**MEDIA RELEASE**

## SAHPRA registers Soolantra 10mg/g Cream- An ivermectin formulation

**Embargo: Immediate release**

**Pretoria, 19 March 2021 –** On 16 March 2021 SAHPRA registered Soolantra 10mg/g cream formulation, which contains ivermectin. The holder of the certificate of registration is Galderma South Africa. Soolantra Cream is indicated for the topical treatment of moderate to severe inflammatory lesions of papulopustular rosacea in adult patients and is not for the prevention or treatment of COVID-19. The registration of Soolantra Cream is not in response to any of the current pending court cases regarding access to ivermectin for the prevention or treatment of COVID-19.

To date, there is insufficient scientific evidence on the efficacy of ivermectin for the prevention or treatment of COVID-19. Thus, SAHPRA's position, as communicated on 28 January 2021, remains as stated. SAHPRA will continue to monitor emerging scientific data in this regard and will respond accordingly. SAHPRA has received no application for the registration of an ivermectin-containing medicine for the management of COVID-19.

Where medical practitioners wish to prescribe a finished pharmaceutical product (such as a tablet) for a patient at risk of or diagnosed with COVID-19, they will still need to apply for access to an unregistered medicine in terms of section 21. Further, SAHPRA's Ivermectin Controlled Compassionate Use Programme, which relies on section 21 of the Act, remains in place.

Refer to

https://www.sahpra.org.za/wp-content/uploads/2021/01/Section_21_Ivermectin_Controlled_Compassionate-Use-Programme_Jan21_FINAL.docx.pdf

and

# APPROVED LICENCES AND REGISTRATIONS - SAHPRA

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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.