SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

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ISO 13485 Certificate as a prerequisite for the approval of a Medical Device Establishment Licence

INTRODUCTION

The international standard ISO 13485 for a quality management system (QMS) is recognised globally to address minimum regulatory requirements for medical devices and *in vitro* diagnostics (IVDs). The standard outlines the requirements for manufacturers and suppliers of medical device and IVDs, and it establishes a minimum quality assurance framework to ensure medical devices and IVDs are managed appropriately with the intention to provide medical device and IVDs which are safe and perform as intended by the manufacturer.

While different jurisdictions may vary in specific regulatory details, the ISO 13485 standard provides a framework for manufacturers and distributors involved in one or more stages of the life cycle of a medical device and IVDs, including the design and development, production, storage and distribution, installation, servicing, final decommissioning and disposal of a medical device, design and development, and provision of associated activities (e.g. technical support) to address the QMS requirements set by the majority of national regulatory authorities (NRAs). The South African Health Products Regulatory Authority (SAHPRA) decided to apply a similar approach to address the management of quality assurance of medical device and IVDs, in South Africa.

On 24 February 2017, the Registrar of the Medicines Control Council (MCC) and the Department of Health published a notice of the resolution of the MCC, whereby all manufacturers, distributors and wholesalers (as referred to in Section 22C (1)(b) of the Medicines Act), were required to obtain a medical device licence within the published timeframe in order to operate within South Africa. As

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contemplated in the Medicines Act read with Regulation 27(2) of the Regulations relating to Medical Devices and IVDs.

Furthermore, the requirements according to Regulation 5(1) of the Regulations relating to Medical Devices and IVDs, were noted in the licensing call-up notice of 24 February 2017. This included, as per Regulation 5(1) (c)(iii), the requirement for the applicant for a licence (as referred to in Section 22C (1)(b) of the Medicines Act) to provide "*acceptable documentary proof of certification to a Quality Management System for Medical Devices and IVDs, as determined by the Council*".

As per Regulation 6 of the Regulations relating to Medical Devices and IVDs, the validity of a licence issued in terms of Regulation 5 is valid for five (5) years from date of issue, and an application for a renewal of a licence must "*contain at least the information or documentation referred to in regulation 5(1) (c), as the case may be*" with the prescribed fee and within the determined timeline.

The purpose of this communication is to:

a) **outline the phased process (refer to annexure A) which SAHPRA has followed to date and will follow from 1 June 2025 to verify ISO 13485 certificates, and**
b) **to provide stakeholders with clarity of the requirements.**

Phase 1.

The initial plan by the MCC and thereafter SAHPRA, was that presentation of documentary proof of certification to the *International Standard ISO 13485 Medical Devices – Quality managements systems – Requirements for regulatory purposes* (herein after referred to as "ISO 13485:2016"), by a holder of a licence issued in terms of Section 22C(1)(b) of the Medicines Act, would be required to be presented to SAHPRA five years after the issue of the first (initial) medical device establishment licence, and as per Regulation 6 of the Regulations relating to Medical Devices and IVDs, that is determined to be a licence renewal.

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This plan was for the first cohort of holders of a medical device establishment licence (issued in 2017 and 2018), in terms of Section 22C (1)(b), to provide an ISO 13485:2016 certificate upon application for renewal for a medical device establishment licence.

On 17 January 2022, SAHPRA published a Communication to Stakeholders_*MD030: Medical Device Establishment Licence Renewal – ISO 13485:2016 Certificate Communication*, outlining the amendment to the timeline, for the implementation of the ISO 13485:2016 certification requirement, from April 2022 to April 2025. This was due to the delay in accreditation of South African Conformity Assessment Bodies (CABs). The additional three (3) years (i.e. after the first 5-year period of grace) were also intended to allow Manufacturers and Distributors (Importers) of medical device and IVDs, time to have the relevant QMS certified by a CAB recognised by SAHPRA, to meet the prevailing ISO 13485:2016 standard.

In September 2022, SAHPRA published a revised communication to stakeholders, *MD031 Medical Device Establishment Renewal Process_v2* regarding the process for renewal of a medical device establishment licence.

A list of required documents was identified under STEP A: DOCUMENTS TO BE SUBMITTED, and included the following on:

iv. An ISO 13485:2016 QMS certificate in the name of the South African licensed medical device establishment and at the same address (as applicable).

v. In case the organisation does not have a valid ISO 13485:2016 certificate, a declaration by the Authorised Representative that the organisation has implemented a quality management system aligned to the ISO 13485:2016 standard and that a certified copy of certification to ISO 13485:2016 standard will be submitted to the Authority once acquired and no later than 01 April 2025.

During this period of grace, from first issue of a licence to 1 April 2025 (referred to as Phase 1) and to facilitate uninterrupted supply of medical device and IVDs in South Africa, SAHPRA relied on each

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holder of a medical device establishment licence to establish, implement and certify the relevant QMS, without providing evidence thereof to SAHPRA.

It is noted that SAHPRA and its predecessor, MCC, provided all stakeholders with sufficient time to implement a QMS relevant for medical device and IVDs to meet regulatory requirements and that communications regarding the process were comprehensive and timely. SAHPRA sensitised the medical device industry for the required certification to the ISO 13485:2016 standard as a prerequisite for the approval of a Section 22C (1)(b) licence and this included

- information shared during industry engagements in 2023, 2024 and 2025;
- the requirements of the SAHPRA reference document; and
- responding to individual queries.

Phase 2

As per previous SAHPRA communications, and from 1 June 2025 it is incumbent upon each holder of a medical device establishment licence, issued in terms of Section 22C of the Medicines Act, to meet the regulatory requirements and hold the relevant documentary proof of certification to the international standard *ISO 13485:2016 Medical Devices - Quality Management Systems – Requirements for regulatory purposes.*

With effect from **1 June 2025**, certification to the international standard *ISO 13485:2016 Medical Devices - Quality Management Systems – Requirements for regulatory purposes* is required to comply with Act 101, as amended, and Regulations 5 and 6 relating to Medical Devices and IVDs.

In summary, all license holders under Section 22C of the Medicines Act must maintain documentary proof of accreditation of their QMS to the international standard ISO 13485:2016. This requirement mandatory even in cases where the license holder is not obligated to submit such evidence to SAHPRA.

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SAHPRA will continue to implement a **phased approach** (Annexure A), requesting each holder of a medical device establishment licence to submit documentary proof of QMS certification to the ISO 13485:2016 standard for purposes of verification.

As per Section 22C (1) of the Act, and Regulation 5(1)(c) relating to Medical Devices and IVDs, the Authority (SAHPRA), requires a person who makes application for a new licence, following an expiry of a licence or late renewal submission and a person who makes application for a renewal of an existing licence, to provide documentary proof of certification of the QMS to the international standard ISO 13485:2016 to SAHPRA, which the Authority may deem necessary.

It is noted that from 1 June 2025

- Manufacturers and Distributors (Importers) of medical devices and IVDs, intending to submit a renewal of a medical device establishment licence will be required to provide a valid ISO 13485:2016 certificate in the name of the South African licensed medical device establishment and at the same address (as applicable), from a CAB recognised by SAHPRA; and
- Manufacturers and Distributors (Importers) intending to submit a renewal of a medical device establishment licence and are currently in the process of obtaining certification to ISO 13485:2016 will be required to provide documentary proof of such agreement from a CAB recognised by SAHPRA, and once the certificate is acquired it must be submitted to SAHPRA for verification; and
- Manufacturers and Distributors (Importers) of medical devices and IVDs, that have already renewed their medical device establishment licence and those who made previous applications for a new medical device licence, will be requested to submit a valid ISO 13485:2016 certificate either on request by SAHPRA or by a date to be determined and communicated by SAHPRA (This is addressed in Phase 3 below).

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In summary;

in terms of Section 22C of the Act, medical device establishment licence holders must be in possession of documentary proof of certification of the QMS at the same address (as applicable) to the international standard ISO 13485:2016 issued by a CAB recognised by SAHPRA.

Documentary proof of certification of the QMS of the South African licensed medical device establishment and at the same address (as applicable), to the international standard ISO 13485:2016 issued by a CAB recognised by SAHPRA, must be submitted to SAHPRA for purposes of verification in the following instances.

i) by the Applicant for a **new** medical device establishment licence, to be issued in terms of Section 22C of the Act, and

ii) for an application for a **renewal** of a medical device establishment licence issued in terms of Section 22C of the Act; and

iii) as requested by SAHPRA (for the purpose of updating information, application reviews, investigations and post market vigilance activities e.g. on receipt of a product complaint / patient injury etc).

Phase 3:

From 1 June 2025, a holder of a licence to Manufacture and Distribute (Import) medical device and IVD,

i) who makes application for an amendment to a licence, and

ii) who is already in possession of a current and valid ISO 13485:2016, regardless of when the medical device establishment licence was issued, and who is not required to apply for a new licence or renewal of a licence or amendment to a licence,

will be required to submit to SAHPRA a valid ISO 13485:2016 certificate issued by a CAB recognised by SAHPRA for purposes of verification by SAHPRA, by a date to be published in a Communication to Stakeholders.

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Phase 4:

Manufacturers and Distributors (Importers) who require an amendment to a current medical device establishment licence and **amendment to the product list** – (previously recognised as a notification), will be required to submit a valid certification to ISO 13485:2016 issued by a CAB recognised by SAHPRA, for purposes of verification by SAHPRA, to SAHPRA by a date to be published as a Communication to Stakeholders.

Note: Phases 3 and 4 may run concurrently.

Phase 5:

SAHPRA plans to have completed the verification of ISO 13485:2016 certificates held by all holders of a medical device establishment licence manufacture and distribute (import) medical device and IVD by **1 April 2028**.

Conclusion

Documentary proof of certification of the QMS to the international standard ISO 13485:2016 must be held by all Manufacturers and Distributors (Importers) of medical device and IVD, in terms of Section 22C of the Medicines Act.

SAHPRA as an agile and responsive African health products regulator has taken into consideration all the recommendations and concerns from the medical devices industry when developing this plan.

This notice/transition may be revised as determined by the Authority.

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Annexure A: Implementation plan for the ISO 13485 requirement as a prerequisite for the approval of a Section 22C(1)b medical devices establishment licence