Public Health Association
AUSTRALIA

MEDICINAL CANNABIS

Background Paper

This paper provides background information to the PHAA Medicinal Cannabis Policy Position Statement, providing evidence and justification for the public health policy position adopted by Public Health Association of Australia and for use by other organisations, including governments and the general public.

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Definition: The term 'cannabis' generally refers to the plant *Cannabis sativa*. The term 'cannabinoids' includes cannabis as well as synthetic and semi-synthetic substances that produce pharmacological effects similar to those produced by cannabis.[1] For simplicity, this background paper uses the term 'medicinal cannabis' inclusively referring to both botanical cannabis and other cannabinoids.

Medicinal and therapeutic uses of cannabis

1. Both scientific research and numerous case reports indicate a range of health conditions for which cannabis has been demonstrated to be beneficial at palliating the symptoms of serious illness, or the adverse side-effects of their treatment. These include – but are not limited to – cancer, HIV infection, multiple sclerosis, and epilepsy.[2-5]
2. A systematic review published in 2015 concluded that "There was moderate-quality evidence to support the use of cannabinoids for the treatment of chronic pain and spasticity. There was low-quality evidence suggesting that cannabinoids were associated with improvements in nausea and vomiting due to chemotherapy, weight gain in HIV, sleep disorders, and Tourette syndrome." [6]
3. Research into medicinal uses of cannabis is limited, with few high-quality trials having been conducted, partly owing to US Government restrictions on making the drug available for medical research purposes.[7, 8] In some jurisdictions medicinal cannabis is used to treat a host of indications, a few of which have evidence to support treatment with cannabis, while many others do not.[9]
4. Current evidence suggests that adverse effects of short-term use of cannabis products for medical indications are generally modest. Potential adverse side-effects include included asthenia, balance problems, confusion, dizziness, disorientation, diarrhoea, drowsiness, dry mouth, fatigue, hallucination, nausea, somnolence and vomiting.[6] However, further research is needed to evaluate adverse effects of long-term use including risk of dependence, exacerbation of cardiovascular disease and precipitation of psychotic disorder, especially in younger people.[10]

The current legal regime – including recent reforms

5. Under international treaties incorporated into Australian domestic law nations may permit the cultivation, import, export, supply, and consumption of cannabis in all its forms for 'medical and scientific purposes'.[11]
6. Legislation to create the Office of Drug Control within the Commonwealth Department of Health, and task it with regulating the import, export and manufacture of controlled drugs, and the domestic cultivation of cannabis for medical or scientific purposes, was enacted at the federal level in 2016 through the *Narcotic Drugs Amendment Act 2016* (amending the *Narcotics Drugs Act 1967*). The new law established a framework to permit cannabis cultivation in Australia for medicinal and related research purposes through one national scheme. The law provides for the cultivation and supply of certain cannabis products under a national licensing scheme.

7. Regulating the manufacture of cannabis products is now a joint responsibility of the Commonwealth and the states and territories. Access to any cannabis products manufactured under the scheme involves supply being controlled by provisions under the national *Therapeutic Goods Act 1989,* working in tandem with state and territory drugs and poisons legislation and agencies.

8. In all states and territories it is now legal for medical practitioners to prescribe, and pharmacists to dispense, medicinal cannabis using Commonwealth and relevant state/territory approvals. State/territory regimes typically involve regulatory oversight by chief health officers and/or health departments. Individual 'approvals' must also be secured from the Therapeutic Goods Administration (TGA) in relation to the supply aspects of the cannabis products. Queensland regulations have an additional requirement that usual therapeutic treatments should have failed.[12]

9. Queensland was the first Australian jurisdiction to produce clinical guidelines for cannabis prescribing.[13] Queensland state health services are making the use of approved medicinal cannabis products possible as a treatment for certain specified conditions when the patient has already tried the conventional treatments available for their condition or symptoms, and these have failed or cause intolerable side-effects.

10. The NSW Government has established a Centre for Medicinal Cannabis Research, and the Victorian Government has established an Office of Medicinal Cannabis within the Department of Health and Human Services.

11. Considerable concern is expressed in the community that the regulatory regime makes it unnecessarily difficult for people to access medicinal cannabis, in part because so few medical practitioners are willing and able to practice in this area of medicine.[14]

Current patterns of medicinal use of cannabis in Australia

12. Many Australians self-medicate (or medicate family members) with cannabis, sometimes with the tacit support of their doctors.[15, 16] Strong support exists in the Australian community for medicinal cannabis, and this support has increased over the last decade.[17]

13. From June 2018 the TGA began granting case approvals for the supply of cannabis products to individuals under the new medicinal usage regime. Monthly approvals have risen significantly from 100-300 approvals per month in late 2018 to over 1,000 approvals per month in mid-2019. As at 31 May 2019 a total of 7,700 approvals have been granted.[18] From 1992 to 2018, a small number of individual approvals for use of cannabis medicinally were granted under the Special Access Scheme.

14. Future research will be required to place this data in context to reveal overall usage of cannabis for medicinal purposes across Australia. It is likely that some previously illegal users are transitioning to a legal, regulated regime, including transitioning from the use of herbal cannabis to TGA-approved pharmaceutical cannabinoids. The extent to which people prescribed medicinal cannabis under the national scheme, were previously using cannabis illicitly, is not known.

Development of a cannabis/cannabinoid industry

15. In line with the recent reforms, a tightly controlled and legal industry is emerging to provide cannabis products legally for medicinal purposes in Australia.

16. Development and differentiation of new products will occur in the normal course of this process. It will be important to ensure that product claims (in particular, those related to health benefits) are properly regulated through existing Australian law. The TGA is positioned to be the primary regulator of any such claims, as it is for all other health-related products. Given the sensitivity of the products in question, TGA should take care (and be appropriately resourced) to ensure that health-benefit claims that are not substantiated by sound evidence do not become a practice in this market.

17. The health benefits of cannabis are highly specific to individual strains, individual populations and individual pharmacological compounds, and such heterogeneity should be acknowledged in regulatory frameworks.[19]

18. There is a risk of advocacy by the cannabis products industry to promote its own interests overrunning public policy development, as occurred in California.[20] Legislatures, governments and regulators should take great care that the cannabis industry does not emerge with undue influence over public policy decisions, as has happened historically with other sectors such as tobacco, alcohol and junk foods.

Opinions on policy reform

19. Medical/therapeutic and recreational use require distinct policy responses aimed at their specific harms, benefits and risks. Some countries have employed liberal legislative instruments for medicinal use that have produced *de facto* legalisation of recreational use.[21] The recent Australian legislative reform has been concerned only with medicinal uses of cannabis.

20. Widespread public support has been reported for changing legislation to permit the use of cannabis (marijuana) for medical purposes (85% of people aged 14 years or older nationally in 2016, compared with 63% in 2013) and for clinical trials in this area (87% in 2016 and 75% in 2013).[17] This implies a regime that entails no penalty for the person with the health condition in question to possess an amount of cannabis that is deemed to be for personal use (i.e. less than the trafficable quantity threshold). The regime would also specify no penalty for that person - or for a third party nominated by the person and/or the relevant authorities (doctor/s and health department) - to cultivate, possess, supply and/or administer personal-use quantities of cannabis product to the person authorised to receive it.

21. A majority of Australian general practitioners are supportive of medicinal cannabis for cancer pain, palliative care and epilepsy, but feel under-prepared and expressed a desire for improved training.[14]

22. Health claims promoted in medical cannabis legislation and media may impact public perceptions of the harms associated with public use, creating a perception that recreational use is less harmful than evidence suggests.[22] Medical cannabis legislation should be complemented by appropriate harm minimisation measures for recreational use to ensure public health objectives are not undermined.

23. Attitudes towards medicinal cannabis expressed by Australian and international professional bodies are mixed. For example:

    - Cancer Council NSW "...supports limited exemptions from criminal prosecution, such as those provided by the Cannabis Cautioning Scheme, for cancer patients who have been certified by an approved medical practitioner as having particular conditions, and who have been counselled by such a practitioner about the risks of smoking cannabis."[23]
    - The Australian Medical Association "…acknowledges that cannabis has constituents that have potential therapeutic uses' and notes that 'Therapeutic cannabinoids that are deemed safe and effective should be made available to patients for whom existing medications are not as effective…Any promotion of the medical use of cannabinoids will require extensive education of the public and the profession on the risks of the non-medical use of cannabis."[24]

Reforms in other jurisdictions

24. As of 2018, medicinal cannabis was regulated in Argentina, Australia, Brazil, Canada, Chile, Colombia, Croatia, Czech Republic, Finland, France, Germany, Greece, Italy, Jamaica, Macedonia, Mexico, the Netherlands, New Zealand, Peru, the Philippines, Poland, Puerto Rico, Romania, Spain, Switzerland, United Kingdom, United States and Uruguay.[25] Additional nations continue to embrace medicinal cannabis initiatives almost every year. Herbal cannabis is permitted in the majority of these nations, though others limit it to pharmaceutical cannabinoids. [25]

25. A significant challenge lies in ensuring medicinal cannabis is used only for conditions for which it is medically indicated.[26, 27] In some USA jurisdictions there are blurred boundaries between the medicinal and recreational cannabis regulatory regimes.[28] PHAA recommends against regulatory options which blur this boundary, while noting the potential benefits and harms associated with legalising the recreational use of cannabis.[29]

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