



## 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 4 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.

PubMed® is a top reference comprising more than 32 million citations for biomedical literature from MEDLINE, life science journals, and online books. There isn't a single citation describing a clinical trial on the use of CBD in cancer patients.

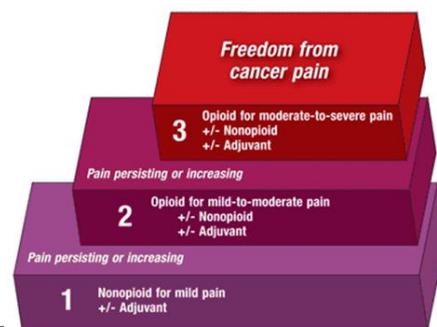
**PLEASE REFER TO THE ADENDA FOR INFORMATION FROM:**  
**ADDENDUM A - THE SOUTH AFRICAN MEDICAL ASSOCIATION**  
**And**

**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: [?]

- 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. [?]

- 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 Cannabis or Cannabinoids for Chronic Pain**

There appears to be many oral testimony, claiming relief from pain by utilising cannabinoids (Cannabis Oils). A peer-reviewed research article published on 08 September 2021 reveals a different picture.

**Busse, J.W., Vankrunkelsven, P., Zeng, L., Heen, A.F., Merglen, A., Campbell, F., Granan, L., Aertgeerts, B., Buchbinder, R., Coen, M., Juurlink, D., Samer, C., Siemieniuk, R.A.C., Kumar, N., Cooper, L., Brown, J., Lytvyn, L., Zeraatkar, D., Wang, L., Guyatt, F.H., Vandvik, P.O. & Agoritsas, T. 2021.**

**CLINICAL QUESTION:** What is the role of medical cannabis or cannabinoids for people living with chronic pain due to cancer or non-cancer causes?

**CURRENT PRACTICE:** Chronic pain is common and distressing and associated with considerable socioeconomic burden globally. Medical cannabis is increasingly used to manage chronic pain, particularly in jurisdictions that have enacted policies to reduce use of opioids; however, existing guideline recommendations are inconsistent, and cannabis remains illegal for therapeutic use in many countries.

**RECOMMENDATION:** The guideline expert panel issued a weak recommendation to offer a trial of non-inhaled medical cannabis or cannabinoids, in addition to standard care and management (if not sufficient), for people living with chronic cancer or non-cancer pain.

**HOW THIS GUIDELINE WAS CREATED:** An international guideline development panel including patients, clinicians with content expertise, and methodologists produced this recommendation in adherence with standards for trustworthy guidelines using the GRADE approach. The MAGIC Evidence Ecosystem Foundation (MAGIC) provided methodological support. The panel applied an individual patient perspective.

**THE EVIDENCE:** This recommendation is informed by a linked series of four systematic reviews summarising the current body of evidence for benefits and harms, as well as patient values and preferences, regarding medical cannabis or cannabinoids for chronic pain.

**UNDERSTANDING THE RECOMMENDATION:** The recommendation is weak because of the close balance between benefits and harms of medical cannabis for chronic pain. It reflects a high value placed on small to very small improvements in self reported pain intensity, physical functioning, and sleep quality, and willingness to accept a small to

modest risk of mostly self limited and transient harms. Shared decision making is required to ensure patients make choices that reflect their values and personal context. Further research is warranted and may alter this recommendation. The increasing legalisation of medical cannabis globally, escalating use by patients, lack of training in the use of medical cannabis or cannabinoids during formal medical education, and inconsistent guidance from professional associations and federal agencies have led to confusion regarding the role of medical cannabis in the management of chronic pain. In this guideline we have sought to address this confusion by asking what is the optimal, evidence based use of medical cannabis or cannabinoids for chronic pain (box 1). The guideline panel developed this recommendation based on a series of linked systematic reviews and use of the GRADE approach and standards for trustworthy guidelines. Box 2 includes all of the articles linked in this *BMJ* Rapid Recommendation package. The infographic provides the recommendation together with an overview of the absolute benefits and harms of medical cannabis or cannabinoids for chronic pain in the standard GRADE format. Clinicians and their patients can find consultation decision aids to facilitate shared decision making in *MAGICapp*.

### **What South African Medical Experts Say About Pain Control**

“There is far too much unnecessary suffering experienced by cancer patients at every stage of their condition, from the moment of diagnosis to either cure or death. There is ample evidence for this, and yet, despite the means now available to control pain and suffering, these means are not always adequately employed by the oncologists, medical or surgical specialists, or general practitioners involved in the management cancer patients. Why is it that in 2015 the suffering of cancer patients is still so prevalent in hospitals, in institutions and in their homes? Why are all doctors and nurses not adequately trained in the scientific methods of relieving pain and symptoms, the art of communicating with their patients and the importance, scientifically as well as good doctoring, of dealing with their emotions?” (Blanchard, C., Chetty, S., Ganca, L., Gwyther, L., Hodgson, E., Kamerman, P., Meiring, M., Sharma, V. Hodgson, E. & Webb, D.).

**Schellack, G., Schellack, N. & Meyer, J.C.** 2018. Opioid analgesics – a 2018 update. *Medpharm S Afr Pharm J*, 2018; 85(1):43-49.

“The opioid analgesic drugs constitute one of the most important groups of pharmacotherapeutic agents in the clinical practice setting. They are vital to pain management, especially moderate to severe cancer and visceral pain, in a myriad of healthcare settings. The key to optimal pain management is the ability to effectively manage patients to ensure optimal pain relief, whilst also minimising or managing the side-effects of their pain medication. This necessitates effective collaboration between all the healthcare professionals managing the patient. This article provides an updated overview of the opioid analgesics, and their usefulness in clinical practice.”

**Blanchard, C., Chetty, S., Ganca, L., Gwyther, L., Hodgson, E., Kamerman, P., Meiring, M., Sharma, V. Hodgson, E. & Webb, D.** 2015.

“Medicinal cannabinoids (nabilone and delta-9-tetrahydrocannabinol, THC) are available in some parts of the world and there is ongoing research into their utility for cancer pain. There is evidence that they may be effective in the treatment of both nociceptive and neuropathic pain syndromes. However, especially at higher doses, THC is highly sedating and adverse effects are common, dose-related and may be severe. The use of cannabinoids is not recommended in South Africa for the treatment of cancer pain.”

## 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 (CANSA) 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

**Blanchard, C., Chetty, S., Ganca, L., Gwyther, L., Hodgson, E., Kamerman, P., Meiring, M., Sharma, V. Hodgson, E. & Webb, D.** 2015. Guide to the Treatment of Cancer Pain in South Africa. South African Cancer Pain Working Group, Gauteng Centre of Excellence for Palliative Care, Chris Hani Baragwanath Academic Hospital, Soweto; Wits Center for Palliative Care, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg.

**Busse, J.W., Vankrunkelsven, P., Zeng, L., Heen, A.F., Merglen, A., Campbell, F., Granan, L., Aertgeerts, B., Buchbinder, R., Coen, M., Juurlink, D., Samer, C., Siemieniuk, R.A.C., Kumar, N., Cooper, L., Brown, J., Lytvyn, L., Zeraatkar, D., Wang, L., Guyatt, F.H., Vandvik, P.O. & Agoritsas, T.** 2021. Medical cannabis or cannabinoids for chronic pain: a clinical practice guideline. *British Medical Journal*, 10.1136/bmj.n2040 on 8 September 2021.

**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.

**Schellack, G., Schellack, N. & Meyer, J.C.** 2018. Opioid analgesics – a 2018 update. *Medpharm S Afr Pharm J*, 2018; 85(1):43-49.

### 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>

### ADDENDUM A

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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

**SAHPRA 8a9263f39.122\_Status\_cannabis\_Jan19\_v1**



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.

*February 2019*