

Sahpra considers use of locally made Covid self-testing kit

By SUTHENTIRA GOVENDER

● A Cape Town biotechnologist is waiting for approval from the South African Health Products Regulatory Authority (Sahpra) for a kit, similar to a pregnancy test, that he devised for a self-administered Covid test.

Ashley Uys, MD of Medical Diagnostech, recently received Sahpra approval for the first locally made antigen rapid-test kit for use by doctors and private laboratories.

He hopes South Africans will be able to self-test without health professionals or laboratories by March, pending a decision by the authority.

His approved rapid-test kit will cost about 35% less than the current price for lab tests, which he believes will make testing more accessible. This comes as three major pathology labs reduced Covid-19 polymerase chain reaction (PCR) testing costs this week. The agreement between the labs and the Competition Commission follows a Council for Medical Schemes complaint in October that alleged the tests were “unfairly inflated” and “exorbitant”.

As SA continues with discussions about self-tests, they have been approved for use in



Self-tests have been approved for use in the US and some European countries, including the UK. Picture: CDC

some European countries as well as the US and UK, despite reservations by some scientists about the accuracy of the results and the change in behaviour a false negative result may illicit.

“Self-testing should be made available only if the devices are user-friendly [and] without additional components and accessories, and if results can be interpreted without error via a smartphone application,” Uys said.

“If home testing is not rolled out properly it could have an adverse effect on the intention of rollout. Antigen tests are accurate for not having false positives but could have

false negative results due to the stage of infection. Hence, two tests must be conducted within 72 hours to cover viral incubation since exposure.”

Sahpra spokesperson Yuven Gounden said discussions with various stakeholders regarding approval of home test kits were under way.

“There are numerous factors considered when approving a product for use, the main ones being the safety, quality and intended use of the product and cost,” he said.

“With the home tests there are numerous factors to consider as well as various stakeholders to be engaged. There are technical requirements that need to be taken into consideration during the discussions, for example usability and sampling, to mention a few.”

According to the scientific journal Nature.com, some scientists believe such tests would miss so many infections that if rolled out in their millions they could cause more harm than good.

Public health lawyer Safura Abdool Karim said home-test kits could ease the burden on labs and allow for quicker results.

“However, the home tests don’t generate

results that can be used for things like travel or medical purposes, so their value is only for people to be informed of their status more quickly and isolate, as well as ease the burden on labs to enable faster turnaround for PCRs,” she said.

“In addition, unlike the current system, the government won’t be notified of a positive result, so it will be on the person who tested positive to self-report their results or contact tracing will not be possible.

“People using the tests need to be informed about how to accurately swab themselves and use the tests to ensure the results are accurate. More importantly, these tests are not as accurate as PCR tests and so people who are using them need to ensure that they test again or get a PCR test if they remain symptomatic after testing negative.”

Former ministerial advisory committee chair and epidemiologist professor Salim Abdool Karim said: “We were ready for home-testing kits to be rolled out long ago, it’s long overdue.”

He said home testing is easy, fast and simple.

The health department did not respond to queries.