

2 April 2019

Professor John McMillan AO
Review of the Narcotic Drugs Act 1967
Health Products Regulation Group
Australian Government Department of Health

Dear Professor McMillan AO,

Consultation Submission: Review of the Narcotic Drugs Act 1967

The Medical Cannabis Council (MCC) is pleased to take part in this review of the *Narcotic Drugs Act 1967* (the Act).

MCC is Australia's peak industry association, representing cultivators, manufacturers, importers, distributors, ancillary organisations, researchers, advocacy groups and more. To see the full scope of our Membership, please visit our website at www.medicalcannabiscouncil.org.au.

MCC's main goal is to facilitate a medicinal cannabis industry in Australia that fosters collaboration and accountability, while maintaining integrity, standards and public health and safety.

A large number of our Members either hold a licence from the Office of Drug Control (ODC), or have submitted an application for a licence which is currently being processed.

This submission has been prepared in consultation with our Members, and represents their opinions.

MCC would like to ensure that the potential changes to the Single Convention that may occur later this year are considered as part of this review, in particular the down-scheduling of THC and the removal of CBD from the Single Convention.

The information below summarises the opinions, issues and concerns raised by the Membership, having regard to the Terms of Reference of the review.

Low-THC Cultivation

Cannabidiol (CBD) is a non-psychoactive compound within the cannabis plant that is shown to have therapeutic benefits, such as in neurological indications including epilepsy.

CBD is not a narcotic drug, and in some nations is considered a food product. It is also present in hemp that is legally cultivated, produced and manufactured for industrial purposes in Australia.

CBD for therapeutic purposes can be extracted from hemp which, by definition, is low-THC cannabis. Under the current regulatory framework, organisations wishing to cultivate hemp or low-THC cannabis with the purpose of extracting CBD for medicinal purposes must follow the same strict regulations as those applying high-THC cannabis.

These regulations, particularly security regulations, are unnecessary for hemp or low-THC cannabis cultivation, as there is no illicit value in these plants or subsequent extracted products.

Therefore, the Membership is of the view that a licence application stream for cultivation of hemp or low-THC cannabis for therapeutic purposes ought to be adopted, with significantly reduced security requirements and regulatory burden.

Licence Application Processing

MCC Members see the existing licensing and permit regime as an attempt to balance the obligations under the Single Convention to control the supply of narcotic drugs, while allowing for the supply of high quality, safe medicinal cannabis products.

However, there are several issues with the Act and its administration, leading to licence applications being bogged down. This has led to a delay in Australian companies supplying to patients, while putting companies at risk as they wait for applications to be processed.

A main concern that has been raised consistently over the past few years is the application processing time. It is understood that a Deloitte study anticipated that only around 18 applications would be made to the ODC, and given that ODC resourcing was put in place in anticipation of that amount, it has been seriously underprepared for and overwhelmed by the actual number of more than 200 applications that have been submitted since 2016.

As an example of the impact this has had on the processing of applications,, one MCC Member submitted an application for a Cannabis Research Licence 18 months ago, with their last response to a section 14J request for further information being submitted in late 2018, and yet has received no further communication on the status of their application.

Another factor contributing to delays and regulatory inefficiencies is the 14J request for further information process. Most applicants receive several such requests, usually with

different, unrelated questions. Consolidating 14J requests into a single set of questions which applicants can respond to in a single submission would assist in speeding up application processes.

To assist in managing the regulatory burden, MCC Members believe that ODC should prioritise renewal applications submitted by existing licence holders and permit applications over applications that are submitted for new (first-time) licences. In addition, MCC Members recommend the introduction of a system to triage applications and screen their quality before they are accepted for evaluation, noting that any applications which have not complied with the regulatory requirements should be automatically refused, rather than ODC resources being expended on writing to applicants to explain the deficiencies with their applications..

This delay in application processing can cause significant issues for organisations that have invested in the construction of facilities and business development, but are then hamstrung while waiting for a licence.

Lastly, many MCC Members have requested that the ODC develop more comprehensive guidelines on licence application expectations. Doing so would help ensure that submitted applications are of an acceptable quality from the outset, thus reducing processing times and the need for 14J requests for further information and/or amendments.

Other Comments

In addition to licence application processing times, MCC Members have noted that they are provided with limited information about how their applications are progressing. It is requested the ODC implement a communication scheme (this could, for example, be an online information portal) so that applicants are regularly updated on the progress of their applications.

It is understood that ODC is moving towards a requirement for applicants to have a fully built and fitted out facility prior to applying for a licence. Considering the current processing times, this will have significant implications for applicants, who would be required to invest millions in a facility that may sit idle for 12 or more months pending a licence. This is a risk most companies will not want, and should not be required, to take, and there is a strong view from MCC members that this requirement should not be implemented.

Conclusion

The Medical Cannabis Council appreciates there are many more concerns that it could raise in relation to the Act, however this submission canvasses the significant issues that have been raised by the breadth of our Members.

We also offer our assistance as and if required for the duration of this Review.

Thank you for the opportunity to make this submission on behalf of MCC Members.

Kind regards,

Blaise Bratter
General Manager
Medical Cannabis Council