Review of Narcotic Drugs Act 1967

Submission from the Lambert Initiative for Cannabinoid Therapeutics, University of Sydney

Background

The Lambert Initiative is a philanthropically funded medical cannabis research group within the University of Sydney. Our aim is to optimise safe and effective cannabinoid therapeutics into mainstream medicine in Australia and beyond to deliver long overdue benefits for patients and to alleviate suffering.

In addition to conducting scientific research, we regularly interact with consumers, patients, affiliated research groups, regulators and politicians. We also speak and collaborate with a variety of medical cannabis industry members and our position in the cannabis community has provided us with valuable insights into the structure and performance of the Narcotic Drugs Act 1967.

In January 2019 we convened an informal meeting of relevant parties to discuss the Review of the Act, share our experiences, and discuss potential solutions. This included domestic and international cannabis companies, senior public servants, legal experts, industry service providers and other cannabis researchers. Although this submission is substantially a summary of those findings, this submission is only on behalf of the Lambert Initiative and does not claim broader representation.

Outcomes for patients

The purpose of the Act and Regulations in order of priority should be to first create a reliable, affordable, high-quality supply of standardised cannabis medicines for Australian patients. Second, to facilitate and support medical scientific research on cannabis and cannabinoids to improve the lives of Australians. And third, to ensure compliance with international treaties.

We have spoken with many dozens of patients who have been prescribed a legal cannabis product but simply cannot afford to fill their script. This is, we believe, mostly due to the extreme delays in the construction of our domestic cannabis industry. The Act and Regulations are responsible for these ongoing delays. This dysfunction is harming vulnerable Australians.

Without a large-scale domestic industry, expensive and imported products will continue to drive thousands of desperate patients into the black market. And research will continue to be hampered by a lack of suitable pre-clinical and clinical material. It should be recognised that, although the scope of this Review is narrowly focused on the Act and the Regulations, these instruments exist to serve a purpose and should be assessed on the outcomes they produce, not just the functions they perform.

Act scope-creep

There is substantial room for improvement in the design of the Narcotic Drugs Act and Regulation. The purpose of the Act is to comply with Single Convention in exclusively managing the cultivation,

production and manufacture of narcotic cannabis products for medical use and medical research. The Act and Regulations should do no more than the Single Convention requires in protecting against diversion and abuse. The Act and Regulations should not apply to non-medical cannabis operations. This should be clarified in the Act.

ODC performance

The ODC has been significantly under-resourced. ODC staff are doing the best they can in a difficult situation and should receive greater financial and operational support from the Department. There are several common issues faced by most organisations when dealing with the ODC. These are summarised here along with some proposed solutions:

Issues	Proposed solutions
New applications take too long to be processed	Minimum turnaround times for applications should be specified and enforced The Office should better triage new applications
Permit applications and license/permit amendment applications take too long to be processed	Applications from existing license and permit holders should be prioritised over new license applications
The same application is handled by multiple different ODC staff with limited historical knowledge of the application	Each application should have a dedicated case manager
14J requests are being made for information already contained in applications Information only relevant to permits is being requested for license applications	Guidance documents should be further clarified and 14J requests should be clearly justified with reference to the Act and Regulation
Duplicated questions from DCS and MCS	DCS and MCS should share information
No visibility on the stage or progress of applications Outdated and inefficient application forms	A single online application submission and management portal should be created and, where possible, communication should be done through a portal to ensure transparency and accountability

Applications

Despite the ODC guidelines, it is challenging to anticipate the minimum requirements of the ODC when submitting an application. Although the case-by-case approach allows for highly customisable operations, it places an extreme burden on the applicant to create a proposal from scratch. And it increases the workload of the ODC which must manage multiple unique operations. The ODC should consider which parts of the scheme can be standardised to streamline and simplify the process.

Permits

There are unique challenges faced by permit holders. For plant breeding programs, it is impossible to

know in advance the type of cannabis plants which will be cultivated, yet this information is required as part of the permit application. Permit variations are often minor – for example transferring 20 seeds from one permit to another – but can take months to be approved. This is also a major challenge for companies negotiating the sale or transfer of seeds and plants, adding unknowable delays to the fulfilment of agreements. Moving from a pre-approval to a notification system for permits could be efficient and appropriate.

Research

The specific activities and compounds captured by the Act and Regulations must be clarified. It is unclear from the Act and the Regulations which molecules require a license prior to their creation through medical chemistry. And for cannabinoids or cannabis products sourced from third party manufacturers, it is unclear what analytical methods these compounds can be subjected to without a license. Furthermore, it is unclear why any additional licenses should be required for low-risk activities (often not involving cannabis plant material) that are already permitted and overseen by State Health Departments.