SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
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Communication to Stakeholders March 2022

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. Professional use only COVID-19 Rapid antigen self-tests which are already approved (i.e. went through performance evaluation by the National Reference Laboratory (NRL) and are authorised by SAHPRA), will not go through a full validation. For abovementioned application only the following documents will be required by SAHPRA:
    a. Updated packaging details (e.g., Instruction for use and Labels) clearly showing that the product is for self-test,
    b. Usability studies (both the plan and report) for application submit of product that has not been approved by the regulator (in this case, SAHPRA), as per SAHPRA usability guidance document
8. COVID-19 test kits that do not meet the predetermined specifications for performance will not be considered by SAHPRA.
9. **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

10. SAHPRA will issue a licence to distribute medical devices to the distributor provided that all the regulatory requirements are met.
11. SAHPRA will issue a Section 21 Authorisation for the use of an unregistered medical device for imported COVID-19 test kits.
12. The licence conditions for unregistered COVID-19 test kits are described in MD011 and MD034

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STEP D: AUTHORISATION FOR USE

13. Only medical device establishments that are licensed by SAHPRA may import medical devices.
14. Only imported COVID-19 test kits that have been issued a Section 21 authorisation by SAHPRA may be made available for sale.
15. 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.
16. The export of imported COVID-19 test kits must be authorised by SAHPRA.

DR B SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER OF SAHPRA
MARCH 2022

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