

## MD011: Licence conditions for manufacturers, distributors and wholesalers of unregistered COVID-19 serological test kits

### 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. 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.
3. In terms of Regulation 5(1)(d) a manufacturer, distributor or wholesaler referred to in section 22C(1)(b) of Act 101 of 1965 must specify, as determined by SAHPRA, the medical devices or IVDs or group or family of medical devices or IVDs to be manufactured, distributed or wholesaled.
4. In terms of Regulation 5(4) Licence to manufacture, distribute or wholesaler of medical devices or IVDs, SAHPRA may approve an application for a medical device establishment licence, with or without conditions, and issue a licence.
5. In terms of Regulation 28(3) Transitional arrangements regarding unregistered medical devices and IVDs, SAHPRA may require a medical device or IVD to comply with the requirements that SAHPRA may determine in order to ensure that the medical device or IVD meets the Essential Principles of Safety and Performance, as determined by SAHPRA.
6. Based on the declaration signed by the appointed Authorised Representative in Section 23 of the licence application submitted to SAHPRA, indicating the availability of full technical documentation for Class C and Class D medical devices and IVDs (Section 23 A. (v)) and the certificates of free sale from the country of origin for imported Class B, Class C and Class D medical devices & IVDs (Section 23 A. (vi)), medical device establishment licence applications are required to be accompanied by full technical documentation and certificates of free sale for each of the serological test kits listed in the licence application.

7. In terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), the Authority may authorise the sale of unregistered medicines, medical devices or IVDs for certain purposes—
- (1) *The Authority may in writing authorise any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine, medical device or IVD which is not registered.*
  - (2) *Any medicine, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.*
  - (3) *The Authority may at any time by notice in writing withdraw any authority granted in terms of subsection (1) if effect is not given to any determination made in terms of subsection (2).*

#### **MANUFACTURE, DISTRIBUTION AND WHOLESALE OF COVID-19 SEROLOGICAL TEST KITS**

8. In terms of Section 22C(1)(b) COVID-19 serological test kits may only be manufactured, distributed (including import and/or export) or wholesaled by a medical device establishment that has a valid SAHPRA licence.
9. In terms of Regulation 5(1)(d) a manufacturer, distributor or wholesaler referred to in section 22C(1)(b) of Act 101 of 1965 must specify, in the licence application each COVID-19 serological test kits to be manufactured, distributed or wholesaled.
10. The manufacture, distribution or wholesale of a COVID-19 serological test kit may only commence upon the issuing of a SAHPRA licence, authorising the manufacture, distribution or wholesale of the COVID-19 serological test kit/s listed in the conditions of the SAHPRA licence.

#### **PERFORMANCE EVALUATION OF COVID-19 SEROLOGICAL TEST KITS**

11. In terms of Regulation 5(4), SAHPRA may approve an application for a medical device establishment licence, provided that the performance of the listed COVID-19 serological test kit/s is evaluated by the national reference laboratory or any other laboratory as determined by SAHPRA.

#### **FOR LOCALLY MANUFACTURED COVID-19 SEROLOGICAL TEST KITS**

12. The performance of locally manufactured COVID-19 serological test kits must be evaluated by the national reference laboratory **prior** to submitting a licence application to SAHPRA.
13. The results of the performance evaluation for each listed COVID-19 serological test kit must be submitted to SAHPRA together with the licence application.

#### **FOR IMPORTED COVID-19 SEROLOGICAL TEST KITS**

14. The performance of imported COVID-19 serological test kits must be evaluated by the national reference laboratory.
15. Applications for a SAHPRA licence to import COVID-19 serological test kits must be submitted **prior** to the performance evaluation of the listed imported COVID-19 serological test kits.
16. Imported COVID-19 serological test kits may only be submitted to the national reference laboratory for performance evaluation **upon receipt of the recommendation by SAHPRA**, indicating the requirement for the imported COVID-19 serological test kit/s to undergo performance evaluation.

#### **LICENCE CONDITIONS**

17. The additional licence specific conditions, made in terms of Regulation 5(4), will be listed in Section 11 of the Medical Device Licence to Manufacture and Section 8 of Medical Device Licence to Distribute.
18. The licence specific conditions will be applicable to each COVID-19 serological test kit that has met the performance criteria, as determined by the national reference laboratory or any other laboratory as

determined by SAHPRA. Only COVID-19 serological test kit/s that meet the performance criteria will be listed under the licence specific conditions.

**AUTHORISATION FOR USE OF UNREGISTERED COVID-19 SEROLOGICAL TEST KITS**

19. Authorisation for the sale of an unregistered in-vitro diagnostic (IVD), in terms of Section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), for COVID-19 serological test kit/s, will be issued by SAHPRA provided that the COVID-19 serological test kit/s meets the performance criteria.
20. In the event that the COVID-19 serological test kit/s does not meet the predetermined performance criteria, the licence application will not be recommended and the licence application process will be concluded.
21. Only SAHPRA licence holders who are authorised to manufacture and/or distribute listed COVID-19 serological test kit/s are eligible to receive Section 21 authorisation for the COVID-19 serological test kit/s. Any other applications for Section 21 authorisation for the COVID-19 serological test kit/s will not be accepted.

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22 JULY 2020**