



Exploring alternative options... Cannabidiol's place in pharmacy practice

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Introduction

The *Cannabis* plant has been used for decades, by many different cultures for recreational and spiritual purposes and to treat a "plethora of ailments".

Cannabis refers to plants belonging to the genus *Cannabis*. There are different species of the Cannabis plant namely *C. sativa*, *C. indica* and *C. ruderalis*.

There are more than 460 different chemicals produced by the Cannabis plant, over a 100 of which are classified as cannabinoids. The two major cannabinoids, which are also the most widely researched, are:

- Delta-9-tetrahydrocannabinol (THC). THC has psychoactive properties and is usually wanted by recreational users for the "euphoric" high.
- Cannabidiol (CBD). CBD works differently to THC and does not appear to trigger a "high" or alter alertness.

The chemical composition of the different *Cannabis* species varies with regards to the amount of THC and CBD. For example:

- Some of the *Cannabis* cultivars, for example *C. sativa*, are grown to produce cannabis for recreational purposes. They contain more THC than CBD.
- Other cultivars, for example *C. indica*, also known as hemp plants, have been cultivated for many years for hemp fibres. These plants produce considerably less THC but higher levels of CBD.

Factors such as climate, temperature, time of harvesting and storage may influence the proportion of THC and CBD.

What does the law say about CBD-containing medicinal products?

The South African Health Products Regulatory Authority (SAHPRA) is the governing body responsible for the registration and regulation of cannabis-containing medicines in South Africa.

According to recent changes in legislation, certain CBD-containing products are now available for general sale (Schedule 0) and may be sold in general outlets such as health shops and pharmacies.

Table 1 contains an extract from SAHPRA regarding the scheduling status of CBD-containing products.

The role of CBD

Although there are not many clinical studies conducted on CBD, there is a growing body of evidence that suggests that CBD may possibly be useful for a range of medical conditions. This article will, however, only focus on CBD's role in the management of pain and stress.

Pain

CBD is believed to have pain-relieving properties. Evidence suggests that CBD also has anti-inflammatory effects which may contribute to pain relief. In addition, it is thought that CBD may regulate the perception of pain.

In a 2018 review article, the authors stated that "although CBD as a monotherapy in pain has not been evaluated clinically, its anti-inflammatory and anti-spasmodic benefits and good safety profile suggest that it could be an effective analgesic".

Table 1: SAHPRA extract**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."

Owing to CBD's clinical features such as potential efficacy, safety profile and its limited misuse potential, it has been suggested that CBD may represent an attractive option for pain management, especially in context of opioid abuse. However, more research is needed to understand CBD's potential efficacy and safety.

Stress

It is believed that CBD has anxiolytic activity and that it may assist with relieving symptoms associated with stress.

The effect of a single dose of CBD on simulated public speaking was evaluated in a preliminary study. They found that pre-treatment with CBD was helpful in decreasing symptoms such as anxiety and discomfort in speech performance.

The evidence on the safety and efficacy of CBD in anxiety and anxiety-related disorders was evaluated in a 2019 review article. According to the authors, "CBD has a promising role as alternative therapy in the management of anxiety disorders". However, they only reviewed eight studies and since most of the studies were small, they recommended that larger, more robust studies are needed to determine CBD's place in managing anxiety.

Safety of CBD

CBD has not been associated with an abuse potential and appears to be well-tolerated when taken orally.

The most common side-effects noted in clinical studies were fatigue and sedation. Drowsiness may be exaggerated if CBD is taken concomitantly with other medication that may cause sleepiness or drowsiness. Since CBD products have shown to cause drowsiness, patients should be advised to not take CBD-containing products before driving or operating heavy machinery.

Other side-effects that have been reported include dry mouth and abnormal results in liver-function tests. High doses may cause diarrhoea, decreased appetite, constipation, weight loss and vomiting.

Possible interactions

Patients should also be advised not to take alcohol with CBD.

CBD may have the potential to interact with other medication. For example, CBD may intensify the side-effects of antidepressants, anti-epileptic medication or medication that may cause sleepiness or drowsiness.

Patients with underlying medical conditions and those who are using any other medicine including complementary or traditional medicines, should consult their doctor or pharmacist before taking CBD-containing products.

Advice for patients – A word of caution

Numerous unapproved CBD products (ranging from alleged medicinal products [tablets, capsules, lotions, oils] to drinks, food, cosmetics, etc.) are being manufactured and distributed without regulatory oversight and the contents of these products are not always confirmed.

Concerns that were highlighted by the US Food and Drug Administration (FDA) are that some manufacturers are making unproven, misleading or false medical claims (describing health benefits with no evidence) and that the quality of many of the unapproved products remains questionable.

Investigations have found that many of the products did not contain the level of CBD they claimed. In a survey, only 26 out of 84 online CBD and hemp oil products were accurately labelled for CBD and THC content.

The FDA is also investigating reports that some CBD products may contain THC or other contaminants such as heavy metals, pesticides, etc.

Careful selection of a product is crucial and patients should be advised to choose the highest-quality CBD products.

Conclusion

Although CBD has gained popularity for medicinal use in a variety of medical conditions, there is still a great deal that is not known about CBD and more robust studies are needed.

Pharmacist's assistants are in a unique position, seeing that some of the CBD products are available without a prescription, to give advice on the safe and appropriate use of CBD-containing products.

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