SAHPRA
South African Health Products Regulatory Authority

CSIR Campus
Building 10F
Meiring Naudé Road
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Communication to Stakeholders 22 July 2020

MD019: Processing of medical device establishment licence applications made to SAHPRA

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—
   a. *prior to commencing business, apply to SAHPRA for a licence to manufacture, distribute (including import and/or export) and/or wholesale medical devices or IVDs; and*
   b. *appoint and designate an authorised representative who must reside in South Africa and be responsible to SAHPRA for compliance with the Act.*

TIMELINES FOR PROCESSING MEDICAL DEVICE ESTABLISHMENT LICENCE APPLICATIONS

3. Medical device establishment licence applications made to SAHPRA will be processed within 6 – 8 weeks.

4. Expedited regulatory pathways will be applied for licence applications listing medical devices and IVDs required during the COVID-19 pandemic (MD005). The licence application process will be expedited with the aim of concluding the licence process within 10 – 15 working days. This timeline is dependent on the submission of complete applications that meet the requirements. This timeline is also dependent on timeous responses from applicants. To meet this timeline, only two response cycles will be permitted to address deficiencies identified within licence applications.

TIMELINES FOR RECEIVING RESPONSES FROM APPLICANTS

5. An observation letter will be sent to the applicant in the event that a licence application does not meet the evaluation criteria. The deficiencies identified within the application will be documented in the observation letter.

6. The applicant is required to respond to the deficiencies noted in the observation letter **within ten working days.**

7. For licence applications, where the expedited regulatory pathway has been applied, the applicant is required to respond to the deficiencies noted in the observation letter **within two working days.**

8. NOTE: Only 2 cycles will be permitted, i.e. the applicant will have two opportunities to address the deficiencies identified in the licence application by submitting a response to SAHPRA within the defined timelines.

9. If the response/s (limited to a maximum of two cycles) from the applicant does not adequately address the deficiencies identified in the licence application, the licence application will not be recommended and the licensing process will be concluded.

10. If the applicant does not respond to the deficiencies identified in the licence application, within the defined timelines, the licence application will not be recommended and the licensing process will be concluded.

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CHIEF EXECUTIVE OFFICER OF SAHPRA

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