SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

Communication to Stakeholders February 2022

MD031: Medical Device Establishment Licence Renewal Process

BACKGROUND

1. The Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, read in conjunction with the General Regulations on Medical Devices, published in Government Gazette Notice 40480, No.1515 of 9 December 2016, provides for the regulatory oversight of Medical Devices including In- Vitro Diagnostics (IVDs) in South Africa.

2. *In terms of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and Regulation 5 of the General Regulations on Medical Devices*
   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 SAHPRA for a licence to manufacture, distribute (including importand/or export) and/or wholesale medical devices or IVDs; and appoint and designate an authorised representative who must reside in South Africa and be responsible to SAHPRA for compliance with the Act.

3. Section 22C *(6) of the Act - 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*

4. *Section 22D of the Act Period of validity and renewal of licence.—A licence issued under section 22C shall be valid for the prescribed 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.*

STEP A: DOCUMENTS TO BE SUBMITTED

i. Completed Medical Device Establishment licence renewal application form as per the company activities (business operations);
- Ensure the form is the same as the current application form submitted to the Authority;
- Ensure the form in a PDF format is initialed in each page and Declaration is signed and dated by the Authorised Representative
- Share both the PDF and Excel spreadsheet (complete all relevant areas)

i. Cover letter
ii. Quality Manual (For Manufacturer, Distributor (importer and Export))
iii. Site Master File (For Wholesaler)

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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 organization does not have a valid ISO 13485:2016 Certificate, a declaration by the Authorised Representative that the organization has implemented a quality management system aligned to the ISO143485:2016 standard and that a certified copy of certification to ISO13485:2016 standard will be submitted to the Authority once acquired and no later than 01 April 2025.

vi. CV of the Authorized Representative

vii. Copy of the current SAHPRA Medical device Establishment licence

viii. Proof of payment of annual licence retention fees for Year 2020, 2021 and 2022

ix. Proof of payment of the Medical Device Establishment licence renewal fee.

x. Other supporting documents deemed relevant to the application as applicable

STEP B: Submission of the application to the authority

a. The license renewal application must be submitted at least 60 days prior to the license expiry date.
b. Submit the application to the authority (SAHPRA) using the following contact details Email: Mdadmin@sahpra.org.za
c. Large submissions can be submitted via secure electronic document transfer

Important to Note: For your email communication please use the following information as email subject:

Establishment License Renewal- XXXXX (i.e., *Company name*)

STEP C: TIMELINES FOR PROCESSING MEDICAL DEVICE ESTABLISHMENT LICENCE RENEWAL APPLICATIONS

The processing of the medical device establishment license renewal application by the Authority may be for a period of at least 4 to 8 weeks

Important notification: The applicant must ensure that all documents are submitted all at once to minimize the unforeseeable delays on the review of the application

The applicant is required to respond to the deficiencies noted in the observation letter within five (5) working days of receiving the communication letter. Only 2 review opportunities are allowed .

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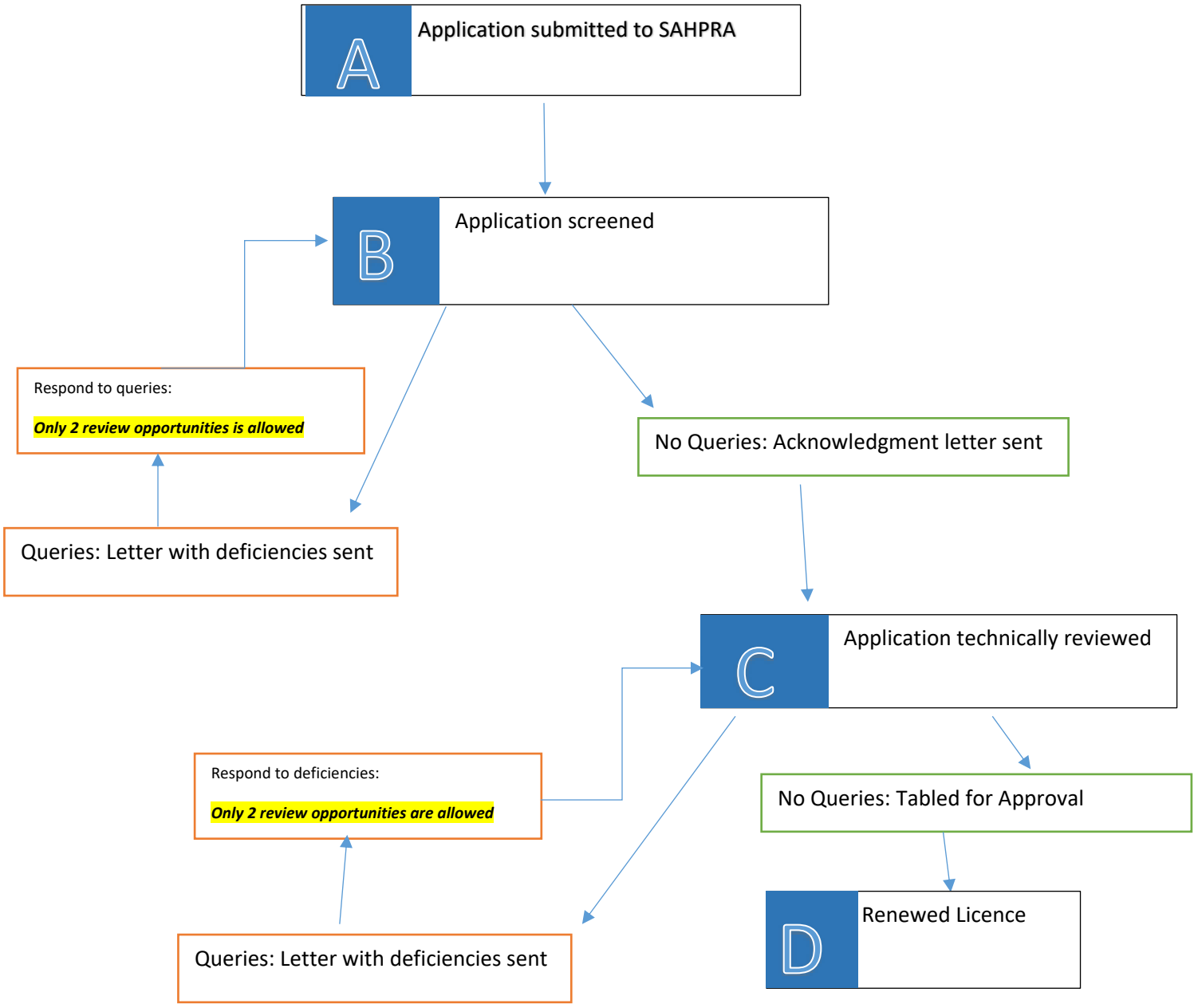
ANNEX 1: PROCESS FLOW FOR LICENCE RENEWAL



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DR B SEMETE-MAKOKOTLELA

CHIEF EXECUTIVE OFFICER OF SAHPRA

DATE: 07 February 2022