

POSITION SUMMARY**Medicinal cannabis****THORNE HARBOUR HEALTH'S POSITION**

Affordable medicinal cannabis products should be accessible to people living with HIV who suffer severe pain from their condition, or side effects from treatment, to alleviate such symptoms. Use should be informed by specific clinical research. Medicinal cannabis should be treated the same way as other prescription medications under road safety laws.

RECOMMENDATIONS

1. Fund clinical trials to determine the appropriate strengths, doses, and methods of administration for medicinal cannabis products, as well as to assess their efficacy when used by people living with HIV.
2. Subject to the results of these trials, consider inclusion of appropriate medicinal cannabis products in the Pharmaceutical Benefits Scheme, at least for people living with HIV.
3. Pending this, add people living with HIV on low incomes who are prescribed medicinal cannabis to Victoria's Compassionate Access Scheme.
4. Improve appropriate access to medicinal cannabis through such measures as additional paid skills training and increasing Medicare rebates for GPs making applications, and increasing and publicising the number of Authorised Prescribers.
5. Treat medicinal cannabis the same way as any other prescription medication under road safety laws such as the *Road Safety Act (Vic)*.

BENEFITS

- Safe and effective use and improved affordability of medicinal cannabis by people living with HIV.
- Improved health outcomes and reduced use of the black market and avoidance of related criminal impacts.

BACKGROUND

- Medicinal cannabis products are quality-assured pharmaceutical products that use the cannabis plant or chemicals contained within it to treat medical conditions.
- People living with HIV have long used cannabis therapeutically to address the side effects of HIV treatments, symptoms of co-morbidities and opportunistic illnesses associated with HIV, and side effects of treatments for these co-morbidities.
- Access in Australia is via a doctor through one of two schemes managed by the Commonwealth Therapeutic Goods Administration: the Special Access Scheme (SAS), or if the doctor is an authorised prescriber, the Authorised Prescriber Scheme.
- The SAS scheme is cumbersome. Currently, around 28,000 approvals have been granted (for all types of patients) compared with an estimated national patient group of 166,000.
- Imported medicinal cannabis products cost, on average, \$300 to \$350 per month. This is unaffordable for most people. Many people living with HIV are in financial stress and sometimes have difficulty accessing antiretroviral or other medication.
- Further research is needed to understand the benefits of medicinal cannabis for people living with HIV as soon as possible.
- Drug driving laws currently focus on testing for the presence of a substance rather than impairment, and medicinal cannabis products are not treated like other prescription medications under road safety laws. This means medicinal cannabis users cannot drive with the confidence they will not be charged with a drug driving offence.

EVIDENCE BRIEF**Medicinal cannabis**

KEY POINTS

- People living with HIV have long used cannabis therapeutically to address the side effects of HIV treatments, symptoms of co-morbidities and opportunistic illnesses associated with HIV, and side effects of treatments for these co-morbidities.
- There is a high general demand for affordable medicinal cannabis products, but access is tightly controlled and products remain unaffordable for many.
- More research is needed to understand the efficacy and appropriate usage of medicinal cannabis products in people living with HIV.
- Road safety laws currently fail to treat medicinal cannabis products like other prescription medications.

BACKGROUND***What is medicinal cannabis?***

Medicinal cannabis refers to quality-assured pharmaceutical products that use plant-derived cannabinoids or cannabinoid molecules that are synthetically produced to treat medical conditions. Of the 100 cannabinoids in the cannabis plant, two main cannabinoids have been studied for potential therapeutic effects: delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). As a result, medicinal cannabis products available in Australia tend to contain mostly THC, mostly CBD or a combination of both in their formulations. THC is psychoactive and classified as a Schedule 8 drug under the Australian Poisons Standard.

How is medicinal cannabis accessed?

Only one medicinal cannabis product is currently registered for use in Australia - Nabixomals (trade name: Sativex) - which is a Schedule 8 product for spasticity due to multiple sclerosis. All other products are currently unapproved for use in Australia. Access is via a doctor through two schemes managed by the Commonwealth Therapeutic Goods Administration (TGA): the Special Access Scheme (SAS), or if the doctor is an authorised prescriber, the Authorised Prescriber Scheme.

Doctors applying to the SAS do so for individual patients. They are required to complete an application that includes a thorough clinical justification for the use of the product, and details of intended monitoring for adverse events and patient response to treatment.

Both TGA and Victorian Department of Health and Human Services approval is required for products that contain THC. This is available through a joint online application process.

Following Commonwealth reforms in 2016 and 2017 that legalised the growing of cannabis for medical and scientific purposes and the export of medicinal cannabis products, a local medicinal cannabis industry is developing. However, Australian demand for medicinal cannabis is currently being supported almost entirely by imported products. At the same time, there is a global shortage of pharmaceutical Good Manufacturing Practice (GMP) product.¹

Cannabis & people living with HIV

People living with HIV have long used cannabis therapeutically to address the side effects of HIV treatments, symptoms of co-morbidities and opportunistic illnesses associated with HIV, and side effects of treatments for these co-morbidities.² The symptoms commonly treated include nausea, vomiting, decreased appetite, headaches, pain, insomnia, depression, anxiety, and weight loss. A recent study indicated that people living with HIV who use cannabis may have a lower likelihood of neural injury leading to cognitive impairment, possibly due to reduced inflammation.³

To the greatest extent possible, people should have the “highest attainable standard of physical and mental health”.⁴ This includes, in consultation with appropriate medical practitioners, decisions about the best course of treatment.

People experiencing chronic medical conditions may want to avoid the side effects of other medications; therefore, they may seek out pain relief provided by medicinal cannabis. A recent Canadian study of people

experiencing chronic pain who use opioids illicitly and are at high risk of opioid overdose indicated that cannabis may serve as an adjunct to or substitute for illicit opioid use, and called for further research.⁵

CURRENT PRACTICE

SAS scheme is cumbersome and requires reform

The SAS scheme is cumbersome. A family, whose son with terminal cancer benefitted from cannabis and who campaigned for legislative change leading up to the Commonwealth 2016 law changes, is campaigning again because, in their view, “the 2016 Amendments to the Narcotic Drugs Act have failed and are failing to deliver on the promise... [of] affordable cannabis products for sick Australians who need them.”⁶

The potential Australian patient group using medicinal cannabis has been estimated by the Victorian Government to be 166,000 people.⁷ However, up to as many as 100,000 Australians currently buy medicinal cannabis on the black market.⁸

Up to 30 June 2020, the TGA has approved over 50,000 SAS Category B applications for unapproved medicinal cannabis products. As of June 2020, there are 84 Authorised Prescribers.⁹

While Category B approvals are increasing, there is a significant gap between the estimated potential patient group and current total approvals.

The Commonwealth Government should give urgent consideration to enabling more GPs to make Category B applications through mechanisms such as additional paid skills training and increasing Medicare rebates. The TGA currently does not release information about Authorised Prescribers, making this pathway to potentially easier access difficult to locate. With their individual approval, the TGA should make this information public and also consider ways to increase the number of Authorised Prescribers.

Affordability of products

Imported medicinal cannabis products cost, on average, \$300 to \$350 per month. Australian products cost \$200 per month but are currently in limited supply.¹⁰ No products are currently subsidised by the Commonwealth Pharmaceutical Benefits Scheme (PBS).

A 2017/18 survey of 847 people living with HIV in Australia showed that nearly four out of five were living on household incomes lower than the average Australian income, while one-third were on incomes of less than \$30,000 (at least \$80,000 less than the average) and had experienced significant financial stress in the previous two years. Also, 7.8% indicated they had not taken HIV medication at least once in the last 12 months due to financial reasons; 38.2% indicated that it was somewhat or very difficult to access medication for financial reasons, and 26.4% indicated it was somewhat or very difficult to access health care for financial reasons.¹¹ The survey data was collected after further subsidisation of HIV medication in November 2018.

This situation underlines the basic unaffordability of current medicinal cannabis products to many people living with HIV.

Over time, the increased availability of Australian products is expected to reduce costs, compared with current costs of imported products. However, inclusion in the PBS is the only affordable option for many people living with HIV and this should be expedited as soon as possible. This requires a substantiated research and evidence base.

This may take significant time. The Victorian Government currently subsidises the cost of medicinal cannabis for ninety children with severe and intractable epilepsy. Pending inclusion of suitable products for people living with HIV in the PBS, the costs of prescribed medicinal cannabis used by members of this group on low incomes should be subsidised by the Victorian Government.

Research and evidence base

The therapeutic benefit of medicinal cannabis products should be subject to the same scrutiny as other medications and pharmaceutical agents.

Anecdotally at least, cannabis has been reported as having therapeutic benefits for people with symptoms of HIV and AIDS-associated co-morbidities. There is also mounting evidence that cannabis can help relieve particular symptoms, such as loss of appetite and neuropathic pain, with few side effects of its own.¹²

The majority of medicinal cannabis use is as an adjuvant, which helps to improve the efficacy of other drugs. This means it can enable a patient to lower the dose of their existing medication, such as pain and nausea medication, so they are not suffering the same level of side effects.¹³

In the UK, it was announced in November 2019 that up to 20,000 patients are to be given medicinal cannabis over two years in an initiative backed by the Royal College of Psychiatrists that aims to create the largest body of evidence on the drug in Europe.¹⁴

There is an urgent need for rigorous clinical trials that test the efficacy of particular methods of administration, dosage, and long-term effects of the use of medicinal cannabis products in people living with HIV so that affordable products in the PBS can be expedited.

Safe driving for people using medicinal cannabis

In Victoria, it is illegal to drive with any level of THC in one's bloodstream. For people prescribed medicinal cannabis, medical advice is not to drive for five days after taking the medication, leaving many people not able to drive at all. Overseas jurisdictions have made arrangements for safe driving by people taking medicinal cannabis. In Ireland, Norway and the UK, people who drive after using cannabis for medical reasons or approved pharmaceutical medicinal cannabis products are exempted from prosecution for cannabis-impaired driving if they can show that they were prescribed the substance and were not impaired.¹⁵ In January 2020, a South Australian man who takes medicinal cannabis for symptoms of multiple sclerosis had drug driving charges against him dismissed on the basis that he was not impaired. However, he still faces arrest the next time he drives as drug driving laws are based on detection rather than impairment.¹⁶ Arrangements so that people taking prescribed medicinal cannabis can drive safely without committing a crime should be considered in Victoria.

CONCLUSION

People living with HIV have long used cannabis therapeutically to address a range of issues, primarily side effects of HIV treatments and treatments associated with HIV-related co-morbidities and opportunistic illnesses. There is considerable scope to refine the effectiveness and safety of such usage through treatments using medicinal cannabis products that are evidence-based and affordable.

RECOMMENDATIONS

1. Fund clinical trials to determine the appropriate strengths, doses, and methods of administration for medicinal cannabis products, as well as to assess their efficacy when used by people living with HIV.
2. Subject to the results of these trials, consider inclusion of appropriate medicinal cannabis products in the Pharmaceutical Benefits Scheme, at least for people living with HIV.
3. Pending this, add people living with HIV/AIDS on low incomes who are prescribed medicinal cannabis to Victoria's Compassionate Access Scheme.
4. Improve appropriate access to medicinal cannabis through such measures as additional paid skills training and increasing Medicare rebates for GPs making applications, and increasing and publicising the number of Authorised Prescribers.
5. Treat medicinal cannabis the same way as any other prescription medication under road safety laws such as the *Road Safety Act* (Vic).

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