SAHPRA
South African
Health Products
Regulatory Authority

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Communication to Stakeholders 22 July 2020

MD015: Process flow – Imported COVID-19 test kits

STEP A: SUBMIT SAHPRA LICENCE APPLICATION

1. Individuals or companies, located within South Africa, wanting to import COVID-19 test kits are required to submit a licence application to distribute (import) medical devices including in-vitro diagnostics (IVDs) to SAHPRA.
2. The regulatory requirements for the manufacture, distribution or wholesale of COVID-19 serological test kits are described in MD002.
3. The regulatory requirements for the manufacture, distribution or wholesale of COVID-19 molecular test kits are described in MD014.

STEP B: PERFORMANCE EVALUATION OF COVID-19 TEST KITS

4. If the information provided in the licence application, the technical dossier and the supportive documents meet the regulatory requirements and evaluation criteria (MD007 for COVID-19 serological test kits and MD018 for COVI-19 molecular test kits), the listed serological and/or molecular test kit/s will be recommended to undergo a performance evaluation by the national reference laboratory (NRL).
5. At this point, authorisation will be given to the applicant to import 250 units, only, of the COVID-19 test kit for the purpose of performance evaluation by the NRL, only.
6. The results of the performance evaluation must be documented in a report prepared by the NRL.
7. COVID-19 test kits that do not meet the predetermined specifications for performance will not be considered by SAHPRA.
8. **COVID-19 test kits that have been evaluated by the NRL and do not meet the predetermined specifications for performance <u>will not be re-evaluated</u> by the NRL.**

STEP C: SAHPRA LICENCE AND SECTION 21 AUTHORISATION ISSUED

9. SAHPRA will issue a licence to distribute medical devices to the distributor provided that all the regulatory requirements are met.
10. SAHPRA will issue a Section 21 Authorisation for the use of an unregistered medical device for imported COVID-19 test kits.
11. The licence conditions for unregistered COVID-19 test kits are described in MD011.

STEP D: AUTHORISATION FOR USE

12. Only medical device establishments that are licensed by SAHPRA may import medical devices.
13. Only imported COVID-19 test kits that have been issued a Section 21 authorisation by SAHPRA may be made available for sale.
14. The use of COVID-19 tests kits will be limited for such purposes, in such a manner and during such a period as determined by SAHPRA.
15. The export of imported COVID-19 test kits must be authorised by SAHPRA.

DR B SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER OF SAHPRA
22 JULY 2020

ANNEX 1: PROCESS FLOW FOR IMPORTED COVID-19 TEST KITS