MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTICS (IVDS) REQUIREMENTS FOR SUPPLY OF MEDICAL DEVICES IN LIGHT OF THE COVID-19 PANDEMIC

Communication to Stakeholders

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. Products intended to be supplied to support the diagnosis or prevention of the spread of COVID-19, such as masks, gloves, antiseptics and germicides used on inanimate surfaces in areas of high risk and IVDs used to diagnose COVID-19 fall within the definition of a medical device and 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 without a valid SAHPRA medical device establishment licence. *NOTE: A SAHPRA acknowledgement letter, acknowledging the submission of an application for a medical device establishment 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).
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/wholesale medical devices that have not been listed on their licence application.
10. Medical device establishments that have a valid SAHPRA licence may apply for a licence amendment to update the product listing and include any medical devices identified to support the diagnosis or prevention of the spread of COVID-19.
11. The notification process for the amendment of a SAHPRA medical device establishment licence is not applicable for Class C and Class D medical devices intended to be supplied to support the diagnosis or prevention of the spread of COVID-19.
12. Medical device establishments that have a valid SAHPRA licence may not manufacture/distribute/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 may be submitted via email to june.searela@sahpra.org.za
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*.
15. 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 and will be completed within 1 – 7 working days provided that the applications submitted are complete and meet the requirements and that timeous responses are received from applicants where relevant.

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)
        - Completed licence application form in MS Excel format
        - Completed licence application form in PDF format, including signed declaration and initialled on each page by the Authorised Representative)
    c. Proof of Payment (Manufacturer: R 23 980 / Distributor: R 14 300)
    d. Curriculum Vitae of the Authorised Representative
    e. Quality Manual (Manufacturers/Distributors)

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 following documents must be submitted upon application to SAHPRA for an amendment to an existing medical device establishment licence:
    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. *Refer to 17b*
    c. Proof of Payment (Manufacturer/Distributor: R 5 000)
    d. *Refer to 17d*
    e. *Refer to 17e*
    f. *Refer to 17f*

LICENCE APPLICATION PROCESS AND TIMELINES (Refer to ANNEX 1)

19. Applicants must submit licence application via email to SAHPRA within 1 working day.
20. A letter of acknowledgment of receipt of the application will be sent to the applicant.
21. The application will be reviewed, followed by a peer review process to ratify the decision to approve licence applications that meet the evaluation criteria.
22. 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.
23. The applicant is required to respond to the deficiencies noted in the observation letter within two working days.
24. The response will be reviewed. If the evaluation criteria is met, the application will serve at the peer review for ratification to approve the licence. If the evaluation criteria is not met in the response, a second observation will be sent to the applicant. (Refer to point 23).

25. The second response will be reviewed. If the evaluation criteria is met, the application will serve at the peer review for ratification to approve the licence. If the evaluation criteria is not met the application will be rejected.
26. If the application is approved the licence will be prepared. A notification of licence collection will be emailed to the applicant. The licence will be emailed to the applicant upon submission of proof of payment of R 3 190 (Refer to point 14).
27. If the application is rejected the applicant will be required to resubmit a new application (Refer to point 13 – 17 (new) / 18(amendments))

DR B SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER OF SAHPRA
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ANNEXURE 1: PROCESS FLOW FOR LICENCE APPLICATION PROCESS