

Medicinal Cannabis – Frequently asked questions. (SAHPRA date)

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## SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY CANNABIS AND RELATED SUBSTANCES FREQUENTLY ASKED QUESTIONS

### 1 What is Cannabis?

Cannabis refers to the plants in the genus Cannabis, which includes various species or sub-species. Cannabis species in the genus include C.sativa, C.indica and C.ruderalis.

### 2 What are Tetrahydrocannabinol and Cannabidiol?

Between 60 and 100 chemicals called cannabinoids and some 300 non-cannabinoid chemicals are produced by the cannabis plant. Delta-9 tetrahydrocannabinol (THC) and cannabidiol (CBD) are two of the many cannabinoids present in the cannabis plant, in varying concentrations. THC is psychoactive in nature and is the cannabinoid most sought after by recreational users for the "euphoric" high. CBD, on the other hand, is not psychoactive in nature.

### 3 What is the difference between marijuana and hemp?

These are colloquial terms often used to describe different species, sub-species or strains of the same Cannabis plant. The cannabis plant can be cultivated to contain varying concentrations of cannabinoids, such THC and CBD, dependant on the intended use. The high THC-containing cannabis plant, generally utilised for recreational purposes, is commonly referred to as marijuana, weed, ganja or insangu. The low-THC-containing cannabis plant, cultivated for the production of fibre (included in such products as bricks,

ceiling boards and textiles) or seeds and the products produced from the seed (such as cosmetics, oils, paint), is commonly referred to as hemp.

#### 4 What is the current status of cannabis in terms of the Medicines Act?

Cannabis (the whole plant or parts or products thereof) and THC are currently listed as Schedule 7 substances in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (the Medicines Act), except when present in processed hemp fibre and products thereof, in a form not suitable for ingestion, smoking or inhaling purposes, and containing not more than 0,1 % THC; or when present in processed products from cannabis seed containing not more than 0.001 % THC; or when separately specified in Schedule 6 for therapeutic use. Synthetic cannabinoid substances are also listed separately in Schedule 7. THC (also known as the synthetic variant, dronabinol) is listed in Schedule 6, when intended for therapeutic purposes. CBD is listed as a Schedule 4 substance. Certain CBD preparations have been excluded from the operation of the Schedules by the Minister of Health for a time-limited period, as per an exclusion notice (R.756) published in Government Gazette No.42477 on 23 May 2019. This does not infer that CBD is excluded from other requirements of the Act. Schedule 7 substances are deemed to have no legitimate medicinal use and can only be accessed by means of a permit issued by the Director-General of the National Department of Health (NDoH). Medicines and substances categorised as Schedule 4 or Schedule 6 are only available on the prescription of an authorised prescriber and can only be obtained from a pharmacy or the holder of a dispensing licence issued in terms of the Medicines Act. However, refer to Question 20 in relation to personal use of cannabis by an adult in private. SAHPRA is responsible for the registration and regulation of cannabis-containing medicines in South Africa. Amendment of the entries for cannabis and related substances in the Schedules is currently undergoing consideration.

#### 5 Are processed hemp fibre products excluded from Schedule 7?

Processed hemp fibre products (e.g. textiles, bricks, ceiling boards) are specifically excluded from Schedule 7 when: (a) the THC concentration is  $\leq$  0,01 %, (b) the product is in a form not suitable for ingestion, inhalation or smoking and (c) does not contain whole cannabis seeds.

#### 6 Are processed cannabis seed products excluded from Schedule 7?

Processed cannabis seed products (e.g. hemp seed oil, cosmetics containing hemp seed oil) are specifically excluded from Schedule 7 when: (a) the THC

concentration is  $\leq 0,001$  % and (b) the product does not contain whole cannabis seeds.

#### 7 What is the difference between hemp seed oil and CBD oil?

Hemp seed oil is the oil obtained by cold pressing the seeds of the Cannabis plant cultivated to contain a THC concentration of  $\leq 0,001$  %, for its fibre or seeds (as mentioned above). Hemp seed oil does not contain cannabinoids, such as CBD, apart from trace levels that may be present (typically less than 25 parts per million). CBD oil is an extract of the Cannabis plant. It may contain various cannabinoids such as CBD and THC, in varying concentrations. CBD oil is obtained by the separation of components from the Cannabis plant using solvents or other means. Extraction of CBD or THC from the Cannabis plant is considered to be 'manufacturing' in terms of the Medicines Act and requires a licence to manufacture issued in terms of section 22C of the Act,.. Hemp seed oil (if within the thresholds mentioned above) is excluded from the Medicines Act. However, depending on the CBD and THC concentrations, and the intended use, the hemp seed oil may be subject to the provisions of the Medicines Act.

#### 8 Is the cultivation of cannabis for industrial purposes excluded from Schedule 7?

Although processed products are exempt from Schedule 7 as explained in Questions 5 and 6, the cultivation of cannabis for industrial purposes (commonly referred to as hemp when containing low concentrations of THC) may be undertaken by persons who hold a permit issued by the Director-General of the NDoH in terms of section 22A(9)(a)(i) of the Medicines Act. Refer to Question 20 in relation to the personal cultivation of cannabis for use by an adult in private. Amendments to the scheduling of cannabis and related substances are currently under consideration.

#### 9 Are all CBD-containing medicinal products excluded from the Schedules to the Medicines Act?

Only certain CBD preparations have been excluded from the operation of the Schedules by the Minister of Health for a time-limited period (12 months from the date of publication of the exclusion notice, 23 May 2019).

Exemptions were made for those preparations that:

(a) contain a maximum daily dose of 20 mg CBD with an accepted low risk claim or health claim; or

(b) consist of processed products made from cannabis raw plant material , 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) and not more than 0,0075 % total cannabidiol (CBD).

CBD-containing preparations for medicinal purposes must satisfy the conditions prescribed in either paragraph (a) or (b). This exclusion notice does not exclude any CBD-containing products which contain any other active pharmaceutical ingredients (APIs), including THC. Any CBD-containing products that are outside the parameters of the exclusion notice or do not meet the criteria and requirements listed above, remain classified as Schedule 4 products, and are subject to the provisions of the Schedules and registration as a medicine. All medicines must be manufactured under Good Manufacturing Practice (GMP) conditions in a facility licensed in terms of Section 22C of the Medicines Act. This requirement applies equally to complementary medicines, including health supplements.

#### 10 When are processed CBD-containing products excluded from the provisions of the Schedules to the Medicines Act?

A processed product containing the naturally occurring trace amounts of THC ( $\leq 0,001$  %) and CBD ( $\leq 0,0075$  %) is specifically excluded from the Schedules, when the product does not contain whole cannabis seeds and does not make any medicinal claim. If such substances align with the definition and annexures identifying health supplements, they may also be considered as health supplements.

#### 11 Can excluded processed CBD-containing products be regarded as foodstuffs?

A processed product e.g. hemp seed oil, hemp powder, containing the naturally occurring trace amounts of THC ( $\leq 0,001$  %) and CBD ( $\leq 0,0075$  %) may be regarded as a foodstuff, provided the product does not contain whole cannabis seeds and does not make any medicinal claim.

#### 12 Can CBD be added to foodstuffs as an ingredient or additive?

CBD as an additive or ingredient is not permissible in foodstuffs. Only the naturally occurring trace amounts are allowed in foodstuffs. Refer to Question 11 above. Section 5(1)(b) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) prohibits the sale of foodstuff which is "false or misleading as regards its origin, nature, substance, composition, quality,

strength, nutritive value or other properties or the time, mode or place of its manufacture".

13 Where can CBD-containing medicinal products that have been excluded by the Schedules to the Medicines Act be purchased?

These products are available for general sale (Schedule 0) and can be purchased from general outlets, including health shops, as well as from pharmacies.

134 Can any person manufacture and import CBD-containing medicinal products?

Any person who imports or manufactures a CBD-containing medicine must be in possession of a licence issued in terms of section 22C(1)(b) of the Act and comply with the relevant standards, including GMP standards. Such persons must be able to present verified assessment by an accredited laboratory of the CBD and/or THC content of any medicinal product, when requested to do so by the Authority.

15 Can any person manufacture and import processed products containing CBD not intended for medicinal purposes?

Manufacturers and importers of CBD-containing processed products which fall within the parameters of paragraph (b) of the exclusion notice, and which are not intended for medicinal purposes, do not require a licence to manufacture or import in terms of section 22C of the Act, but must be able to provide verifiable proof of the CBD and/or THC content of the product and comply with the provisions of other applicable legislation (for example, the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972))

16 Can any person import CBD as a raw active pharmaceutical ingredient?

CBD, as an active pharmaceutical ingredient (API) intended for the production of a medicine, is currently listed as a Schedule 4 substance in the Schedules to the Act and has not been excluded except as described above. An importer of CBD, as an API or raw material, must be in possession of a section 22C(1)(b) licence issued by SAHPRA. However, in terms of section 22A(7)(a) of the Medicines Act, no person other than a pharmacist, pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, shall sell a Schedule 4 substance for analytical purposes, the manufacture of foods or cosmetics, for educational or scientific purposes, unless in possession of a permit from the Director-General of Health. The term "sell" includes importation and sale by wholesale or retail.



17 How can the public access cannabis and cannabis-containing medicinal products, other than as described above?

Other than the CBD-containing medicinal products that have been excluded from the Schedules (see Questions 9, 10 and 11), cannabis and cannabis-containing medicines can be accessed through specific permits. Section 22A(9)(a)(i) of the Act allows for the acquisition, use, possession, manufacture or supply of a Schedule 7 or 8 substance provided that a permit is obtained from the Director-General of Health. A permit may be obtained for various purposes including education, analysis, research or medicinal use by a medical practitioner for the treatment or prevention of a medical condition in a particular patient. Permit applications can be accessed via the SAHPRA website or through the Regulatory Compliance Unit of SAHPRA. Section 21 of the Medicines Act read together with General Regulation 29 published in terms of the Medicines Act, allows for an authorised practitioner to apply for individual patient access to unregistered medicines. This includes medicines containing cannabis, THC or CBD. The application process is outlined in the SAHPRA section 21 guidance document, accessible here: ([https://www.sahpra.org.za/documents/06b69aa69.113\\_Section\\_21\\_Authorisation\\_Oct18\\_v2.pdf](https://www.sahpra.org.za/documents/06b69aa69.113_Section_21_Authorisation_Oct18_v2.pdf)). Electronic submissions can be made via the web portal: (<https://goo.gl/forms/RcM1Kbh6Q9tEUy5Z2>).

18 Are there any registered cannabis-containing medicines in South Africa?

To date, there are no registered cannabis-containing medicines in South Africa and any access to these medicines is via the section 21 approval process described above.

19 What cannabis-containing registered medicines are available globally?

Epidiolex oral solution, registered by the FDA and EMA, contains CBD and is indicated for treating seizures in very rare, but severe forms of epilepsy in children - Lennox Gastaut and Dravet syndromes. Sativex spray, containing CBD and THC, registered in the UK and Canada, is indicated for treating spasticity symptoms in multiple sclerosis patients. Marinol capsules, containing dronabinol (synthetic THC), are registered in the USA and the UK, and indicated for use in chemotherapy-induced nausea and vomiting and to treat anorexia associated with weight loss in patients with AIDS. Marinol was previously registered in South Africa, but is no longer marketed in this country.

20 How does the Constitutional Court judgement impact on the Medicines Act?

The Constitutional Court found sections of the Medicines Act, which restrict cannabis use, to be unconstitutional in certain limited circumstances. It is, therefore, not a criminal offence for 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.

The court did not make a distinction between using, possessing or cultivating cannabis for recreational or medicinal use. Parliament is required to pass new legislation or to amend the Medicines Act within 24 months of the date of the judgment (18 September 2018).

### 21 Does the Constitutional Court judgement mean that I can now grow my own cannabis legally?

Yes. However, cannabis cultivated in a private place for a person's own use may only be used by the grower/ cultivator and may not be sold/supplied to others.

### 22 How is cannabis used for medicinal purposes?

Cannabis for medicinal use refers to the crude, standardised and quality-assured cannabis plant material that is cultivated, harvested, processed and packaged to be used in the manufacture of pharmaceutical preparations which are required to meet the requisite quality, safety and efficacy standards. Cannabis-containing medicines cover a range of quality-assured cannabis preparations intended for therapeutic use, including as oils or tinctures or other pharmaceutical dosage forms such as tablets and suppositories. The dried flowering buds of the female plant may also be presented as "flos", which can also be presented in granular form. Pharmaceutical preparations of cannabis contain specific active components (cannabinoids) in known amounts. The dose and strength of the preparation can be controlled and standardised, making it safer for patients to use.

### 23 Is it legal to cultivate cannabis for medicinal use on a commercial basis?

The cultivation of cannabis for medicinal purposes on a commercial basis requires a licence issued in terms of section 22C(1)(b) from SAHPRA and a permit in terms of section 22A(9)(a)(i) from the Director-General. A licence can be issued for any or all of the following activities, including to:

- grow and produce cannabis and cannabis resin;
- extract and test cannabis, cannabis resin and/or cannabinoids;

manufacture a cannabis-containing or cannabinoid-containing medicine;  
import a cannabis-containing medicine or cannabinoid-containing medicine;  
export a cannabis-containing medicine or cannabinoid-containing medicine; or  
distribute a cannabis-containing medicine or cannabinoid-containing medicine.

24 What are the processes and requirements for permit and licence applications for the cultivation of cannabis?

In November 2017, SAHPRA published a guideline on the "Cultivation of cannabis and manufacture of cannabis-related pharmaceutical products for medicinal and research purposes" accessible here: (<https://www.sahpra.org.za/Publications/DownloadDoc/5576>). This document provides the framework for the cultivation and processing of cannabis as a herbal starting material for the production of registered medicines. The application forms for section 22A permits can be accessed via the SAHPRA website or by contacting the Regulatory Compliance unit of SAHPRA. The application for a licence to cultivate, manufacture or import cannabis for medicinal purposes is available here: [https://www.sahpra.org.za/documents/ed469ea66.25\\_Licence\\_application\\_Cannabis\\_Sept17\\_v1.pdf](https://www.sahpra.org.za/documents/ed469ea66.25_Licence_application_Cannabis_Sept17_v1.pdf)