SCHEDULING OF CANNABIS AND SPECIFIC CANNABINOIDS – MEETING THE REQUIREMENTS SET BY THE CONSTITUTIONAL COURT IN 2018

To all stakeholders

In its 25 November 2019 communication to stakeholders about cannabis and related substances, SAHPRA drew attention to the 18 September 2018 decision of the Constitutional Court, which found sections of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (the "Medicines and Related Substances Act"), to be unconstitutional in certain limited circumstances.[i] The court required Parliament to make amendments to the Medicines and Related Substances Act or pass new legislation within 24 months of the date of the judgment, in order to enable an adult person to: a) use or be in possession of cannabis for his or her personal consumption in private; and b) to cultivate cannabis in a private place for his or her personal consumption in private.

On 23 May 2019, the Minister of Health excluded cannabidiol (CBD), one of the naturally occurring non-psychoactive cannabinoids found in the cannabis plant, from the Schedules for a period of 12 months, under restricted conditions.[ii] CBD-containing products were only excluded if they contained a maximum daily dose of 20 mg CBD and make only an accepted low-risk claim or health claim which only refers to: (a) general health enhancement without any reference to specific diseases; (b) health maintenance; or (c) relief of minor symptoms (not related to a disease or disorder); or consisted of processed products made from cannabis raw plant material and processed products, where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product, and which contain not more than 0,001% of tetrahydrocannabinol (THC) (i.e. not exceeding 10 parts per million) and not more than 0,0075% total CBD (i.e. not exceeding 75 parts per million). The exclusion notice was due to expire on 22 May 2020.

In Government Notice No. 586, Government Gazette No. 43347, issued on 22 May 2020, the Minister of Health has amended the Schedules as follows:

1. Previous entries for **cannabis, dronabinol,** and **tetrahydrocannabinol** in Schedule 7 have been deleted.

2. Cannabidiol (CBD) is listed in Schedule 4, except -

a. in complementary medicines containing no more than 600 mg cannabidiol per sales pack, providing a maximum daily dose of 20 mg of cannabidiol, and making a general health enhancement, health maintenance or relief of minor symptoms (low-risk) claim; or

b. processed products made from cannabis raw plant material intended for ingestion containing 0,0075 percent or less of cannabidiol where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product.

Products that meet those listed conditions will instead be regulated as Schedule 0.

3. (-)-transdelta-9-tetrahydrocannabinol (THC) is listed in Schedule 6, except –

a. in raw plant material and processed products manufactured from such material, intended for industrial purposes and not for human or animal ingestion, containing 0,2 % percent or less of tetrahydrocannabinol;

b. processed products made from cannabis containing 0,001 percent or less of tetrahydrocannabinol; or

c. when raw plant material is cultivated, possessed, and consumed by an adult, in private for personal consumption.

These changes to the Schedules have several implications. Firstly, the exclusion of certain CBD-containing products from Schedule 4 has been confirmed, but with important differences from the 2019 exclusion notice. When included as or part of a Complementary Medicine (Category D), not only are daily dose limits stipulated, but also maximum pack sizes. Secondly, cannabis as a plant is removed from Schedule 7. Instead, the psycho-active ingredient tetrahydrocannabinol (THC) is listed in Schedule 6, with specific exemptions made for industrial application of low-THC cannabis. In addition, personal use of the cannabis plant by an adult, in private, is enabled in accordance with the 2018 Constitutional Court judgment.

The Constitutional Court specifically identified section 22A(9)(1)(*a*) of the Medicines and Related Substances Act as unconstitutional. That section states that "No person shall … acquire, use, possess, manufacture or supply any Schedule 7 or Schedule 8 substance, or manufacture any specified Schedule 5 or Schedule 6 substance unless he or she has been issued with a permit by the Director-General for such acquisition, use, possession, manufacture or supply".

By removing cannabis (and THC) from Schedule 7, the possession of cannabis by an adult, for personal cultivation and use in private, is enabled. The requirement of a permit for the manufacture of a Schedule 6 product is in accordance with South Africa's obligations as a signatory to the 1961 Single Convention on Narcotic Drugs.[iii] Accordingly, no further amendment to the Medicines and Related Substances Act is required in order to meet the September 2020 deadline set by the Constitutional Court.

SAHPRA's frequently asked questions document on cannabis and related substances will be updated to reflect these changes.

To date, no CBD- or THC-containing medicines have been registered by SAHPRA. Access to cannabis-related products for medicinal purposes remains subject to the requirements of the Medicines and Related Substances Act, the Regulations and Schedules issued in terms of the Act, and the guidelines issued by the Authority.

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CHIEF EXECUTIVE OFFICER

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[i] SAHPRA. Cannabis and related substances: frequently asked questions. 25 November 2019. https://www.sahpra.org.za/wp-content/uploads/2020/01/Cannabis_and_related_substances_A5_final-1.pdf

[ii] Minister of Health. Government Notice No. R755, Government Gazette No. 42477, 23 May 2019.

[iii] Single Convention on Narcotic Drugs, 1961. http://www.incb.org/incb/en/narcotic-drugs/1961_Convention.html