South African Health Products
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MEDICAL DEVICES RELIANCE GUIDELINE

This guideline is intended to provide information and outline the principles of reliance-based review for both premarketing and post-marketing regulatory activities in the regulation of medical devices, including IVDs. The document seeks to define how and which Regulatory Reliance pathway mechanism will the South African Health Regulatory Authority (SAHPRA) adopt in making regulatory decisions as it relates to granting of medical device including IVDs establishment license, product registration, Clinical trials approvals, ISO 13485 audits, Post-marketing surveillance, marketing surveillance, and other regulatory functions such as importation for activities such as donation, exhibitions and appraisal. It represents the South African Health Products Regulatory Authority's (SAHPRA) current thinking on the safety, quality, and performance of medical devices and IVDs. The Authority reserves the right to request any additional information to establish the safety, quality and performance of a medical device in keeping with the knowledge available at the time of evaluation. The Authority is committed to ensuring that all registered and listed medical devices including IVDs will be of the required quality, safety and performance. Applicants must adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Document History

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1	First publication released for implementation	31 October 2025
2		

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Glossary

Term/ Abbreviation	Meaning
AMDF	Africa Medical Devices Forum
AMA	Africa Medicines Agency continental procedure
Establishment License	A licence that is legally required to sell medical devices it is obtained from SAHPRA through submitting the relevant application form for all establishments that manufacture, distribute, or wholesale medical devices.
GRP	Good Regulatory Practices
IN VITRO Diagnostic Medical Devices (IVDs)	Means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the body solely or principally to provide information for diagnostic, monitoring, or compatibility purposes.
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
Manufacture	All operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, reprocessing, releasing, packaging, repackaging, labelling and refurbishing of a medical device or IVD, as the case may be, and includes putting a collection of medical devices or IVDs, and possibly other products, together for a medical purpose in accordance with quality assurance and related controls
MD	Medical Device
Medical device	Any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent- (a) used or purporting to be suitable for use or manufactured or sold for use in- (i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof; or (ii) restoring, correcting or modifying any somatic or psychic or organic function; or (iii) the diagnosis or prevention of pregnancy, and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or (b) declared by the Minister by notice in the Gazette to be a medical device, and includes any part or an accessory of a medical device
Market surveillance	Market surveillance of health products is a critical function of regulatory bodies, ensuring that products like medicines, medical devices, and other health-related items continue to meet quality, safety, and performance standards after they are placed on the market. This surveillance involves monitoring, inspecting, and investigating products to identify potential issues and ensure compliance with regulations.
NRA	National Regulatory Authority (NRA); for this document, the term also refers to regional regulatory authorities.
Reliance	The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority

	remains independent, responsible, and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others
RRA	Recognized Regulatory Authority – a term used to refer to the list of regulatory authorities with which SAHPRA aligns itself.
SAHPRA	South African Health Products Regulatory Authority
SANS	South African National Standard (usually an ISO standard accepted as mandatory in South Africa, forms part of the product specification)
MDSAP	Medical Devices Single Audit Programme - Is a single audit system that allows medical device manufacturers to undergo one audit to meet the regulatory requirements of multiple jurisdictions, thereby reducing audits and increasing efficiency. The program involves manufacturers being audited by a recognised auditing organisation.
OEM	Original Equipment Manufacturer
WHO	World Health Organization
WHO Listed Authority	WHO Listed Authorities (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking (GBT) and a performance evaluation process.
WHO-PQ	World Health Organization Prequalification
WHO CRP	WHO Collaborative Registration Procedure

1. INTRODUCTION

Reliance is seen by a growing number of regulatory Authorities as an important tool for improving the efficiency of regulatory operations. It allows the Authority to optimise use of resources, build expertise and capacity, increase the quality of regulatory decisions, reduce duplication of effort, and ultimately, promote timely access to safe, and quality-assured health products. By adopting reliance measures whenever possible, regulators may focus their resources on key activities that cannot be undertaken by others and that contribute to public health. Reliance principles (Universality, Sovereignty of decision-making, Transparency, Respect of national and regional legal bases, Consistency, and Competence) can be applied to any and all stages of the medical device product lifecycle, and the extent to which a given regulatory authority (or jurisdiction) relies on the work of another body can vary. Noting that reliance can be unilateral, bilateral (mutual) or multilateral. SAHPRA will leverage the information in the shared reports and/or decisions to arrive at a regulatory decision, but will maintain its sovereignty and remain autonomous in its decision-making. Effective implementation of reliance will benefit not only the Authority but also patients and other stakeholders.

SAHPRA has adopted the reliance review process as a pathway for routine listing of medical devices, including IVDs, pre-marketing, post-marketing, as well as demonstration (imported), appraisal, personal use, and donation. This approach allows the authority to leverage evaluation efforts done by a recognized regulatory authority (RRA) that SAHPRA aligns with to make evaluation process more efficient and enhance market access. Reliance can facilitate/support regulatory preparedness and response, particularly during public health emergencies.

It should be noted that this guideline does not replace the already published SAHPRA reliance guideline **(SAHPGL-BAU-01)** for medicines and vaccines.

1.1 PURPOSE

This guideline is intended to provide information and guidance to applicants on the requirements to be considered for reliance -based evaluation for the following processes:

i) Routine listing of medical devices, including IVDs, as part of licensing establishments,
ii) Auditing: ISO 13485 certification,
iii) Product pre-marketing activities: Including Clinical Trials,
iv) Product registration: Market authorisation and performance testing,
v) Product post-marketing: Performance testing, variations, vigilance, post-marketing

surveillance,

vi) Product risk classification as determined by the Regulator and proposed classification in the Republic,

vii) Other: Demonstration (imported), appraisal, personal use, donation, regulatory documentations.

1.2 SCOPE

This guideline is applicable for the evaluations of, pre-approval product registration, new product registration, post-approval product changes, and renewals of applications submitted under the reliance-based review.

This guides applicant submitting applications for review using one of the following reliance pathways:

i) Listing of medical devices, including IVDs, as part of licensing establishments

ii) Auditing: ISO 13485 certificate for medical device establishments as per section 22C (1) of the Act, and medical device manufactures and distributors

iii) Registration of medical devices, including IVDs

iv) Product performance testing

v) Product importation (such as demonstration & appraisal, and personal use),

vi) Clinical Trials (Pre and Post Marketing)

vii) Post-market applications (variations) and market surveillance

viii) Product risk classification as determined by the Regulator.

This guideline is not applicable to

- Class A (non-measuring and/or non-sterile characteristics) medical devices, including IVDs.
- A medical device that has not obtained any prior approval from any of the listed medical device recognised regulatory authorities at the point of application will be subject to the full evaluation route.
- Registration of medical devices, including IVDs for emergency use or during disease outbreaks. Applicants should refer to the Public Health Emergency guideline **SAHPGL-PEM-01**

2. LEGAL PROVISION

Refer to the Medicines and Related Substances Act (101/1965) and to the Regulations relating to medical devices and in vitro diagnostic medical Devices (IVDs) (No. 40480).

3. PRINCIPLES OF RELIANCE

The adopted principles of reliance are in line with the WHO recommendations, to optimize innovative and more effective forms of collaboration to make the best use of the available resources and expertise, avoid duplication, to ensure quality and safe Health Products.

The following principles of reliance are adopted:

i) Universality

Reliance applies to all NRAs, irrespective of their levels of maturity or resources**.** Different NRAs use reliance for different reasons. Some use it to increase or build in-house capacity, while others use reliance to gain expertise that they do not have locally.

ii) Sovereignty of decision-making

Reliance does not imply dependence; it is not an Authority outsourcing its decision-making or responsibility. NRAs maintain independence, sovereignty, and accountability in regulatory decision-making.

iii) Transparency

Transparency is a key enabler to adopting new, more efficient ways of conducting regulatory operations, both locally and internationally. NRAs should conduct transparent regulatory operations and decision-making, not only as a fundamental principle of GRP but also to build trust and maximize opportunities for cooperation and reliance as part of a shared regulatory community responsibility

iv) Respect of national and regional legal bases

Reliance practices should be coherent with national and regional legal frameworks and policies on medical products, supported by clear mandates and regulations that ensure efficient implementation of reliance as part of government policy on good regulation.

v) Consistency

The scope of regulatory activities in which reliance may be practised should be clearly defined, and the practice of reliance should be transparent and predictable. Thus, reliance should be expected to be applied consistently for products and processes in the same categories.

vi) Competence

Implementation of reliance approaches requires that NRAs have the necessary competence for critical decision-making. Equally, the authorities being relied upon should have and maintain competence and operate within a robust, transparent regulatory system based on international standards and guidelines, as well as GRP, and a well-functioning quality management system

4. RELIANCE-BASED PATHWAYS FOR MEDICAL DEVICES INCLUDING IVDs

Reliance may take many forms and be applied to varying degrees in recognizing or taking into account the assessment conducted, outcome reports, and decisions of the other Authorities.

SAHPRA, as an autonomous regulator, remains responsible and accountable for the final decisions taken, even when it relies on the decisions and any other relevant information from other regulators.

Reliance-based evaluation pathways for medical devices including IVDs applications, in South Africa will follow at least one of the following pathway (s):

a) Abridged review

b) Recognition

c) Work sharing/Joint assessment

d) Verification

4.1 GENERAL DESCRIPTIONS OF THE RELIANCE-BASED EVALUATION PATHWAYS

a) **Abridged review:** Abridged review is a process that involves streamlining a review by relying to some extent on the comprehensive assessment previously performed by another trusted regulatory authority. This process typically involves a review of a subset of the documentation, focusing on aspects that may be unique or additional to the new market or where some specific confirmation is warranted. It is particularly useful for devices that have obtained approval in one jurisdiction, and the manufacturer is seeking approval in another jurisdiction with similar regulatory requirements. It is expected that the use of reliance in these pathways will save resources and time as compared with standard pathways, while ensuring that the standards of regulatory oversight are maintained.

Such as: The use of RRAs, WLAs, Facilitated Registration Process (CRP, PQ &EUL), Continental procedure.

i) RECOGNISED REGULATORY AUTHORITIES

An application must have been approved by one or more of the RRAs with which SAHPRA aligns itself. The list of RRA is available on the SAHPRA website. (https://www.sahpra.org.za/agreements-mous-with-other-regulators-or-similar-organisations/).

ii) World Health Organization facilitate Review Process (FRP): (https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction)

- Prequalification (PQ) (https://extranet.who.int/prequal/)
- WHO Collaborative Registration Procedure (CRP) (https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction/collaborative-registration-procedure)
- Emergency Use Listing (EUL) (https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction/facilitated-procedure-for-eul-mpox-(mpxv)-ivds)

iii) Continental review

African Medicines Regulatory Harmonization Initiative (AMRH)-the African Medicines Agency (AMA), (https://www.nepad.org/sites/default/files/resourcefiles/V1.0%20August_2021_Guidelines%20on%20Regulatory%20Requirements%20for%20issuance%20%20of%20Market%20Authorisation_DRAFT.pdf)

iv) WHO Listed Authority (WLA)

https://www.who.int/publications/m/item/list-of-who-listed-authorities-wlas

b) **Recognition:** Recognition is the process of accepting a regulatory decision made by another authority or a trusted institution. It involves accepting that the standards and requirements of the reference authority are adequate to satisfy the requirements of the relying authority. Recognition-based reliance can be in the form of unilateral or bi/multilateral recognition. In the specific case of bi/multilateral recognition, a formal agreement among the involved parties may be required.

Such as: The use of Conformity assessment bodies (https://www.sahpra.org.za/wp-content/uploads/2022/09/CAB-Requirement-checklist-Final_v2.pdf) and MDSAP (https://www.mdsap.global/documents/library/eligibility-medical-device-organizations-mdos-apply-mdsap-certification)

c) **Work sharing /Joint assessment:** Work-sharing is a process where multiple regulatory authorities collaborate to complete a regulatory task. It also entails the exchange of information consistent with the provisions of existing agreements and compliant with each agency's or institution's legislative framework for sharing such information with other NRAs. It is intended to optimize resource use and leverage the specialized knowledge and expertise of different regulatory authorities.

The opportunities for work sharing include joint assessment of applications for authorization of clinical trials or marketing authorizations, joint inspections for good practices, joint post-marketing surveillance of the quality and safety of medical products, joint development of technical guidelines or regulatory standards, and collaboration on information platforms and technology.

Such as: Continental process under AMA (https://www.nepad.org/sites/default/files/resourcefiles/V1.0%20August_2021_Guidelines%20on%20Regulatory%20Requirements%20for%20issuance%20%20of%20Market%20Authorisation_DRAFT.pdf); WHO PMS (https://www.who.int/publications/i/item/9789240015319).

d) **Verification:** Verification of sameness of the medical device is used to ensure that the medical device submitted to SAHPRA is the same as the one that has been assessed by the reference regulatory authority. This Reliance pathway can be practiced only if the Authority has the assurance that the medical device being assessed is essentially the same as the one submitted to the reference regulatory Authority. It is the role of the manufacturer to confirm the sameness of a product and to provide the same documentation as submitted to the reference regulatory Authority.

5. RELIANCE PATHWAY ADOPTED BY SAHPRA

5.1 LISTING OF MEDICAL DEVICES INCLUDING IVDS, AS PART OF LICENSING ESTABLISHMENTS

For Issuing of medical device establishment license, the Regulatory Authority shall undertake the verification pathway (refer to guideline **SAHPGL-MD-06**; https://www.sahpra.org.za/document/guideline-for-a-license-to-manufacture-import-export-or-distribute-medical-devices-and-ivds/)

i) Conformity of quality management system (i.e., ISO 13485) certification by the establishments. SAHPRA relies on audits conducted by locally recognised Conformity Assessment Bodies (CABs) This applies to manufacturers and importers of class A (with

measuring and/or sterile characteristics), B, C, D medical devices including IVDs

ii) Product information submitted for class C and D for listing to ensure the sameness as the one that has been approved by the Recognised Regulatory Authority.

5.2 MEDICAL DEVICES INCLUDING IVDs PRODUCT REGISTRATION

All information and documents submitted in support of the registration of Class B, C, D medical devices, including IVDs, must be submitted as per guidance documents **SAHPGLMD09** Registration of an IVD Technical Dossier and **SAHPGLMD10** Registration of a non-IVD Technical Dossier.

The SAHPRA Guideline on Medical Device Registration Process will provide specific document requirements for each of the following reliance pathways.

For medical devices, including IVD products registration, the regulator shall undertake verification of:

- Sameness of the product despite the reliance pathway followed.

5.2.1 Abridged Review

An abridged review is applicable for the following types of applications evaluated and approved by RRA, WLA, and Continental initiatives.

i. All new product registration applications for a medical device already registered/ approved/authorised:

- By an RRA (refer to https://www.sahpra.org.za/agreements-mous-with-other-regulators-or-similar-organisations/)
- By WLA (refer to https://www.who.int/publications/m/item/list-of-who-listed-authorities-wlas)
- WHO Collaborative Registration Procedure (https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction/collaborative-registration-procedure)
- WHO PQ (https://extranet.who.int/prequal/)
- WHO EUL (https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction/facilitated-procedure-for-eul-mpox-(mpxv)-ivds)

ii) Continental Registration Procedure

- African Medicines Regulatory Harmonization Initiative (AMRH)-(

https://www.nepad.org/sites/default/files/resourcefiles/V1.0%20August_2021_Guidelines%20on%20Regulatory%20Requirements%20for%20issuance%20%20of%20Market%20Authorisation_DRAFT.pdf)

iii) Conformity Assessment bodies (CABs) (https://www.sahpra.org.za/wp-content/uploads/2022/09/CAB-Requirement-checklist-Final_v2.pdf)

- Product ISO 13485 Certification
- Confirm Review report for product certification

iv) MDSAP (https://www.mdsap.global/documents/general-documents-and-procedures)

- Verification of the audit report for the MDSAP audited manufacturer

5.2.2 Recognition

A recognition review is applicable during product registration evaluation process to verify and confirm the audit outcome of the Original Equipment Manufacturer (OEM) using the MDSAP initiative. SAHPRA as an affiliate member of MDSAP will verify and recognise the OEMs as listed in the MDSAP system (https://www.mdsap.global/documents/library/eligibility-medical-device-organizations-mdos-apply-mdsap-certification)

5 2.3 Work sharing /Joint assessment

Under this pathway, SAHPRA will engage in joint assessments or work-sharing arrangements with one or more regulatory authorities. This process will involve a primary review conducted by one authority, a secondary review by another authority, and a collaborative joint assessment session to finalize the assessment report and address any comments.

This approach applies to products evaluated and approved by the African Medicines Regulatory Harmonization Initiative (AMRH)-the African Medicines Agency (AMA) and the audits report. (https://www.nepad.org/sites/default/files/resourcefiles/V1.0%20August_2021_Guidelines%20on%20Regulatory%20Requirements%20for%20issuance%20%20of%20Market%20Authorisation_DRAFT.pdf)

5.2.4 Verification

SAHPRA shall undertake a verification assessment of the product dossier submitted for registration to ensure that the same information is submitted as the information that has been approved by the reference regulatory authority. This review is primarily based on verifying, instead of evaluating, information submitted in the application against information that has already been approved by SAHPRA or an RRA.

5.3 CLINICAL TRIAL APPLICATION

Clinical Trial data is crucial in supporting the safety and efficacy of the product intended for registration. During the review process, the Authority considers information regarding the review status of the clinical trial with other Regulatory Authorities, as requested in the application form. As most of the clinical trials are multi-centre trials, the Authority will further take into consideration proper monitoring of the trial and local conditions or prevalence of disease within the context of South Africa. It should be noted that this is for local data; for multi-centre clinical trials, population representation is important.

5.3.1 Recognition

SAHPRA recognises the registration status of a medical device, including IVDs, from other RRA with which SAHPRA shares relevant agreements (e.g., signed memorandum of understanding (MOUs), Confidentiality Agreement (CA)), ISO 14155 standard for Good Clinical Practice (GCP), ICH GCP E6 latest version implemented by the Regulator, in medical device clinical investigations as a basis for its decision-making for approval of the Clinical trials. (https://www.sahpra.org.za/wp-content/uploads/2020/01/31828e7f4thCombinedChapt3rdRevisedNHREC_CTC_SAGCP24May2019_v3clean_Draftforcomment__10.07.2019.pdf)

5.4 POST MARKET SURVEILLANCE

Post Market Surveillance is important for ensuring that medical devices, including IVDs, available on the South African markets are safe, and perform as intended throughout the life cycle of the product.

5.4.1 Verification

To ensure that the Authority fulfils its mandate of monitoring the benefit-risk profile of the medical device, including IVDs, the Authority will consider and verify the safety information communicated, public reports shared by the RRA, WLA, and WHO (WHO global surveillance and monitoring system).

General Note: Applicants must note that additional documentation requirements for the various types of applications may be stipulated in other guidelines.

6. REFERENCES

The following related documents are referenced:

a) Annex 10 Good reliance practices in the regulation of medical products: high level principles and considerations. https://www.who.int/publications/m/item/annex-10-trs-1033

b) BOTSWANA https://www.bomra.co.bw/wpfd_file/policy-recognition-and-or-reliance-on-information-on-medical-devices-including-ivds-from-regional-and-international-regulatory-agencies-bomra-er-med-policy-no/

c) IMDRF Playbook for Medical Device Regulatory Reliance Programs https://www.imdrf.org/consultations/playbook-medical-device-regulatory-reliance-programs

d) OVERVIEW OF REGULATION OF MEDICAL DEVICES AND IVDS https://www.standardsalliance-mdrc.org/wp-content/uploads/2023/09/4-Overview-of-regulation-of-Medical-Devices-and-IVDs.pdf

e) REPUBLIC OF KENYA MINISTRY OF HEALTH PHARMACY AND POISONS BOARD https://web.pharmacyboardkenya.org/download/guidelines-on-reliance-mechanisms-for-marketing-authorization-of-health-products-and-technologies-in-kenya/?wpdmdl=11610&refresh=68666151ed27b1751540049&ind=1744026284472&filename=GUIDELINES-ON-RELIANCE-MECHANISMS-FOR-MARKETING-AUTHORIZATION-OF-HEALTH-PRODUCTS-AND-TECHNOLOGIES-IN-KENYA-.pdf

f) RWANDA FDA GUIDELINES ON RELIANCE FOR REGULATORY DECISION https://rwandafda.gov.rw/wp-content/uploads/2024/02/Guidelines%20on%20Reliance%20for%20Regulatory%20Decision-Making%20Rev3.pdf

g) Tanzania medicine and medical devices Authority https://www.tmda.go.tz/uploads/1748325406-23_Guidelines%20on%20Regulatory%20Reliance%20for%20MA%20of%20Medicinal%20Products-17-04-2025.pdf

h) WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices https://iris.who.int/bitstream/handle/10665/255177/9789241512350-eng.pdf

i) World Health Organization (WHO). Emergency Use Listing Procedure. https://cdn.who.int/media/docs/default-source/medicines/eulprocedure.pdf?sfvrsn=55fe3ab8_8&download=true

j) Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics. https://iris.who.int/server/api/core/bitstreams/bf37980e-d286-4e4f-bda8-d49165619225/content

7. VALIDITY

This guideline is valid for a period of 5 years from the effective date It will be reviewed on this timeframe or as and when required.