

## MD001: Regulatory requirements for the supply of medical devices in light of the COVID-19 pandemic

The Communication to Stakeholders, dated 19 March 2020, titled Medical Devices including In-Vitro Diagnostics (IVDs) Requirements for Supply of Medical Devices in light of the COVID-19 Pandemic is hereby rescinded and replaced with the requirements set out below:

### 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 09 December 2016, provides for the regulatory oversight of Medical Devices including In-Vitro Diagnostics (IVDs) in South Africa.
2. Provision is made within this legislative framework to define a medical device, an IVD and medical device establishment as well as provide the definitions of a manufacturer, distributor and wholesaler.
3. Any company or individual intending to manufacture, distribute (import/export) or wholesale a medical device/IVD is required, in terms of Section 22 C of the Medicines Act to be licensed by SAHPRA.
4. Any products that fall within the definition of a medical device are regulated by SAHPRA as medical devices under the ambit of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. Individuals/companies may not manufacture/distribute/wholesale medical devices without a valid SAHPRA medical device establishment licence. *NOTE: A SAHPRA acknowledgement letter, acknowledging the submission of an application for a medical device establishment or acknowledging the amendment of a current SAHPRA licence will not suffice in lieu of a valid SAHPRA licence.*

### NEW APPLICATIONS FOR A SAHPRA MEDICAL DEVICE ESTABLISHMENT LICENCE

6. Any individual/company may submit an application to SAHPRA to be licensed as a manufacturer/distributor/wholesaler of medical devices.
7. The application forms are available on the SAHPRA website ([www.sahpra.org.za](http://www.sahpra.org.za)):
  - a. 6.21 Licence to Manufacture (Manufacture/Import/Export/Distribute)
  - b. 6.22 Licence to Distribute (Import/Export/Distribute)
  - c. 6.26 Licence to Wholesale (Wholesale)

8. 16.03 Guideline for a Licence to Manufacture, Import, Export or Distribute Medical Devices and IVDs provides guidance pertaining to the requirements for the licence application process.

#### AMENDMENT OF AN EXISTING SAHPRA LICENCE

9. Medical device establishments that have a valid SAHPRA licence may not manufacture, distribute and/or wholesale medical devices that have not been listed on their licence application.
10. Medical device establishments that have a valid SAHPRA licence and that are authorised to manufacture, distribute and/or wholesale Class A, B, C and/or Class D medical devices must apply for a licence amendment to update the product listing and include any medical devices related to COVID-19.
11. The notification process for the amendment of a SAHPRA medical device establishment licence may not be used for any medical devices related to COVID-19.
12. Medical device establishments that have a valid SAHPRA licence may not manufacture, distribute and/or wholesale medical devices, included in the application for licence amendment, until authorisation has been received from SAHPRA to do so. *NOTE: A SAHPRA acknowledgement letter, acknowledging the submission of an application for the amendment of a medical device establishment will not suffice in lieu of a valid SAHPRA licence.*

#### SUBMITTING AN APPLICATION FOR A NEW LICENCE OR LICENCE AMENDMENT

13. Applications must be submitted via email to [MDCovid@sahpra.org.za](mailto:MDCovid@sahpra.org.za) only. **Applications submitted by any other means or to any other email address will not be processed.**
14. The fee for a medical device establishment licence application (new/amendment) is payable upon application and proof of payment should be submitted together with the completed licence application. *Note: Fees may be updated from time to time. The onus is on the applicant to ensure that payment is made in line with the current fees structures, as published in the *Government Gazette*.*
- Fee for application for a new licence (Manufacturer): R 23 980
  - Fee for application for a new licence (Distributor/Wholesaler): R 14 300
  - Fee for application for licence amendment: R 5 000
  - Fee for licensing for any manufacturer, distributor, wholesale, the licence of which has been approved by SAHPRA in terms of Section 22(1)(b) of the Act: R 3 190
  - Annually, in respect of the retention of a licence issued in terms of Section 22C(1)(b) of the Act: R 4 000
15. The relevant supportive evidence must be provided for each of the medical devices listed, by the applicant, in the licence application.
16. 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.

## DOCUMENTS TO BE SUBMITTED UPON APPLICATION

17. The following documents must be submitted upon application to SAHPRA for a new medical device establishment licence:
  - a. Cover letter on company letter indicating intention to apply for a new SAHPRA licence. *NOTE: the subject of the letterhead should state: RE: COVID-19 APPLICATION FOR NEW LICENCE*
  - b. Licence Application (6.21 Manufacturer / 6.22 Distributor / 6.26 Wholesaler)
    - Completed licence application form in MS Excel format
    - Completed licence application form in PDF format, including signed declaration and initialed on each page by the Authorised Representative)
  - c. Proof of Payment (Manufacturer: R 23 980 / Distributor or Wholesaler: R 14 300)
  - d. Curriculum Vitae of the Authorised Representative
  - e. Quality Manual (Applicable to Manufacturers/Distributors) or Site Master File (Applicable to Wholesalers)
  - f. Supportive evidence for each Class C and Class D medical device listed in the product list including:
    - Evidence of pre-market approval or registration for the medical device or IVD from at least one of the six jurisdictions recognised by SAHPRA (Australia, Brazil, Canada, Europe, Japan, United States of America) or pre-qualification by the World Health Organization (Refer to Guideline 16.03).
    - Certificate of Free Sale confirming evidence that the medical device is legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in at least one of the six jurisdictions recognised by SAHPRA.
    - Evidence of ISO13485:2016 certification of the original manufacturer for each medical device.
    - Copy of Instructions for Use for each medical device.
    - Copy of labelling and packaging of each medical device. *(NOTE: Any change in product name or branding will invalidate the originating approval of a medical device)*
18. The same documents listed in section 17 must be submitted upon application to SAHPRA for an amendment to an existing medical device establishment licence.
19. However, for the application of an amendment to a SAHPRA licence the cover letter and fee payable will differ as follows:
  - a. Cover letter on company letter indicating intention to apply for an amendment to a SAHPRA licence. *NOTE: the subject of the letterhead should state: RE: COVID-19 APPLICATION FOR LICENCE AMENDMENT*
  - b. Proof of Payment (Manufacturer/Distributor: R 5 000)

## LICENCE APPLICATION PROCESS AND TIMELINES

20. Applicants must submit the licence application via email to SAHPRA (MDCovid@sahpra.org.za) only.
21. An electronic letter of acknowledgment of receipt of the application will be sent to the applicant.
22. A review of each application will be performed to determine if the relevant regulatory criteria are met.
23. Where relevant, the evidence of compliance against the minimum requirements and/or certification against relevant standards and specifications will be verified.

24. An observation letter will be sent to the applicant in the event that a licence application does not meet the evaluation criteria.
25. The deficiencies identified within the application will be documented in the observation letter.
26. The applicant is required to respond to the deficiencies noted in the observation letter within two working days. NOTE: Only 2 cycles will be permitted. Failure to respond will result in the rejection of the licence application.
27. If the evaluation criteria are not met the application will not be recommended and the licence application process will be concluded.
28. A notification of licence collection will be emailed to the applicant, once the licence application has been approved. The licence will be emailed to the applicant upon submission of proof of payment of R 3 190.

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**CHIEF EXECUTIVE OFFICER OF SAHPRA**  
**22 JULY 2020**