SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
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COMMUNICATION TO STAKEHOLDERS

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Medical Device Establishment Licence Renewal Process

1. BACKGROUND

1.1 The Medicines and Related Substances Act 101 of 1965, as amended, read together with the Regulations related to Medical Devices and IVDs, provides for the regulatory oversight of Medical Devices including *In Vitro* Diagnostics (IVDs) in South Africa. In terms of Section 22C(1)(b) of the Medicines and Related Substances Act 101 of 1965 (also referred to as the Medicines Act) and Regulation 5 of the Regulations relating to Medical Devices and IVDs (also referred to as Medical Devices Regulations),

1.2 A manufacturer, distributor (including importer and/ or exporter) or wholesaler referred to in Section 22C(1)(b)of the Act must– *prior to commencing business, apply to the South African Health Products Regulatory Authority (SAHPRA) for a licence to manufacture, distribute (including import and/ or export) and/ or wholesale medical devices or IVDs; and appoint and designate an authorised representative who must reside in South Africa and be responsibleto SAHPRA for compliance with the Act.*

1.3 Section 22C (6) of the Medicine Act states *"No medical device or IVD establishment, manufacturer, wholesaler or distributor referred to in subsection (1)(b) shall manufacture, act as a wholesaler of or distribute, as the case may be, any medicine, Scheduled substance, medical device or IVD unless he or she is the holder of a licence contemplated in the said subsection".*

1.4 Section 22D of the Medicine Act read together with Regulation 6 of the Regulations related to Medical Devices, states *"A licensee issued under section 22C shall be valid for the prescribed*

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period but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the Director-General or the Authority, as the case may be, may allow and on payment of the prescribed fee".

"A licence issued in terms of Regulation 5 (1) is valid for a period of five (5) years from the date of issue."

1.5 In terms of Regulation 6 (3)(c) of the Medical Devices Regulations, an application for the renewal of a licence must be made at least 90 days before the expiry of the existing licence.

2. DOCUMENTS TO BE SUBMITTED

2.1 Latest completed medical device establishment licence application form (**GLF-MD-06A, GLF-MD-06B** and **GLF-MD-06C**) as per the company activities (business operations);

2.1.1 Ensure the details submitted on the application form are the same as the current license issued by the Authority (no changes allowed during a renewal application);

2.1.2 The completed application form must be submitted in a PDF format that is initialed on each page, and the Declaration must be signed and dated by the Authorised Representative (*Medical Devices and in Vitro Diagnostics Application Forms - SAHPRA).*

2.2 Cover letter dated and signed by the authorised representative.

2.3 Quality Manual (For Manufacturer, Distributor (importer and Export) or Site Master File (For Wholesaler).

2.4 Proof of payment of the Medical Device Establishment license renewal fee (*Regulations Regarding Fees Payable In Terms Of The Provisions Of The Medicines And Related Substances Act, 1965 (Act No. 101 Of 1965) - SAHPRA*):

2.4.1 Proof of payment of licence retention fees

2.4.2 CV of the authorised representative

2.4.3 Copy of the existing license

2.4.4 Manufacturers and Distributors (Importers) of medical devices and IVDs are required to provide a valid ISO 13485:2016 certificate in the name of the South African licensed

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medical device establishment and at the same address (as applicable), from a CAB recognised by SAHPRA *(ISO 13485 Certificate as a prerequisite for the approval of a Medical Device Establishment Licence - SAHPRA*). In case the organisation is in the process of obtaining certification to the latest version of ISO 13485, it will then 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 *(List of Recognised Conformity Assessment Bodies - SAHPRA)*

2.5 Other supporting documents deemed relevant to the application, as applicable.

3. SUBMISSION OF THE APPLICATION TO THE AUTHORITY

3.1 The license renewal application must be submitted at least **90 days** prior to the expiry of the existing license.

3.1.1 Please note that submissions of establishment application for a licence renewal that has superseded and or passed the expiry date will not be accepted. Applicants will be required to submit a new licence application.

3.1.2 Ensure that all GMDN codes are verified against the GMDN agency prior to submission of a license renewal application, thus meaning an observation letter will be issued for all GMDN codes which are found to be invalid as per the GMDN agency (Updating of GMDN codes does not change the details stated on the approved licence nor does it affect the classification of medical devices or IVDs on the product listing). Applicants may refer to the GMDN agency (*Home - GMDN*) with regards to identifying alternative terms for obsolete terms.

3.2 **Applications must be submitted to mdadmin@sahpra.org.za and the email subject must be the following information:** Establishment License Renewal- XXXXX (i.e., *Company name*)

3.3 Large file types can be submitted via secure electronic document transfer.

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4. PROCESSING TIMELINES FOR RENEWAL APPLICATIONS

4.1 The processing of the medical device establishment license renewal application by the Authority typically takes between 6 to 8 weeks.

Important notification: The applicant must ensure that all documents are submitted all at once to minimise the unforeseen delays in the review of the application.

4.2 The applicant is required to respond to the deficiencies noted in the observation letter within two (2) working days of receiving the communication letter. Only two (2) review opportunities are allowed.

Boitumelo Semete-Makokotlela

SIGNIFLOW

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ANNEXURES

Annexure 1: Process Flow for Licence Renewal