

MEDIA RELEASE

SAHPRA Statement on the ANHP Judgement

Embargo: Immediate release

Pretoria. 27 May 2022 - On 7 May 2022, the South African Health Products Regulatory Authority (SAHPRA) published a statement indicating that it would join the Minister of Health in approaching the Constitutional Court for leave to appeal the Supreme Court of Appeal (SCA) judgement delivered on 11 April 2022 in the Alliance of Natural Health Products (ANHP) case.¹ SAHPRA has since been advised that the Minister will not apply to the Constitutional Court for leave to appeal.

The SCA judgement confirmed the decision of the High Court, suspending the declaration of invalidity in respect of the General Regulations insofar as they relate to complementary medicines for a period of twelve (12) months from the date of judgement. This period will allow the Minister of Health to correct the identified defect in the regulations. During this period of suspension, the existing regulations remain in place, together with the applicable SAHPRA guidelines.

Accordingly, all applications and requests will continue to be reviewed and processed. This applies, *inter alia*, to licensing, section 21, certificate of free sale, health supplement Annexure B applications, and Category D registration applications. Products detained at ports of entry in terms of the Customs and Excise Act, 1964 (Act 91 of 1964), or the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), will continue to be managed in accordance with existing procedures. Requests to SAHPRA for verification of products may be made by way of an online form.²

SAHPRA is committed to the establishment of an appropriate regulatory process for those products which are *bona fide* medicines, the importance of which is affirmed by the SCA judgement. SAHPRA will therefore advise the Minister on the necessary amendments to the General Regulations, as enabled by section 35 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and will consult with stakeholders in line with its normal operations, regarding any review of the technical guidances required as a result of these amendments.

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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>
2. The application for review of detained products at ports of entry application form can be accessed at www.sahpracm.org.za

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.

Notes to Editors:

SAHPRA will post this media release on our website. Navigate to the News section on the website.

Should you request an interview for television, please send your request to media@sahpra.org.za and copy yuveng@sahpra.org.za. Include your discussion points in your request.