SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
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Loftus Park
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Kirkness Road
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Communication to Stakeholders January 2022

MD030: Medical Device Establishment Licence Renewal - ISO13485 Certificate Communication

Background

Act 72 of 2008 (and effectively therefore also Amendment Act 14 of 2015), which broadened the regulatory scope of the Medicines and Related Substances Act, 1965 (Act 101 of 1965; the "Act"), to include the regulation of medical devices.

In terms of Section 22C(1)(b) of the Act–

the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device establishment, manufacturer, wholesaler or distributor of a medicine, Scheduled substance, medical device a licence to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such medicine, Scheduled substance, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.

The regulations relating to medical devices (Regulation No 1515 published in Government Gazette No 40480 on 9 December 2016), published by the Minister of Health in terms of section 35(1)(xxvii) of the Act, make provision for the licensing of medical device establishments.

On the 24 February 2017 a call-up notice was published in the Government Gazette (No. 40637) whereby manufacturers and distributors of medical devices were required to apply for a medical device establishment licence within 6 months of the publication of said call-up notice.

Current Regulatory and Licensing Requirements

The Medicines and Related Substances Act 101 as amended, requires a medical device establishment to hold an establishment licence in recognition of the activities conducted by the organisation. Such a licence is issued upon the fulfilment of the regulatory model requirements that includes, but not limited to, managing a (scope-relevant) quality management system which meets the recognised international standard for medical device establishments, i.e. ISO13485.

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The international standard, ISO13485:2016 *Medical Devices – Quality Management systems-Requirements for regulatory purposes* identifies the requirements for a quality management system that is used by an organization involved in one or more stages of the life-cycle of a medical device, including the design and development, production, storage and distribution, installation, servicing, final decommissioning and disposal of a medical device, design and development, or provision of associated activities (e.g. technical support). The requirements in this international standard can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations.

The fulfilment of these requirements is intended at ensuring that all South Africans have confidence in the safety and performance of medical devices available for use.

Amended requirements

Due to the delay in accreditation of South African Conformity Assessment Bodies, the requirement to provide an ISO13485 certificate upon application for renewal of a medical device establishment licence is extended for a period of three (3) years from date of signing of the document and or until further communication is shared by SAHPRA.

The establishment and implementation of an appropriate quality management system is the responsibility of all medical device establishment licence holders. The South African Health Products Regulatory Authority has the power to revoke, suspend or amend licences in terms of Section 22E of Act 101 of 1965.

DR B SEMETE-MAKOKOTLELA

CHIEF EXECUTIVE OFFICER OF SAHPRA

DATE: 17 January 2022