

Communication to Stakeholders

12 May 2021

MD028: Payment of Retention Fees for Medical Device Establishment Licences

1. Your attention is drawn to the provisions of the Medicine and Related Substances Act, 1965 (Act 101 of 1965), specifically 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 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”.
2. 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.
3. Regulation 6(1) states–
“A licence issued in terms of regulation 5 is valid for a period of five (5) years from the date of issue.”
4. Regulation 5(6) states–
“Despite the period of validity of the licence, the licensee must pay the annual fee for continued registration as determined by the Council.”
5. SAHPRA would like to remind holders of medical device establishment licences that have not paid the annual (retention) fees for the year ending March 2021, to make payment within ten (10) working days of publication of this document.
6. The company must submit the proof of payment, using the relevant reference number **MDRET**, to the following email address: june.searela@sahpra.org.za and constance.mnguni@sahpra.org.za.
7. The fees applicable to the retention of medical device establishment licences are published in the Government Gazette dated 22 December 2020
[\[http://www.gpwonline.co.za/Gazettes/Gazettes/44026_22-12_Health.pdf\]](http://www.gpwonline.co.za/Gazettes/Gazettes/44026_22-12_Health.pdf).
8. To provide clarity for the submission of fee payments and categorization, SAHPRA has published a guideline [SAHPRA Payment Guideline_Nov 2020, <https://www.sahpra.org.za/wp-content/uploads/2020/11/SAHPRA-Payment-Guideline-Nov-2020.pdf>].

DR B SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER OF SAHPRA
12 May 2021