SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

Press Release

EXEMPTION OF SOME PRODUCTS WHICH CONTAIN CANNABIDIOL FROM CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965).

To all stakeholders

From: The Acting CEO of SAHPRA

Date: 27 May 2019

Cannabidiol (CBD) is one of the naturally occurring non-psychoactive cannabinoids found in the cannabis plant (including *Cannabis sativa* L.). Prior to 23 May 2019, CBD was classified in terms of the Medicines and Related Substances Act 101 of 1965 (Medicines Act), as either Schedule 4 (when intended for therapeutic use), or Schedule 7 (when not for therapeutic use). Medicines and substances which fall into Schedule 4 are only available on a doctor's prescription, while those classified in Schedule 7 are not readily available to members of the general public. On the recommendation of SAHPRA, the Minister removed CBD from schedule 7, classifying all CBD containing products as Schedule 4 substances. (see Government Notice No. R755, *Government Gazette* No. 42477).

All available safety information indicates, however, that CBD at lower doses (less than 20mg per day) is generally well tolerated and has a good safety profile. The Minister of Health in recognition of the known safety profile of low-dose CBD, thus also excluded from Schedule 4, those CBD-containing products that:

1. contain 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
2. consist 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)** (Government Notice No. R756, *Government Gazette* No. 42477).

Any CBD-containing products which do not meet the specifications listed above, will remain subject to the control measures applicable to Schedule 4, as outlined in section 22A of the Medicines Act.

Any person importing a CBD-containing product in terms of the exclusion notice will need to provide proof of the CBD and/or THC content of the product. Any product sold as a medicine (including the low risk indications provided) will have to comply with the required labelling requirements as prescribed. The SAHPRA has, however, also noted that some products containing CBD, available on the open market are in some cases associated with unverified claims for the treatment or prevention of high-risk conditions. Furthermore, the means of production/manufacture and quality oversight of these products (which may

include various forms of oils, supplements, gums, and high concentration extracts) is unknown. Adverse effects may also occur as a result of interactions between CBD and other medicine used. The public is therefore advised of the importance of seeking care from a medical doctor when CBD is used at higher doses.

CBD-containing products are known to interact with other medicines resulting in these medicines having reduced or enhanced effects, including side-effects. CBD-containing products should not be used with other medicines unless expressly so advised. When consulting your health care provider, always tell him/her about any CBD containing products you are using. Also consult with a registered health care provider if you do not experience the desired effects or experience any unusual symptoms when taking CBD-containing products. All suspected adverse events associated with the use of CBD should be reported to: SAHPRA in Pretoria via telephone on (012) 842 7609/10 or by email: adr@sahpra.org.za or to the National Adverse Drug Events Monitoring Center on (021) 447 1618 or fax: (021) 448 6181.(The ADR reporting form can be accessed via the SAHPRA website using this link :

https://www.sahpra.org.za/documents/12e54dcaADRForms.pdf

SAHPRA will closely monitor the compliance with requirements relating to labelling, advertising, manufacture, dosing, purported benefits and sale of CBD containing products. Based on this monitoring, the Authority will consider any need to call up any CBD products as medicines for registration in terms of section 14(2) of the Medicines Act, as may be required. Any products found not to be in compliance with the exclusion notice must be immediately withdrawn from the market or be reported to SAHPRA for investigation.

It is also important to note that the exclusion notice is limited to a period of 12 months. During this time, stakeholders will be consulted regarding possible further amendment of the scheduling of CBD and related substances.

For any queries please do not hesitate to contact Mr Molewa or Ms Daphney Fafudi from the Office of the CEO : Regulatory Compliance unit by email at Mogale.Molewa@sahpra.org.za or Mokgadi.fafudi@sahpra.org.za alternatively via telephone on 071 604 7751 or 066 3011878.

.....

MS P NKAMBULE
ACTING CHIEF EXECUTIVE OFFICER