MEDIA RELEASE

FDA's stance on ivermectin aligned to SAHPRA's position

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Pretoria, 3 September 2021 – The South African Health Products Regulatory Authority (SAHPRA) is aligned with the United States Food and Drug Administration (USFDA) call to not use Ivermectin for the treatment of COVID-19. This stance is reflected in the SAHPRA statement, dated 28 January 2021, outlining SAHPRA's views on Ivermectin and the Controlled Compassionate Use Programme.

SAHPRA echoes the USFDA's stance that Ivermectin does not have proven antiviral properties against SARS-COV-2, but it is currently used to treat parasitic conditions in animals. It is also used to treat certain conditions in human such as very specific doses for some parasitic worms, and there are topical formulations for head lice and skin conditions like rosacea.

The USFDA was made aware of reports of individuals self-medicating with Ivermectin and some even using the animal formulation. SAHPRA in its statement on 28 January 2021, reiterated that taking such a drug without it undergoing the requisite testing and protocols could impact one's health adversely and could also lead to death.

In South Africa, SAHPRA registered Soolantra 10mg/g cream formulation, which contains ivermectin. Soolantra Cream is indicated for the topical treatment of moderate to severe inflammatory lesions of papulopustular rosacea in adult patients and is not suitable for the prevention or treatment of COVID-19.

The Ivermectin Controlled Compassionate Use Program, implemented by SAHPRA on 28 January 2021, makes approved ivermectin products accessible. These are deemed suitable for human use. The list is available on https://s21portal.sahpra.org.za/.

SAHPRA, like the USFDA, warns against fake news and misinformation. Medical treatment of any disease should be overseen by medical professionals.

“As SAHPRA’s focus is on the health and well-being of the South African public, SAHPRA continuously engages the scientific and medical community to explore the options for controlled, monitored access to reliable quality ivermectin-containing products for human use with simple but essential reporting requirements. SAHPRA is also monitoring the illegal sale of so-called Ivermectin by unscrupulous individuals. The public should not buy any drug online or from unauthorised dealers,” indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

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About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA’s mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.