MEDIA RELEASE

SAHPRA Statement - Latest Development on Ivermectin Court Case

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Pretoria, 23 November 2022 – On 6 April 2021, the Pretoria High Court issued a consent court order pertaining to four cases that were brought against the South African Health Products Regulatory Authority (SAHPRA) and the Minister of Health regarding access to Ivermectin for use in treating COVID-19. The parties settled the matter which culminated in the consent court order, after SAHPRA published a Compassionate Controlled Access Programme ("the Programme").

In addition to the parties' settlement agreement, the Court further ordered that SAHPRA is required to report back to the Court every three months on *inter alia* the adjustments made to the Programme and why such adjustments were necessary, for the prevention and/or treatment of COVID-19 as well as the number of Ivermectin products made available for named patients under the Programme. The court also ordered that any party to the proceedings will be permitted to return to court under the same case number for further relief, if required by merely amending the pleadings.

Consequently, SAHPRA and the Minister of Health appealed to the Supreme Court of Appeal (SCA).

The appeal was heard on 14 November 2022 in the SCA, and on 21 November 2022, the SCA delivered its judgment setting aside controversial aspects of the consent order, granted in April 2021, compelling SAHPRA to report back to court every three months on access to Ivermectin for use in the treatment of COVID-19 patients, and for returning to court under the same case number for further relief if required by merely amending the pleadings.

The SCA ruled that there was no evidence to justify the order made by the Pretoria High Court. The judge in the Pretoria High Court had also failed to provide his reasons for making such orders, the court said.

"SAHPRA reiterates that to date, there is insufficient scientific evidence on the efficacy of Ivermectin for the prevention or treatment of COVID-19. We wish to assure the public that

SAHPRA has been and will continue to monitor emerging data regarding the use of Ivermectin for the treatment of COVID-19. SAHPRA has thus far still not received an application for the registration of an Ivermectin-containing medicine for COVID-19," indicates Dr Boitumelo Semete-Makokotlela, CEO of 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.