SAHPRA
South African
Health Products
Regulatory Authority

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Communication to Stakeholders 22 July 2020

MD002: Regulatory requirements for the manufacture, distribution or wholesale of COVID-19 serological test kits

NOTE: The Communication to Stakeholders, dated 30 March 2020, titled "Regulatory Requirements for the manufacture, distribution or wholesale of Serological COVID-19 Rapid Test Kits" is hereby rescinded and replaced with this Communication.

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. 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. COVID-19 serological test kits (including but not limited to point-of-care (POCT) and laboratory-based test kits) are classified as Class D IVDs according to Classification Rule 1 for IVDS - Detection of transmissible agents posing a high public health risk.
   An IVD medical device intended to be used for any of the following purposes is classified as a Class D IVD medical device:
   a) to detect the presence of, or exposure to, transmissible agents in blood, blood components, blood products, cells, tissues or organs or any derivatives of these products of human or animal origin, in order to assess their suitability for transfusion or transplantation;
   b) to detect the presence of, or exposure to, a transmissible agent that causes a serious disease with a high risk of propagation.

4. COVID-19 serological test kits may only be manufactured, imported, exported or distributed/sold at wholesale level by medical device establishments that hold a valid Medical Device establishment licence issued by the South African Health Products Regulatory Authority (SAHPRA), in terms of Section 22 C of the Medicines Act.

5. Regulation 21: Advertising of Medical Devices and IVDs states that Class D IVDs may not be advertised to the public or lay person. As such COVID-19 serological test kits may not be advertised to the public.

6. The sale of COVID-19 serological test kits may only be used under the conditions described in the National Department of Health Testing Strategy and the National Department of Health Clinical Guideline which may be changed from time to time.

7. Regulation 22: Labelling of a Medical Device or IVD (p)(vi) requires that the labelling/packaging of COVID-19 serological test kits contains an indication that the test is intended 'for professional use only".

8. Regulation 24: Instructions for use (IFU) of IVD (d) and (e) require that the instruction for use of COVID-19 serological test kits contains an indication of the intended user and that the IVD is not to be used for diagnostic use in acute infections and that it is for "professional use only".

9. Locally manufactured and imported COVID-19 serological test kits must be undergo performance evaluation by the national reference laboratory.

10. The results of the performance evaluation conducted by the national reference laboratory must be provided to SAHPRA and will inform the decision by SAHPRA to issue a licence for the manufacture, distribution or wholesale of a COVID-19 serological test kit.

11. The process to apply for a new licence of amendment of a licence for a manufacturer, distributor or wholesaler and the supporting documentation required for COVID-19 serological Rapid Test Kits is as follows:

NEW APPLICATIONS FOR A SAHPRA MEDICAL DEVICE ESTABLISHMENT LICENCE

12. Any individual/company, located in South Africa may submit an application to SAHPRA to be licensed as a manufacturer/distributor/wholesaler of a medical device/s.

13. The application forms are available on the SAHPRA website (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)

14. 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

15. 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.

16. Medical device establishments that have a valid SAHPRA licence and that are authorised to manufacture/distribute/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 COVID-19 serological test kit/s (classified as Class D medical devices).

17. The notification process for the amendment of a SAHPRA medical device establishment licence may not be used for Class D COVID-19 serological test kits.

18. Medical device establishments that have a valid SAHPRA licence may not manufacture/distribute/wholesale COVID-19 serological test kits, 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

19. Applications must be submitted via email to **MDCovid@sahpra.org.za** only. Applications submitted by any other means or to any other email address will not be processed.

20. 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.
    a. Fee for application for a new licence (Manufacturer): R 23 980
    b. Fee for application for a new licence (Distributor/Wholesaler): R 14 300
    c. Fee for application for licence amendment: R 5 000
    d. 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
    e. Annually, in respect of the retention of a licence issued in terms of Section 22C(1)(b) of the Act: R 4 000

21. Supportive evidence must be provided for each of the listed serological COVID-19 test kits, by the applicant, in the licence application.

22. 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

23. 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 Serological Test Kits 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/Wholesalers)
    f. Supportive evidence for each COVID-19 serological test kit/s (Class D medical device) including:
       - Evidence of pre-market approval/registration/evidence of emergency use authorisation for each listed COVID-19 serological test kit/s 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), together with evidence of the intended use of the test (i.e. for serological surveys). NOTE: CE certificates obtained through self-certification will not be recognised for COVID-19 serological test kits
       - Certificate of Free Sale confirming evidence that each listed COVID-19 serological test kit/s 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 listed COVID-19

serological rapid test kit/s
- Copy of Instructions for Use (IFU) for each listed COVID-19 serological test kit/s
- Copy of labelling and packaging of each listed COVID-19 serological test kit/s
  (NOTE: Any change in product name or branding will invalidate the originating approval of the test kit)

g. Technical Dossier for each listed COVID-19 serological rapid test kit/s
h. Written declaration of sameness by the original manufacturer that each COVID-19 serological test kit/s being imported is the same as the product listed or registered in another jurisdictions.

24. The same documents listed in section 23 must be submitted upon application to SAHPRA for an amendment to an existing medical device establishment licence.

25. 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 Serological Test Kits FOR LICENCE AMENDMENT
    b. Proof of Payment (Manufacturer/Distributor: R 5 000)

LICENCE APPLICATION PROCESS AND TIMELINES (Refer to ANNEX 1)

26. Applicants must submit the licence application via email to SAHPRA (MDCovid@sahpra.org.za) only.

27. An electronic letter of acknowledgment of receipt of the application will be sent to the applicant.

28. A primary review of each application will be performed to determine if the relevant regulatory criteria are met.

29. The technical dossier for each listed COVID-19 serological test kit/s will be reviewed by a scientific committee of SAHPRA.

30. An observation letter will be sent to the applicant in the event that a licence application does not meet the evaluation criteria.

31. The deficiencies identified within the application will be documented in the observation letter.

32. 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.

33. If the evaluation criteria are not met the licence application will not be recommended and the licence process will be concluded.

34. If the licence application meets the evaluation criteria, the listed serological test kit/s will be recommended to undergo a performance evaluation by the national reference laboratory.

35. The results of the performance evaluation will inform the decision of SAHPRA to issue the licence.

36. The COVID-19 serological test kit/s that meet the specifications for performance (Refer to MD007) will be listed on the SAHPRA licence as a condition of the licence. Only COVID-19 serological test kit/s listed on the SAHPRA licence may be manufactured, distributed and/or wholesaled.

37. A Section 21 Authorisation will e issued to authorise the use of the COVID-19 serological test kit. Conditions of the Section 21 Authorisation include but are not limited to the following:
    a) Lot-to-lot verification performed by the national reference laboratory
    b) Submission of a post-market surveillance plan
    c) Monthly reporting to SAHPRA

38. 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

ANNEX 1: PROCESS FLOW DIAGRAM FOR LICENCE APPLICATION PROCESS (COVID-19 Serological Test Kits)