MEDIA RELEASE

SAHPRA statement on the termination of the "Ivermectin Controlled Compassionate Use Access Programme"

Embargo: Immediate release

Pretoria, 30 May 2022 - The use of Ivermectin for the treatment and prevention of COVID-19 received a lot of public interest in 2020. Early evidence, mostly from studies with a small number of patients and conducted with varying degrees of scientific rigour, indicated some potential benefit in the management of COVID-19.

At the time, there were reports of illicit Ivermectin-containing products entering the South African market, as well as the use of veterinary Ivermectin products. In response to the demand for access to Ivermectin for human use, SAHPRA enabled a controlled compassionate use programme ("the Programme"), relying on section 21 of the Medicines and Related Substances Act. The Programme was initiated in January 2021. Permission was granted to five importers of unregistered Ivermectin oral solid dosage forms, and health facilities were enabled to hold bulk stock, in anticipation of patient need. Individual named patient applications were still required, after prescribers had initiated use of Ivermectin. SAHPRA also undertook to monitor the emerging evidence of safety and efficacy, for both treatment and prevention.

There have been several developments regarding the evidence of efficacy of Ivermectin since the Programme was adopted. These include:

- The studies that suggested potential efficacy of Ivermectin in the prevention and treatment of COVID-19 and which motivated the adoption of the Programme have since been retracted.
- The key meta-analysis by Hill et al, upon which the proponents of Ivermectin relied, has been retracted by the authors. This was due to serious ethical concerns regarding a study on which the meta-analysis heavily relied.
- The findings of two large clinical trials[1] conducted in 2021 do not support the use of Ivermectin for patients with COVID-19.

[1] I-TECH Randomized Clinical Trial and the Together Randomized Clinical Trial.

- Two national health organisations updated their guidelines and do not recommend the use of Ivermectin in patients with COVID-19, except in the context of clinical trials.[2]
- The health regulatory authority of the United States, the Food and Drug Administration (FDA), cautions against the use of Ivermectin for COVID-19, except in the context of clinical trials. The FDA's consumer update of 12 October 2021 states that:[3]
    - "*The FDA has not authorized or approved Ivermectin for the treatment or prevention of COVID-19 in people or animals. Ivermectin has not been shown to be safe or effective for these indications*";
    - "*Taking large doses of Ivermectin is dangerous*"; and
    - *"Even the levels of Ivermectin for approved human uses can interact with other medications, like blood-thinners. You can also overdose on Ivermectin, which can cause nausea, vomiting, diarrhoea, hypotension (low blood pressure), allergic reactions (itching and hives), dizziness, ataxia (problems with balance), seizures, coma and even death.".*
- Subsequent to the adoption of the Programme, the World Health Organisation (WHO) issued an advisory recommending that Ivermectin only be used within the context of clinical trials.

SAHPRA is under a duty to consider all the published data and the conclusions of the forementioned reputable authorities.

The effect of these developments is that where there was equipoise at the point in time when the Programme was adopted, there is no longer equipoise. A further important development is that vaccines for COVID-19 are now widely available. SAHPRA has made available other vaccines and therapeutics for COVID-19 through section 21 of the Act.

No new applications for importation of unregistered Ivermectin products have been received since August 2021. A marked decline in the number of health facilities applying for permission to hold bulk stock was noted after August 2021. No individual named patient applications have been approved since December 2021, and a lack of reporting by the treating healthcare providers of the outcomes achieved was also noted.

The scientific evidence, as set out above as well as the other developments summarised above has caused SAHPRA to revise its approach to the Programme in accordance with Regulation 29(4).

Given that there is currently no credible evidence to support a therapeutic role for Ivermectin in COVID-19, SAHPRA has decided to terminate the Programme with immediate effect. No further importation of unregistered Ivermectin products will be allowed, and health facilities will no longer be enabled to hold bulk stock in anticipation of prescriptions for such unregistered Ivermectin products. Prescribers will still be expected to report on the clinical outcomes achieved in patients for whom section 21 approval has been issued.

SAHPRA will continue to monitor the peer-reviewed, scientific literature regarding the safety and efficacy of Ivermectin.

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2 Rapid review of Ivermectin for COVID-19 Update, 30 July 2021, NEMLC Sub-committee on COVID-19; National Institute for Communicable diseases (NICD)/National Department of Health (NDOH) guideline, Clinical Management of Suspected or Confirmed Covid-19 Disease, December 2021.

3 https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-Ivermectin-treat-or-prevent-covid-19

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Notes

1. The Supreme Court of Appeal judgment in Minister of Health and Another v Alliance of Natural Health Products (South Africa) (Case no 256/2021) [2022] ZASCA 49 (11 April 2022) is accessible at: https://www.supremecourtofappeal.org.za/index.php/component/jdownloads/summary/38-judgments-2022/3781-minister-of-health-and-another-v-alliance-of-natural-health-products-south-africa-case-no-256-2021-2022-zasca-49-11-april-2022

About SAHPRA:

SAHPRA is tasked with regulating (by the monitoring, evaluation, regulation, investigation, inspection, registration, and control of) medicines, scheduled substances, clinical trials, and medical devices, IVDs and related matters in the public interest. 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, 1965 (Act No 101 of 1965) as well as the Hazardous Substances Act, 1973 (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.

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