The Golden Mortar

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AS A PHARMACIST, WHAT IS YOUR PROFESSIONAL OPINION ON THE USE OF CANABIDIOL?

Stephani Schmidt
Amayeza Information Services

INTRODUCTION

The popularity of cannabidiol (CBD) has increased over the past few years. Due to changes in legislation, several CBD products are now available to consumers. These products are easily accessible via the internet and from general outlets including pharmacies and 'health' shops.

THE ROLE OF CBD

CBD and delta-9-tetrahydrocannabinol (THC) are the two most researched and well-understood phytocannabinoids (pharmacologically active ligands) in the cannabis plant. CBD works differently to THC. CBD is not associated with a "high" and studies indicate that CBD is not associated with the potential for abuse, and as a result, CBD has gained popularity for its use in the medical field.

Research on the medical use of CBD is most advanced in the treatment of rare forms of epilepsy. Epidiolex® was the first CBD-based medicine approved by the US Food and Drug Administration (FDA) for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome. Epidiolex® is also, to date, the only CBD product that has been approved by the FDA.

CBD's use has also been hypothesised for a variety of other conditions ranging from inflammatory conditions, and migraines, to anxiety and depression. According to Van Dolah H.J *et al.* 2019, CBD represents an "attractive option for the management of chronic pain, especially in the context of opioid abuse". Although there are preclinical or pilot studies that suggest that CBD may be useful for a variety of conditions, more robust studies are needed to understand CBD's potential efficacy for these and other indications.

SAFETY

CBD has been found to be generally well-tolerated in clinical studies and according to the

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World Health Organization (WHO), CBD has a "good safety profile." **CBD-associated side effects** include (but are not limited to) drowsiness, decrease in appetite, diarrhoea, vomiting, pyrexia, fatigue, and abnormal results on liver function tests (transaminase elevations seen with CBD appear to be dose-related). One of the concerns raised by the FDA is that potential liver injury associated with CBD may go unnoticed, if liver function is not monitored.

It has been suggested that some of the side effects observed in the studies may have been related to drug-drug interactions between CBD and the patients' existing medication. Studies have found that concomitant use of medication known to affect the liver (e.g. valproate and clobazam) increased the incidence of transaminase elevations. Concomitant use with CNS depressants, including alcohol, may increase the risk of sedation and drowsiness.

There is still a paucity of data regarding **CBD's potential for drug interactions.** CBD is metabolised by the cytochrome P450 enzymes. Interactions are mainly mediated through inhibition or induction of the cytochrome P450 enzymes. CBD may alter the plasma concentration of other medicines metabolised by this pathway. For example, coadministration of clobazam and Epidiolex® resulted in a 3-fold increase in plasma concentrations of the active metabolite of clobazam. This could result in an increase in clobazam-related side effects. Conversely, CBD concentrations may be altered by other medication.

More rigorous clinical studies are needed to fully understand CBD's safety and potential for interaction with not only other medicines, but also with herbs and botanicals used in dietary supplements. In addition, the FDA has identified risk associated with cumulative exposure and efficacy, and risk in special groups such as children, elderly, pregnant and lactating women as areas where more research is needed.

Important points to consider when recommending CBD

* From an ethical perspective, as healthcare professionals, pharmacists not only have to respect the autonomy of the patient, but also have to take into account evidence of efficacy and safety of the countless CBD products available on the open market – this could constitute "an ethical predicament."
* CBD has a complex pharmacodynamic and pharmacokinetic profile. In the risk-benefit assessment of CBD, it is important to remember that CBD is not "a biologically inert compound". It has its own side effects and it has the potential to interact with other medications. There is also a possibility of compounding of side effects when CBD is used concomitantly with other medicines.
* Research for other indications for CBD are not as advanced as for the treatment of epilepsy. Before recommending CBD, it is important to find out whether the indication is supported by evidence.
* The amount of CBD in non-medicinal products may be far lower than the amount used in clinical trials
* Besides being marketed with unsubstantiated medical claims, it has been found that some unregistered and unregulated CBD products were incorrectly labeled. Discrepancies were found with regards to the labeling of concentrations of CBD. Many products tested did not contain the level of CBD as claimed. In addition, some of the products that were sold as pure CBD contained THC. Reports of CBD products potentially containing other contaminants such as pesticides or heavy metals have also been investigated. Those who choose to experiment with CBD, should therefore be advised to use the highest-quality products.

As a final thought …

*In an article **"Clinicians' guide to cannabidiol and hemp oils"** the authors stated that "although CBD and hemp oils remain an unproven therapeutic option, physicians should remain open to the possible future role these products may play in the management of a variety of difficult to treat diseases, in particular pain and addiction treatment in the context of the opioid crisis."[1] They also encouraged doctors "to not disregard patients' interest in these therapies and instead to retain clinical curiosity as well as healthy scepticism when it comes to attempts to explore new options, especially in the context of curbing addiction and opioid overuse."*

The South African Health Products Regulatory Authority (SAHPRA)

For information regarding products containing CBD that have been excluded by SAHPRA from the schedules to the medicines act, please follow the link provided below.

* SAHPRA: Cannabis and related substances, CBD-containing products. Frequently asked questions. Available from: https://sahpra.org.za/wp-content/uploads/2020/01/Cannabis_and_related_substances_A5_final.pdf

REFERENCES ON REQUEST

THE SOUTH AFRICAN ASSOCIATION OF HOSPITAL AND INSTITUTIONAL PHARMACISTS

35th Annual Conference and 64rd Annual General Meeting (AGM)

11 – 14 March 2021

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ABSTRACT SUBMISSION GUIDELINES

INFORMATION FOR AUTHORS

Authorship of papers: Duplicate abstracts on the same topic from one author or one institution will not be accepted. Once a paper has been submitted to SAAHIP and accepted, changes cannot be made to the title or the author(s). The presenting author must be a paid-up member of the PSSA or an observer. Authorship is reserved for those who were primarily responsible for the content of the project or for those who made a substantial scientific or professional contribution to the project. The substantial contribution may include: a) conception and design, or analysis and interpretation of data, or both, and B) drafting the paper summary. Participation solely in the collection of data does not qualify for authorship.

Presentation Category: Authors must indicate whether they wish their presentation to be considered as a podium, poster or scenario presentation. The academic committee may contact authors if a change in presentation format needs to be considered. Authors are asked to co-operate with the academic committee in this regard to ensure that a wide range of appropriate topics is covered in all the presentation areas.

Presenting Author: If a submission is accepted, it will be assumed that the presenting author will be at the conference to present her/his work. All presenters must inform their SAAHIP Branch Chairperson of their intent to present at the conference in order to be included in their branch delegations. Only ordinary members of SAAHIP may be branch delegates. Other presenters will attend as observers.

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Acceptance, rejection or changes in presentation category: The relevant information will be communicated to the presenting author via email by the SAAHIP Conference Academic Committee by 19 October 2020.

LAYOUT AND FORMAT OF ABSTRACTS

Publication rights: SAAHIP retains first publication right to all original papers (abstracts only) presented at the conference. SAAHIP may publish all abstracts in FORUM in the South Africa Pharmaceutical Journal during the year following the conference. Final abstracts for publication can be submitted at the conference. If no abstract is submitted the original copy will be published, regardless of any changes made.

SUBMISSION OF ABSTRACTS

Abstracts should be submitted via the following link: https://forms.gle/4amuhSFoRRf83S6L7 . All abstracts should be received by 20 September 2020.

Contact the organisers for further information at the following address: recoetzee@uwc.ac.za

Abstracts must be prepared in text format in MS WordTM. Save the abstract as a document with the following file name format: SurnameINITIALS_SAAHIP2021 (e.g. SmithAC_SAAHIP2021). Use the layout and format guidelines below, for all abstracts:

- **Font:** Use Arial, regular font,, size 10
- **Spacing:** Leave a blank line between the main sections of the abstract, otherwise single spacing. Do not indent the start of a paragraph. Use full justification for text alignment.
- **Title:** Use **BOLD** font and CENTRE the title. The title should be brief and clearly indicate the topic of the presentation. Capitalise only the first letter of each word in the title as appropriate. Try to avoid the use of "A", "An" or "The" as the first word of the title.

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- **Author(s) and affiliation:** Use normal font and centre the text. Type the author's surname first, followed by the initials. Underline the presenting author's name. Do NOT include titles or degrees. Include only the place of employment or institutional affiliation.
- **Body of abstract:** This should be a maximum of **350** words **ONLY** (excluding the title, authors and author/s affiliation/s). Avoid using tables, graphs and graphics in the abstract. The body of the abstract must address the following aspects and split into relevant headings. Type headings in bold and start with the relevant text in the next line.

The following headings are suggested:

RESEACH PROJECTS	PRACTICE INNOVATION OR SIMILAR PROJECTS e.g. SCENARIO PRESENTATION
• Introduction / Background	• Setting(s) or background
• Objectives	• Purpose of the project / objectives / Description of case/event
• Methods (Include study design)	• Approached used
• Results	• Results (include improvements made) / outcome of case/event
• Recommendations and conclusion	• Lessons learnt / key learning points
	• Recommendations and conclusions

Instructions

- Draft your abstract on the next page according to the required abstract layout and format guidelines.
- Please note: Maximum of 350 words ONLY, excluding the title, authors and author affiliation.
- Use ONE of the templates on the next two pages as a guideline. Change the section headings to suit the presentation category of your abstract.
- Delete the other template and any other guiding text in the template.

Title of Abstract (Guiding template: Research projects)

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Introduction / Background:
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Objectives:
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Results:
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Conclusions and Recommendations:
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Title of Abstract (Guiding template: Practice innovations e.g. scenario presentation)

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Setting / Background:
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Purpose of the project / Objectives / Description of case/event:
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