**MEDIA RELEASE**

## SAHPRA Statement- High Court Order - Ivermectin

**Embargo: Immediate release**

**Pretoria, 9 April 2021 –** On 6 April 2021 the Pretoria High Court issued a court order pertaining to four cases that were brought against SAHPRA and the Minister of Health regarding access to Ivermectin for use in COVID-19. The court order was as a result of settlement agreements reached between SAHPRA, the Minister of Health and the applicants in the four cases.

There were three (3) important features of the settlement agreement for SAHPRA and the Minister of Health.

1. There was no concession of liability (fault) or of any breach of constitutional obligations.

2. The terms of the agreement largely mirrored the Ivermectin Controlled Compassionate Programme (the Programme) that has been implemented by SAHPRA since 28 January 2021 and prior to any court hearing in this regard. Details of the Programme are accessible on the SAHPRA website.

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

3. Without admission of any liability, a joint contribution to part of the applicants' costs by SAHPRA and the Minister of Health was agreed to as part of the settlement in order to put an end to what, in SAHPRA's view, could be protracted litigation.

Therefore, any claim of victory by the parties who brought cases against SAHPRA and the Minister of Health is inaccurate and misleading.

**The part of the order that SAHPRA will appeal**

The Court ordered that SAHPRA is required to report back to the Court every three months and parties will be permitted to return to court under the same case number for further relief if required. However, this was not agreed to by the parties nor were they asked for, by any of the applicants. SAHPRA will therefore be appealing these specific orders as per the legal advice it has obtained.

**What the court order means**

In relation to compounding the court order confirmed that medicines containing Ivermectin may be compounded and accessed in accordance with the provisions under the Medicines Act (section 14.4). Further, unregistered Ivermectin-containing finished pharmaceutical products for human use remain accessible only under the Programme through the authorised suppliers of such products. The Controlled Compassionate Use Programme remains firmly in place.

"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 received no 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.