Bod on current barriers to patient access to medicinal cannabis in Australia

About Bod Australia (Bod)

Bod is a cannabis centric healthcare company, with a global focus and a mission to innovate and transform the way we live and enjoy life. Our goal is to deliver premium, proven and trusted products for both the consumer markets and medical markets.

We aim to lead the way in research and development, through collaborations with research partners on clinical trial programs. We are committed to supporting healthcare professionals on cannabinoid applications with education, research and knowledge.

Need for improved access

Bod has welcomed the steps taken to date by State and Federal Governments to provide patients with access to cannabinoid applications and allow for greater access to life changing cannabinoid products.

However, there remain further opportunities to streamline and improve access for patients who stand to benefit from cannabinoid applications which are supported with appropriate clinical evidence, and Bod appreciates the opportunity to provide our views on where these opportunities exist.

The challenge

Bod is of the view that many of the challenges that arise in patients receiving access to medicinal cannabis in Australia result from the treatment of all cannabis products as products which allow patients to get 'high' and restrict access on that basis.

However, not all medicinal cannabis products are the same, and vary depending on the quantity of the two main cannabinoids that have been found to have therapeutic benefits, which are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

The main difference between the two cannabinoids is that THC has strong psychoactive effects, meaning it makes a person 'high', whereas CBD does not have psychoactive effect, while still providing positive benefits to patients.

The levels of THC and CBD contained within the plant vary depending on the species of cannabis, with hemp having high levels of CBD but negligible THC content. (See attachment A for an illustration).

Other cannabinoids are also present in medicinal cannabis products; however, these, like CBD are non-psychoactive and thus not associated with patients getting 'high'. The clinical efficacy of these other cannabinoids has not been fully investigated.

Currently, all medicinal cannabis products are treated as one and the same, and all such products are controlled drugs under Schedule 8 of the Poisons Standard. The only exception is that CBD in a relatively pure form where other cannabinoids make up less than two per cent of the product (CBD isolate). In this case, CBD isolate can be considered as a Schedule 4 (Prescription Only) substance.

However, it would be more appropriate if the distinction was drawn between those cannabis products which contain the psychoactive THC and cannabis products which do not. For the products that do not contain THC, access needs to be improved in-line with the consumer health benefits and the extremely low risk they pose. These restrictions should mirror the regulations that apply to CBD

isolate, and should be down scheduled to a Schedule 3 (Pharmacist Only Medicine) of the Poisons Standard.

Doing so would allow for the continued limitation of products containing large quantities of psycho-active THC (the cannabinoid which allows users to get 'high'), while providing more streamlined access to medicinal cannabis products which do not contain significant quantities of THC (less than 0.3%) but still provide considerable patient benefits for common conditions such as anxiety and stress, and chronic pain.

The opportunity

As previously outlined, a significant opportunity exists to improve patient access to medicinal cannabis products by treating products which do not allow patients to experience a 'high' differently to those products which do.

Bod would recommend that restrictions on access to medicinal cannabis products containing less than 0.3% THC be amended to remove many of the regulatory hurdles that patients and medicinal cannabis suppliers must currently go through that limit consumers' access.

All cannabis products containing CBD, but negligible THC should need to be treated as an allowed ingredient, appropriate to the negligible risk they pose.

To do this the following steps could be taken as a matter of priority:

1. Cannabis products which do not include THC (less than 0.3%) should be down-scheduled from a controlled drug - Schedule 8 in line with the current treatment of CBD isolate products. This should see these products available over the counter in pharmacies under Schedule 3 of the Poisons Standard and would remove the need for Special Access Scheme (SAS) prescribing, thereby reducing cost to the Government. Products containing greater than 0.3% of the psychoactive THC would continue to be *regulated as a controlled drug*.

2. The Therapeutic Goods Administration (TGA) needs to allow for cannabis products with less than 0.3% THC to be included as an ingredient in medications. Currently this is not occurring due to cannabis products which do not include THC being restricted as Schedule 8 (Controlled Drug) and CBD isolate being considered as a Schedule 4 (Prescription-Only) substance in best-case scenarios. Following the example of other nations, moving cannabis products with less than 0.3% THC present to Schedule 3 (Pharmacy medicine) would allow for greater medicinal access.

3. Companies with the relevant licences should be allowed to import and export hemp related products without the current regulatory burdens from the TGA/ODC. This should extend to extracts from strains of the cannabis sativa plant which contain low or negligible amounts of THC.

4. State and Federal Governments should take measures to ensure they treat hemp and cannabis medicines consistently across states and territories, with a consistent approach to regulation. Bod acknowledges the work of COAG to date and would welcome additional measures through COAG to ensure the consistency in the regulatory approach adopted.

Concluding Comments

The current regulatory approach by the TGA and other regulatory agencies results in difficulties in patients accessing medicinal cannabis products in Australia. It is also significantly stifling industry development onshore.

Bod is of the view that the regulatory approach regarding medicinal cannabis should be streamlined to better reflect the risks to patients. We have outlined a number of opportunities which exist that could immediately improve access for patients while continuing to limit products with a high THC content.

Bod would welcome the opportunity to address the committee to provide further details on the opportunities that are outlined within this submission. Alternatively, should the committee require further details on any of the matters raised, please do not hesitate to contact Bod and we will endeavour to provide further information.

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The confusion

Cannabis has two species

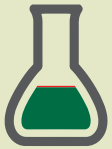
Species I

Hemp

Hemp is a variety grown for its heavy duty fibres, low level of THC and higher levels of CBD.

Hemp is Non-psychoactive

Hemp contains an average of **20% of CBD** and less than **0.3% of THC**



Species II

Cannabis

Cannabis is a variety grown for its higher levels of THC. It is also referred to as Marijuana

Cannabis contains an average of **18.7% of THC** 10% of CBD

Cannabis is Psychoactive

Current uses

MEDICAL	HEALTH AND SKINCARE	MEDICAL	RECREATIONAL
Extracted from flowering tops, leaves and stalk. Available only on authorised prescription and SAS-B.	Extracted from hulled Hemp Seeds. Used in foods, cosmetics and supplements. Listed on Poisons schedule.	Extracted mainly from flowers. Available only on authorised prescription and SAS-B.	Extracted mainly from flowers. In Australia, accessed only on black market - also known as Marijuana.

CBD/Hemp and its benefits

It's known to have over 50,000 different uses

Actives (CBD) concentration

Flower
(up to 20% CBD)

Seeds
(no CBD)

Leaves

Stalk

Roots
(no CBD)

Flower
- CBD
- Other Cannabinoids
- Terpenes
- Unique Phyto Chemicals
- Virtually zero THC!

Other uses:

Textiles
- Clothing
- Diapers
- Handbags
- Denim
- Shoes
- Fine fabrics

Industrial Textiles
- Rope
- Canvas
- Tarps
- Carpeting
- Netting
- Caulking
- Moulded parts

Paper
- Printing
- Newsprint
- Cardboard
- Packaging

Foods
- Hemp Seed Hearts
- Hemp Seed Oil
- Hemp protein powder
- EFA food supplements

Building Materials
- Oil paints
- Varnishes
- Printing kits
- Fuel
- Solvents
- Coatings
- Fibreboard
- Insuation
- Acrylics
- Fibreglass subsitute

Body Care
- Soaps
- Shampoos
- Lotions
- Balms
- Cosmetics

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