658	Multiple antimycobacterial minimum inhibitory concentration (MIC) IVD, kit
36285	Antimycobacterial minimum inhibitory concentration (MIC) IVD
44408	Multiple Mycobacterium species culture isolate identification IVD, kit
45367	Multiple antimycobacterial susceptibility testing kit IVD
48190	HIV1/HIV2/Mycobacterium tuberculosis antibody IVD, kit, rapid ICT, clinical
51143	Multiple Mycobacterium species antigen IVD, kit, rapid ICT, clinical
51144	Multiple Mycobacterium species antigen IVD, kit, enzyme immunoassay (EIA)
51148	Multiple Mycobacterium species nucleic acid IVD, kit, microarray
51149	Multiple Mycobacterium species nucleic acid IVD, kit, nucleic acid technique (NAT)
51151	Mycobacteriophage nucleic acid IVD, kit, nucleic acid technique (NAT)
51155	Mycobacterium (phage-indicator) antimicrobial susceptibility testing IVD, kit, nucleic acid technique (NAT)
51157	Mycobacterium leprae antigen IVD, kit, rapid ICT, clinical
51158	Mycobacterium leprae antigen IVD, kit, agglutination
51159	Mycobacterium leprae antigen IVD, kit, enzyme immunoassay (EIA)
51163	Mycobacterium leprae nucleic acid IVD, kit, nucleic acid technique (NAT)
51167	Mycobacterium leprae total antibody IVD, kit, fluorescent immunoassay
51168	Mycobacterium leprae total antibody IVD, kit, enzyme immunoassay (EIA)
51172	Mycobacterium tuberculosis complex species antigen IVD, kit, rapid ICT, clinical
51173	Mycobacterium tuberculosis complex species antigen IVD, kit, agglutination
51174	Mycobacterium tuberculosis complex species antigen IVD, kit, enzyme immunoassay (EIA)
51178	Mycobacterium tuberculosis nucleic acid IVD, kit, nucleic acid technique (NAT)
51182	Mycobacterium tuberculosis immunoglobulin A (IgA) antibody IVD, kit, enzyme immunoassay (EIA)
51186	Mycobacterium tuberculosis immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
51190	Mycobacterium tuberculosis immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)
62717	Multidrug-resistant nontuberculous Mycobacterium (NTM) nucleic acid IVD, kit, nucleic acid technique (NAT)
62999	Mycobacterium tuberculosis complex species total antibody IVD, kit, enzyme immunoassay (EIA)
65233	Mycobacterium tuberculosis complex species nucleic acid IVD, kit, nucleic acid technique (NAT)
65814	Mycobacterium tuberculosis immunoglobulin G (IgG)/IgM antibody IVD, kit, rapid ICT, clinical
66567	Mycobacterium tuberculosis total antibody IVD, kit, rapid ICT, clinical
66576	Multiple Mycobacterium species nucleic acid IVD, kit, nucleic acid amplification/mass spectrometry
61517	MDR-TB/XDR-TB nucleic acid IVD, kit, nucleic acid technique (NAT)

non-IVDs

3.6.3 Medical devices used for diagnosis of TB which are within the collective terms.

C999	Radiological devices
CT692	Basic diagnostic x-ray systems and associated devices
CT1515	Basic diagnostic x-ray systems

This includes stationary, portable and mobile analogue and digital x-ray systems.

37626	Mobile basic diagnostic x-ray system, analogue
37642	Portable basic diagnostic x-ray system, analogue
37643	Portable basic diagnostic x-ray system, digital
37644	Stationary basic diagnostic x-ray system, analogue
37645	Stationary basic diagnostic x-ray system, digital
37647	Mobile basic diagnostic x-ray system, digital
37657	Hand-held basic diagnostic x-ray system, analogue

37658	Hand-held basic diagnostic x-ray system, digital

3.6.4 Medical devices used to prevent pregnancy and for the transmission of infections during coitus which are within the GMDN terms

CT1068 Condoms
CT1070 Female condoms
CT1071 Latex condoms
CT1072 Latex-free condoms
CT1069 Male condoms

34151	Basic male condom, synthetic polymer
45138	Basic male condom, Hevea-latex
47717	Micro-condom, Hevea-latex
47718	Micro-condom, synthetic polymer
47719	Medicated male condom, Hevea-latex
47720	Medicated male condom, synthetic polymer
47721	Female condom, Hevea-latex
47722	Female condom, synthetic polymer
60379	Basic male condom, animal-derived
60405	Coitus kit, Hevea-latex condom
60406	Coitus kit, synthetic polymer condom

3.5. Medical device registration voluntary feasibility study – Expression of Interest process

The opportunity to submit interest in the Medical device registration voluntary feasibility study will open on the 20th of May 2024 and interested parties will have 30 working days to submit an Expression of Interest with a completed document as noted in Annexure A.

SAHPRA will give priority to the medical devices identified by the NDOH, NICD and NHLS as priority medical devices, and thereafter advise interested parties of the acceptance or not to the medical device voluntary registration feasibility study. Since there is a limited resource available to proceed with the study , acceptance into the medical device voluntary registration feasibility study, is at the discretion of SAHPRA.

Failure to submit a complete application or timeous response to queries from SAHPRA, may result in the expiry of the application for Medical device registration voluntary feasibility study and participation in the Medical device registration voluntary feasibility study no longer being valid.

The Medical device registration voluntary feasibility study process will be as follows:

- SAHPRA publish "Expression of Interest for Medical Device voluntary registration feasibility study," communication (this document).
- Each interested party complete Annexure A EOI and returns to SAHPRA, using email mdreg@sahpra.org.za within 30 working days.
- SAHPRA acknowledge each EOI submitted within 5 working days.
- SAHPRA conduct an administrative first review of each Expression of Interest and identify & communicate relevant queries or omissions to interested party, where applicable.
- The interested party responds to SAHPRA within 5 working days.
- SAHPRA acknowledge response, where applicable.
- SAHPRA confirm participation in the medical device voluntary registration feasibility study, or advise of non-acceptance into the medical device voluntary registration feasibility study,.
- SAHPRA advise study participants to submit registration application, as per the requirements noted below in section XXX.
- SAHPRA conduct verification of each application for registration. The application must include the technical dossier and supporting evidence submitted to identify that the Essential Principles of Safety and Performance of the medical device are adequately addressed with each application for registration.

2. Medical device registration voluntary feasibility study documents required

Cover letter

Completed checklist – refer Annexure B

Complete technical file as per SAHPGL_MD_09_v2 Registration of an IVD Technical Dossier or SAHPGL_MD_10_v2 Registration of a non-IVD Technical Dossier

Refer to Annexure C

Each approved study participant will be provided with a unique link to submit documents to SAHPRA in an electronic format using a designated link. Documents must be named according to the name in the technical file and must be in pdf format which facilitates in-document links (i.e., the document submitted must not be a photocopy).

3. CONFORMITY ASSESSMENT REQUIREMENT

Refer to SAHPGL_MD_11_v1 Conformity assessment guideline, for a class C and a class D medical device.

4. FEES FOR MEDICAL DEVICE REGISTRATION VOLUNTARY FEASIBILITY STUDY

SAHPRA will not charge a fee to participate in this medical device voluntary registration feasibility study, For this reason, SAHPRA will not issue a certificate of registration for the medical devices which are participants in this medical device voluntary registration feasibility study.

5. MEDICAL DEVICE REGISTRATION VOLUNTARY FEASIBILITY STUDY FOLLOW-UP

A review of the study applications and processes used will be conducted by SAHPRA after six months. The on-going learnings from the study will be incorporated into the guidelines and templates in order to streamline the registration process for medical devices. A summary report of the study will be published after six months after the study .

6. REGISTRATION SUBMISSION SCHEDULES AND OTHER INFORMATION

By means of providing further clarity and guidance – refer to Annexure C for the Medical device registration voluntary feasibility study .

Implementation may be amended according to demand for registration for different categories of medical devices and the resources available to SAHPRA.

7. ANNEXURES

Annexure A: Expression of Interest for Medical device registration voluntary feasibility study

Annexure B: Medical device registration voluntary feasibility study document Checklist

Annexure C: Medical device registration voluntary feasibility study qualification decision tree and registration pathways.

Annexure A: Expression of Interest for Medical device registration voluntary feasibility study

Persons who are interested to participate in the Medical device registration voluntary feasibility study are requested to submit at least the following information to mdreg@sahpra.org.za :

Name of Medical Device Establishment Licence Holder (as reflected on the Licence)
Name and contact details of Authorised Representative

Activities for which the holder of medical device establishment is authorised and licensed to conduct in South Africa, e.g. import class D IVD / non-IVD medical device.

The following details for the medical device to be considered for Medical device registration voluntary feasibility study

- Full product name (including brand / commercial / proprietary / trademark name)
- Type of medical device
- GMDN term number and term name
- Risk class of medical device (refer SAHPGL-MD-04_v3 Guideline for Classification of Medical Devices)
- Intended use of medical device (as in IFU)
- Market status of the medical device – i.e., on the market or new medical device not yet imported into South Africa or manufactured in South Africa.
- For imported medical device – details of the originating approval/s (refer SAHPGL-MD-06_v3 Licensing guideline)
- For medical device locally manufactured in South Africa – certification status of the QMS at the licensed facility and any other market approval / authorisations / certifications held for proposed medical device.

Refer to Annexure C for documents to be submitted with the Medical device registration voluntary feasibility study application.

Annexure B: Medical device registration voluntary feasibility study document Checklist

Document name	**Document reference**	**Included by Applicant**		**Confirmed** (for SAHPRA use)	
	As determined by applicant	**Yes**	**No**	Yes	No
Cover letter					
[Supporting certifications must be provided in the technical file]					
IVD / non-IVD TECHNICAL DOSSIER: [7]					
Chapter 1. Regional and Administrative information					
Chapter 2. Submission context					
Chapter 3. Non-clinical evidence (including Essential Principles checkllist)					
Chapter 4. Clinical evidence					
Chapter 5. Labelling and promotional material					
Chapter 6A. QMS information and supporting certification/s					
Chapter 6B. QMS Device specific information					

Annexure C: Medical device registration voluntary feasibility study qualification decision tree and registration pathways.

1. Is the medical device a class C or D medical device – as classified in South Africa? Refer SAHPGL-MD-04 Guideline for Classification of Medical Devices

   Yes / No (If No – the product does not qualify for Medical device registration voluntary feasibility study .

2. Is the Class C or D medical device used to prevent, treat or diagnose HIV or TB?

   Yes / No (If No – the product does not qualify for Medical device registration voluntary feasibility study ?).

3. Is the importer or manufacturer of the medical device a holder of a valid medical device establishment licence in South Africa?

[7] SAHPGLMD09v2 Registration of an IVD Technical Dossier or SAHPGLMD10v2 Registration of a non-IVD Technical Dossier

Yes / No (If No – the product does not qualify for Medical device registration voluntary feasibility study).

4. Is evidence of conformity assessment of the original manufacturer to ISO13485 by an accredited (ISO17021) in-country Conformity Assessment body (CAB) in South Africa/ Australia/ Brazil/ Canada/ European Community (EU) (notified body)/ Japan/ UK/ USA or WHO PQ (for IVD) available?

   Yes / No (If No – the product does not qualify for Medical device registration voluntary feasibility study).

5. Is the medical device authorised for sale in at least one of the follow jurisdictions;

   Australia(TGA) / Brazil (ANVISA) /Canada (Health Canada) / Europe (EC Certificate) / USA (USA FDA 510k or PMA) or WHO (WHO IVD Pre-Qualification certificate) - referred to as an "originating approval[8]", available?

   Yes / No

   If "Yes", then a RELIANCE registration pathway will be followed (refer to section 6 below).

   If "No", then a SOUTH AFRICAN ASSESSMENT registration pathway will be followed (refer to section 7 below).

6. RELIANCE MEDICAL DEVICE REGISTRATION VOLUNTARY FEASIBILITY STUDY PATHWAY

This is applicable for a medical device authorised for sale in at least one jurisdiction recognised by SAHPRA, where;

a) conformity assessment is conducted by in-country accredited CAB (ISO17021) or notified body in Australia/ Brazil/Canada/EU/Japan/UK/USA or WHO PQ (for IVD), and

b) a registration certificate/ regulatory market approval by TGA /ANVISA/Health Canada/EC / USA FDA or WHO PQ certificate (for IVD) - referred to as an "originating approval[9]", is available.

The South African Authorised Representative (i.e., a natural person appointed by a holder of SAHPRA medical device establishment licence) will;

a) Classify the medical device according to SAHPRA SAHPGL-MD-04 Guideline for Classification of Medical Devices and

b) Prepare the application for Medical device registration voluntary feasibility study and the technical file (refer SAHPGL-MD-09v2 Registration of an IVD Technical Dossier or SAHPGL-MD-10v2 Registration of a non-IVD Technical Dossier, and include the following documents (but not limited to) which must be valid for at least the next 6 months from date of application for Medical device registration voluntary feasibility study:

   - ISO13485 certificate for ORIGINAL manufacturer (in country of origin),
   - Evidence of accreditation (ISO17021) & recognition of the Conformity Assessment Body (e.g. Notified body in EC) in a jurisdiction recognised by SAHPRA,
   - product specific regulatory registration certificate /market approval = reference "originating approval" (see above);

[8] SAHPGL-MD-06 Licensing guideline
[9] SAHPGL-MD-06 Licensing guideline

- ISO13485 certificate for the South African medical device establishment (i.e. according to the activities conducted in South Africa by the licence holder);
- SAHPRA medical device establishment licence,
- South African Authorised Representative's Declaration of Conformity to the Essential Principles of Safety & Performance.

c) Submit the application for feasibility study to SAHPRA and address any queries from SAHPRA.

7. SOUTH AFRICAN ASSESSMENT REGISTRATION PATHWAY

This is applicable for a class C or D medical device which is manufactured in South Africa, and which does NOT hold a market authorisation ("originating approval") for a jurisdiction recognised by SAHPRA.

a) The local South African manufacturer will

- establish a Quality Management System (QMS) and acquire a SAHPRA medical device establishment licence according to the activities conducted on site[10].
- Classify the medical device according to SAHPRA SAHPGL-MD-04 Guideline for Classification of Medical Devices
- Arrange for assessment of the QMS and medical device conformity to ISO13485 and the Essential Principles of Safety & Performance by an accredited CAB (ISO17021) which has been formally recognised by SAHPRA (refer SAHPGL-MD-11 Conformity Assessment and Essential Principles of Safety & Performance). This will include full review of the medical device technical file by a technical expert employed by the CAB.

b) The South African Authorised Representative (i.e., a natural person appointed by a holder of SAHPRA medical device establishment licence) will prepare the application for Medical device registration voluntary feasibility study and the technical file (refer SAHPGLMD09v2 Registration of an IVD Technical Dossier or SAHPGL-MD-10v2 Registration of a non-IVD Technical Dossier), and include the following documents (but not limited to) all valid for at least the next 6 months from date of application for Medical device registration voluntary feasibility study:

- ISO13485 certificate/s for the ORIGINAL South African manufacturer,
- Evidence of accreditation (ISO17021) by SANAS & recognition of the Conformity Assessment Body by SAHPRA,
- ISO13485 certificate for South African medical device establishment (i.e. according to the activities conducted in South Africa by the licence holder). (This may be the same company as the original manufacturer);
- SAHPRA medical device establishment licence for the ORIGINAL South African manufacturer and the South African owner / distributor of the medical device (where different),
- South African Authorised Representative Declaration of Conformity to the Essential Principles of Safety & Performance.

c) The South African Authorised Representative will submit the application for Medical device registration voluntary feasibility study to SAHPRA and address any queries from SAHPRA.

[10] SAHPGL-MD-06 Licensing guideline

Refer:
SAHPGL-MD-04 Guideline for Classification of Medical Devices
SAHPGL-MD-06 Guideline for a License to Manufacture, Import, Export, or Distribute Medical Devices and IVDs
SAHPGL-MD-01 (in draft) Essential Principles of Safety and Performance
SAHPGL-MD-11 Conformity assessment of a medical device guideline (originally 8.03) (awaiting QMS to allocate number)
SAHPGLMD09v2 Registration of an IVD Technical Dossier
SAHPGLMD10v2 Registration of a non-IVD Technical Dossier