



## Cancer Association of South Africa (CANSA)

### Fact Sheet and Position Statement on Cannabis in South Africa

#### Introduction

Cannabis is a drug that comes from Indian hemp plants such as *Cannabis sativa* and *Cannabis indica*. Cannabis is a generic term used to denote the several preparations of the plant *Cannabis sativa*, commonly known as 'dagga'.



#### The Legal Status of Cannabis in South Africa

The Drugs and Drug Trafficking Act, 1992 (Act No 140 of 1992) is currently still the controlling legislation on street drugs in South Africa including Cannabis even though certain Sections pertaining to cultivation, possession, and use of Cannabis by adults in private, and for private use, have been declared invalid with immediate effect. Supply and dealing in Cannabis, however, is still illegal.

The Cancer Association of South Africa (CANSA) noted the unanimous judgment, read by Deputy Chief Justice Ray Zondo in the Constitutional Court on Tuesday, 18<sup>th</sup> September 2018, that Sections 4 (b) and 5 (b) of the Drugs and Trafficking Act, 1992 (Act No 140 of 1992) and Section 22A of the Medicines and Related Substances Control Act, 1965 (Act No 101 of 1965) were inconsistent with the Constitution of the Republic of South Africa, 1996 (Act No 108 of 1996 [as amended]).

The Court Order read out by Deputy Chief Justice Zondo is as follows:

In short, the Court Order:

- (a) decriminalises the use or possession of cannabis by an adult in private for that adult person's personal consumption in private; and
- (b) it decriminalises the cultivation of cannabis by an adult in a private place for that adult's personal consumption in private.

The Constitutional Court order provided the South African Parliament with a time frame of 24 months to prepare legislation in line with the Constitutional Court's Order.

The Cancer Association of South Africa (CANSA) also noted the inclusion of Cannabidiol (CBD) under Schedule 6 in Regulation No 748, proclaimed under the Medicines and Related Substances Act, 1965 (Act No 101 of 1965) in terms of Section 22A(2) by the Minister of Health, and published in Government Gazette No 41009 of 28 July 2017.

### **CANSA's Position on Cannabis and its Derivatives**

The Cancer Association of South Africa (CANSA) has the mandate to look after the interests of patients diagnosed with cancer as well as all those individuals affected by the disease. Furthermore, CANSA has the responsibility, by means of evidence-based scientific information, to educate the public regarding cancer, how to live a healthy lifestyle, and how to reduce one's risk for cancer.

CANSA is aware of the inclusion of Cannabidiol (CBD) as a recognised Schedule 6 medicine. It is expected that Government will soon regulate other aspects of medicinal cannabis for prescribed health conditions. Until such time as all the remaining legal processes have taken place, medicinal cannabis becomes available in South Africa, and valid clinical trials on Cannabidiol has been successfully concluded, CANSA maintains the following position:

- CANSA cannot support the use of Cannabis (excluding medically prescribed Cannabidiol) as long as Cannabis is still illegal in South Africa.
- CANSA cannot support the smoking of Cannabis as smoking is dangerous to health – whether one speaks of tobacco products or Cannabis.
- CANSA cannot currently recommend the use of Cannabidiol for use by cancer patients until such time as successful clinical trials have been concluded indicating that the benefits of Cannabidiol use outweigh any possible associated risks with the use of Cannabidiol in the palliation and/or treatment of cancer.
- CANSA, however, recognises the right of any patient to request a prescription for the use of Cannabidiol from his/her doctor and also recognises the right of medical practitioners to prescribe Cannabidiol to their patients.
- CANSA supports the World Health Organization in its guidelines for the control of cancer pain. To this end CANSA believes that there are medicines available for the control of pain. Morphine is one of the drugs of choice for the control of severe pain and is also available at a reasonable cost.
- CANSA is also of the opinion that there are currently medicines available for use in South Africa for the effective treatment of nausea, vomiting and other conditions related to cancer including palliative and end-of-life care until other complimentary medicines may become available.
- CANSA can also not support the use of natural and/or synthetic cannabinoids and/or THC and/or any other possible active substances (natural or synthetic) that can be derived from Cannabis until such time as successful clinical trials have been concluded and clear indications for the specific use of Cannabidiol in the palliation and/or treatment of cancer has become available.

- Whenever the legal processes have taken their course, and a decision is taken to allow the legal importation and/or manufacture and/or distribution of medicines containing natural and/or synthetic cannabinoids and/or THC and/or any other possible active substances (natural or synthetic) that can be derived from Cannabis, and until such time as successful clinical trials have been concluded and clear indications for the specific use of Cannabidiol in the palliation and/or treatment of cancer has become available, CANSA will investigate and reconsider its position with regard to medicinal cannabis.

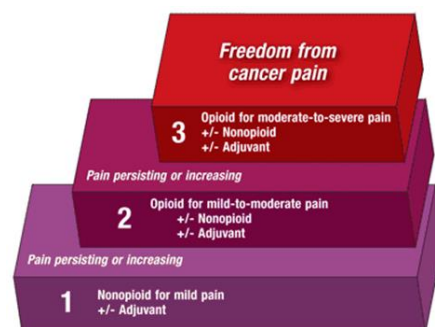
**PLEASE REFER TO THE ADENDA FOR INFORMATION FROM:  
ADDENDUM A - THE SOUTH AFRICAN MEDICAL ASSOCIATION  
And**

**ADDENDUM B - THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY [SAHPRAH]  
REGARDING THE STATUS OF CANNABIS-CONTAINING PRODUCTS (INCLUDING OILS) AND THE  
CULTIVATION OF CANNABIS FOR MEDICINAL USE**

**The World Health Organization and Cancer Pain Relief**

The World Health Organization (WHO) introduced the 3-step WHO ladder approach to cancer pain relief.

If pain occurs, there should be prompt oral administration of drugs in the following order: non-opioids (aspirin and paracetamol); then, as necessary, mild opioids (codeine); then strong opioids such as morphine, until the patient is free of pain.



[Picture Credit: WHO 3-stel Ladder]

In the case of cancer pain in children, WHO recommends a two step ladder approach.

Using a two-step strategy for pain relief in children - the WHO recommends treating pain in two steps, based on pain severity assessment: [2]

- Step 1 is for mild pain. The medicines used are non-opioid analgesics like paracetamol and ibuprofen. These substances have a fixed maximum dosage and can provide only limited analgesia. [2]
- Step 2 is for moderate and severe pain. Strong opioids are used, e.g. morphine, using a weight-appropriate starting dose. The dosages recommended by WHO are lower than those

recommended elsewhere. As long as the pain is not sufficiently addressed, the dosage needs to be increased in steps of no more than 50% per 24 hours.

According to Mercadante & Fulfaro (2005) the WHO method remains of paramount importance and should continue to be encouraged when approaching advanced cancer patients with pain, for the high chances of success, ranging between 70 and 90%. Despite the lack of strong evidence to produce unbiased estimates of the proportion of patients in whom the ladder produces satisfactory results and the fact that no controlled studies with other methods have been conducted to assess its validity, there is the risk to underestimate the educational meaning of this simple approach. Although these guidelines can be implemented, currently the correct use of the WHO method can lead to adequate long-term pain control in most patients with advanced cancer disease. (World Health Organization; Persisting Pain in Children; Mercadante & Fulfaro).

### **Medical Disclaimer**

This Fact Sheet and Position Statement is intended to provide general information only and, as such, should not be considered as a substitute for advice, medically or otherwise, covering any specific situation. Users should seek appropriate advice before taking or refraining from taking any action in reliance on any information contained in this Fact Sheet and Position Statement. So far as permissible by law, the Cancer Association of South Africa (CANSAs) does not accept any liability to any person (or his/her dependants/estate/heirs) relating to the use of any information contained in this Fact Sheet and Position Statement.

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### **References and Sources Consulted or Utilised**

**Drugs and Drug Trafficking Act, 1992** (Act No 140 of 1992)

**Mercadante, S. & Fulfaro, F.** 2005. World Health Organization guidelines for cancer pain: a reappraisal. *Annals of Oncology* 16 (Supplement 4): iv 132 – iv 135, 2005. doi:10.1093/annonc/mdi922.

#### **Persistent Pain in Children**

<http://apps.who.int/medicinedocs/documents/s19992en/s19992en.pdf>

#### **Regulation No 748**

Regulations issued under the Medicines and Related Substances Act, 1965 (Act No 101 of 1965) in terms of Section 22A(2) by the Minister of Health, and published in *Government Gazette* No 41009 of 28 July 2017.

#### **World Health Organization**

<http://www.who.int/cancer/palliative/painladder/en/>

#### **WHO 3-step Ladder**

<https://www.uspharmacist.com/article/overview-of-adult-outpatient-cancer-pain-management>

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## **CANNABIS FOR MEDICINAL USE : THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY (SAHPRA) CLARIFIES THE STATUS OF LOCAL PRODUCTS**

The South African Health Products Regulatory Authority (SAHPRA) has issued a statement clarifying the regulatory status of cannabis-containing products, including cannabis oils.

To date, SAHPRA has received 21 licence applications for the cultivation of cannabis for medicinal use.

No licences have yet been issued for cultivation and production in the country.

SAHPRA said that there are a number of outlets and individuals selling cannabis-containing products, including oils, for medicinal use, in contravention of the Medicines and Related Substances Act, as these products are not approved.

However, as pointed out in the statement, in the interim, section 21 approval has been given for the importation of unregistered cannabis-containing products, in order to meet local needs.

To date, 56 such applications have been approved by SAHPRA, based on motivation for use in specific patients by an authorized prescriber.

Kind Regards

The SAMA Knowledge Management and Research Team

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STATUS OF CANNABIS-CONTAINING PRODUCTS (INCLUDING OILS) AND THE CULTIVATION OF CANNABIS FOR MEDICINAL USE

## 1 INTRODUCTION

On the 18<sup>th</sup> September 2018 the Constitutional Court handed down a judgment<sup>1</sup>, which declared existing legislation, criminalising the use, possession, and cultivation of cannabis, unconstitutional. It would, therefore, now not be an offence for an adult person to:

- a. use or be in possession of cannabis in private 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 also found section 22A(9)(a)(i) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) to be unconstitutional, to the extent that it prohibits the actions listed above, and suggested amended wording to that section, which will be in effect until reviewed by Parliament.

## 2 STATUS OF CANNABIS-CONTAINING PRODUCTS (INCLUDING OILS)

The Constitutional Court judgment should not be misconstrued to mean that persons may be allowed to prepare cannabis-containing products, including extract cannabis oils from cannabis cultivated in a private place, and then to sell such products to the public.

Currently, there are a number of outlets and individuals that are selling cannabis-containing products (including oils) for medicinal use. In terms of the provisions of section 14(1) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), *“no person shall sell any medicine, medical device or IVD which is subject to registration by virtue of a declaration published in terms of subsection (2) unless it is registered.”* The cannabis-containing products and oils that are currently available in South Africa and which have not been registered or approved by SAHPRA are, therefore, illegal. Suppliers and users of such illegal products are exposing themselves and others to legal and health risks as the safety, efficacy and quality of these products cannot be assured.

An applicant wishing to apply for registration of a cannabis-containing product must lodge an application with the SAHPRA. At the same time, an application to licence the manufacturer, importer, distributor of the product has to be submitted (*see section 3*). The safety, efficacy and quality of the product will be evaluated as well as the compliance with GMP requirements.

If, after review, SAHPRA finds that the product is safe, effective and of good quality, and the manufacturer is GMP compliant, it will be registered, allowing it to be available on the market.

In certain specific instances, however, it is possible to apply for individual patient access to unregistered medicines containing cannabis, or specific cannabinoids (tetrahydrocannabinol and/or cannabidiol), in terms of section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). As no quality-assured sources for such products are as yet available in South Africa, approval will need to be sought for the importation thereof from other countries (e.g. Canada and The Netherlands).

To date, 56 such applications have been approved by SAHPRA, based on motivation for use in specific patients by an authorized prescriber.

### **3 CULTIVATION OF CANNABIS FOR MEDICINAL USE**

In order to ensure the availability of standardised, quality-assured, locally grown cannabis for the manufacture of suitable pharmaceutical products, the SAHPRA and the Department of Health may permit the cultivation of cannabis solely for medicinal and research purposes. This framework, developed in consultation with the Department of Agriculture, Forestry and Fisheries (DAFF), is intended to control the cultivation, production and manufacturing of cannabis-containing products intended for medicinal use in South Africa. Licensed domestic cultivation of cannabis for medicinal use is aimed at ensuring sufficient local supply for medical, scientific and clinical research purposes and the implementation of control measures necessary to prevent diversion and misuse, as well as to ensure patient safety.

In November 2017, SAHPRA published a guideline on the “Cultivation of Cannabis and Manufacture of Cannabis-related Pharmaceutical Products for Medicinal and Research Purposes” (Doc No: 2.44; accessible at <https://www.sahpra.org.za/Publications/DownloadDoc/5576>).

This guideline provides information relating to the standards and controls required for the cultivation and processing of cannabis as a herbal starting material and identifies the critical production steps that are needed to ensure a product of reliable and reproducible quality.

An applicant may apply to SAHPRA for a licence in terms of the provisions of Section 22C(1)(b) of the Medicines and Related Substance Act, 1965 (Act 101 of 1965) for any or all of the following activities:

- Cultivate/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;
- Export a cannabis-containing medicine;
- Distribute a cannabis-containing medicine.

The cultivation of cannabis for medicinal use and the manufacturing of cannabis-containing pharmaceutical products shall be subject to strict monitoring to avoid any diversion for unapproved purposes. SAHPRA inspectors will conduct compliance investigations and inspection of sites applying for a licence to conduct regulated activities as well as licensed sites.

#### **4 STATUS OF LICENCE APPLICATIONS FOR THE CULTIVATION OF CANNABIS FOR MEDICINAL USE**

To date, SAHPRA has received 21 licence applications for the cultivation of cannabis for medicinal use. Of these, one application has subsequently been withdrawn. Of the remaining applicants, 16 applicants have been inspected and four (4) applicants are scheduled for inspection. No licences have yet been issued, but a developmental approach to the approval of suitable licencees is being pursued.

However, as pointed out above, in the interim, section 21 approval has been given for the importation of unregistered cannabis-containing products, in order to meet local needs.

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