SAHPRA
South African
Health Products
Regulatory Authority

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
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WARNING: COVID-19 - CAUTION FOR THE USE OF HEALTH PRODUCTS

At a time of unprecedented demand for health products that can be used to prevent, diagnose or manage the novel coronavirus disease COVID-19, there is a very real risk of the public and healthcare professionals being offered sub-standard or falsified medicines, personal protective equipment or diagnostic tests. There is also a risk of these products (medicines and medical devices) being misused or used inappropriately.

In terms of section 14 of the Medicines and Related Substances Act (Act 101 of 1965) (the Medicines Act), “no person shall sell any medicine, medical device or IVD which is subject to registration” which is not registered. “IVD” refers to *in vitro* diagnostic tests, such as those used to test for SARS-CoV-2, the virus responsible for COVID-19. Section 22C also mandates that every “medical device or IVD establishment, manufacturer, wholesaler or distributor of a medicine, Scheduled substance, medical device or IVD” is licensed by the SAHPRA, and complies with “acceptable quality assurance principles and good manufacturing and distribution practices”. The importation of unregistered health products requires specific permission from the SAHPRA.

Members of the public and health care professionals are urged not to buy medicines or medical devices (including IVDs) from unauthorised vendors and websites, including those on social media platforms. Such health products may be sub-standard or falsified, or contain the wrong or no active ingredients or the right active ingredients in the wrong amount. They may also contain harmful substances that are undisclosed. Health products, including diagnostic tests, may not be fit for purpose. Relying on such products may result in severe health problems.

As yet there is no known cure or effective preventive therapy for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is the cause of COVID-19.

WARNING: RISK OF SUB-STANDARD AND FALSIFIED HEALTH PRODUCTS IN RELATION TO THE COVID-19 PANDEMIC

Medicines are available for treating symptoms associated with COVID-19 such as fever, as guided by a healthcare professional (medical practitioner, nurse, or pharmacist). Only buy medicines from registered pharmacies, licensed dispensing practitioners, or obtain them from public sector health facilities. Schedule 0 medicines such as paracetamol, can be obtained from retailers, and are labelled in accordance with the Act. Do not buy medicines (including complementary medicines) advertised as cures or preventive treatments for coronavirus, SARS-CoV-2 or COVID-19.

No serological tests (also referred to as rapid tests or finger-prick tests) for the diagnosis of COVID-19 have as yet been approved for use in South Africa.The only tests that can be relied upon are molecular tests that are conducted by accredited laboratories in the public and private sectors (Refer to Communication MD003).

Any medicine (including complementary medicine), or medical device or IVD advertised for conditions such as COVID-19 without the appropriate authorisation from the SAHPRA may be-

i) subjected to immediate call up for registration with the cessation of sale in terms of section 14(2) of the Medicines Act;
ii) the subject of a public notice of the status of such product with SAHPRA in terms of section 22B of the Medicines Act; or
iii) declared as undesirable in terms of section 23 of the Medicines Act.

Any complaints related to complementary medicines may be submitted on the SAHPRA CM website (www.sahpracm.org.za). No complementary medicines have been approved for use in high-risk conditions such as COVID-19.

Please report any suspicious health products to the SAHPRA Regulatory Compliance Unit: Ms Daphney Fafudi via email at Mokgadi.fafudi@sahpra.org.za by telephone on 066 301 1878 **and** Mr Mlungisi Wondo at Mlungisi.wondo@sahpra.org.za or on 082 256 2626.

The following SAHPRA Regulatory Compliance officials are available to assist:

Masilo Mopai	Masilo.mopai@sahpra.org.za	082 315 5649
Moletele Maebana	Moletele.maebana@sahpra.org.za	071 608 2504

Ramarumo Chepape	Ramarumo.chepape@sahpra.org.za	082 492 4955
Shonisani Lambani	Shonisani.lambani@sahpra.org.za	064 754 8760
Russel Coote	Russel.coote@health.gov.za	082 441 5998

Healthcare professionals, consumers and patients are urged to report any adverse drug reactions (ADRs) or product quality issues to SAHPRA via the eReporting link available on the SAHPRA website (www.sahpra.org.za).

Alternatively, please complete the ADR reporting form accessible via the SAHPRA website (https://www.sahpra.org.za/documents/12e54dcaADRForms.pdf) and email it to adr@sahpra.org.za or fax to 021 448 6181. For more information on ADR reporting, please call the SAHPRA vigilance unit on 012 842 7609/10 or the National Adverse Drug Events Monitoring Centre (NADEMC) on 021 447 1618.

The SAHPRA will provide the public with updates relating to products authorised for the prevention, treatment or diagnosis of COVID-19.