

Communication to Stakeholders

MD004: Use of Acknowledgement Letter in lieu of Medical Device Establishment Licence

1 BACKGROUND

- 1.1 On 01 June 2017, the President of the Republic of South Africa signed into effect Amendment 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 "Medicines Act"), to include the regulation of medical devices.
- 1.2 In terms of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965)–
the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a medicine, Scheduled substance, medical device or IVD 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.
- 1.3 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 Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) make provision for the licensing of medical device establishments.
- 1.4 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 the call-up notice (24 August 2017) and Wholesalers were required to apply for a medical device establishment licence within 12 months of the publication of the call-up notice (24 February 2018).

2. TRANSITIONAL ARRANGEMENTS

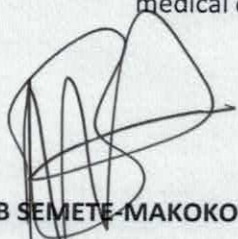
- 2.1 Upon submission of a medical device establishment licence application to SAHPRA, a letter of acknowledgement, acknowledging receipt of the application by SAHPRA was issued to the applicant.
- 2.2 A transitional arrangement was made with stakeholders to allow the use of the acknowledgement letter to facilitate trade in lieu of a medical device establishment licence so as to ensure continuation of business and access to medical devices while the SAHPRA licensing process developed over time.

3. USE OF ACKNOWLEDGEMENT LETTER IN LIEU OF MEDICAL DEVICE ESTABLISHMENT LICENCE

- 3.1** The previous deadline of 1 April 2020, prohibiting the use of an acknowledgement letter in lieu of a licence has been extended to the **17 April 2020**.
- 3.2** As of the **17 April 2020** the use of an acknowledgement letter in lieu of a medical device establishment licence will not be permitted.
- 3.3** No medical device may be manufactured, distributed, imported, exported or sold without a valid SAHPRA medical device establishment licence.

Note 1: Providing evidence of a valid SAHPRA medical device establishment licence will be required to be eligible to bid for national and provincial tenders.

Note 2: A manufacturer, distributor, wholesaler of a non-sterile, non-measuring Class A medical device is exempt from the provisions of clause 3 stated above.



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