SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

COMMUNICATION TO STAKEHOLDERS

Issue No.: PEM04-2023/24

2 June 2023

SAHPRA Statement on Regulation of Category D Medicines

In response to the Supreme Court of Appeal (SCA) judgment on 11 April 2022 regarding the Alliance of Natural Health Products (ANHP), the Minister of Health recently released, for public comment, draft amendments to the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) on 24 March 2023.

The draft amendments align with the SCA and High Court judgments, which stated that only substances classified as "medicines" or "scheduled substances" as defined in section 1 of the Medicines Act should be subject to regulation and included in the scope of Category D medicines. Considering these judgments and the draft regulation amendments, SAHPRA initiated the relevant revision of its technical guidelines. These will be made available for a period of public comment.

This revision will primarily involve Guideline 7.02 (The roadmap and transitional process for the regulation of Category D medicines) and the proposed adjustments to the risk levels applied to Category D medicines. Guideline 7.02 will also clarify which products or substances will or will no longer be subject to regulation. All other technical guidelines related to Category D medicines will be aligned with Guideline 7.02 as revised, where relevant.

SAHPRA, will engage the industry stakeholders in line with its normal operation on the technical amendments of the revised Guideline 7.02 once it has been published for comment. The date of this engagement will be communicated accordingly.

While comments on the published regulations are still awaited, Category D medicines falling under the definition of "medicines" or "scheduled substances" in the Medicines Act will be regulated as outlined in the revised Guideline 7.02. All applications and requests, including licensing, section 21, certificate of free sale, health supplement Annexure B applications, and Category D registration applications, will be reviewed and processed. Products detained at ports of entry under the Customs and Excise Act, 1964 (Act 91 of 1964), or the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), may continue to be submitted for verification using the online form.

SAHPRA is fully committed to establishing an appropriate regulatory process for "medicines" and "scheduled substances" as defined, recognising the significance of the SCA judgment.

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SAHPRA will continue to advise the Minister on any amendments to the General Regulations, in accordance with section 35 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

Dr Boitumelo Semete-Makokotlela
SAHPRA Chief Executive Officer (CEO)

Digitally Signed by:
Boitumelo Semete-Makokotlela
CEO
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