LEAFCANN
HARVESTING NATURE'S HEALING POWER

RE: REVIEW OF THE NARCOTIC DRUGS ACT 1967

To who it may concern,

LeafCann Group's mission is to be a thought leading pioneer in the emerging new medicinal cannabis industry. With a philosophy of Patient before Profit, our goal is to provide patients and professionals with a safe, high quality, reliable and affordable cannabis medicines. We welcome the opportunity to contribute to this review of the Narcotic Drugs Act 1967 (The ND Act).

Before addressing the Key Themes and Specific Issues outlined in the discussion paper, LeafCann would like to make the following comments to the review panel for consideration:

- World Health Organisation recommendations to investigate the potential to down-schedule cannabis, or remove it entirely, from the Single Convention on Narcotic Drugs would allow an approach more in line with actual experience, data and outcomes. In the absence of this we would ask that GPs in Australia be given authority to prescribe both CBD and THC containing preparations across a wider range of conditions.
- The current licence assessment process is unnecessarily long and convoluted, placing an excessive burden on applicants, with many waiting a year or more to receive licences. Delays in the approval process notwithstanding, there is much duplication that can be removed. There is also a high administrative burden on those seeking to amend or expand their existing licence.
- Serious consideration should be given to merging Research and Cultivation licences into a new class of licence. This would reduce the workload of the ODC and allow the new licence to have all the benefits of the two previous licences.
- The fit and proper assessment should occur as the first step in the application process, this would allow non-conforming applicants to be rejected early in the process, reducing the burden on the ODC to assess applications that would not pass, and reducing the queue for conforming applicants. The fit and proper requirements for individuals and companies are essentially treated the same way in each of the three licence classes and should not require duplication for each application. Additionally, the requirement to redo the fit and proper person checks upon renewal of a licence is an unnecessary burden. A more appropriate approach is to confirm that no details have changed on licence renewal and only pursue further information if there have been changes to personnel, or the status of fit-and-proper or authorised persons (which under the Act must be notified immediately).
- Overall, the detail required from applicants for a licence is excessive and open to interpretation. As licence submissions often vary substantially in length, detail and quality, a framework approach to obtaining information, rather than filling in blank sections of forms with unnecessary detail, can still achieve the purpose of determining an applicant's suitability for a licence without imposing an administrative toll on both applicant and the ODC.
- Lastly, LeafCann suggests that successful licence holders should not have to go through the same extensive application process should they wish to extend or change aspects of their operations. This includes opening new facilities, trying new methods or using new strains. Certainly, the applicant must apply again and be assessed on changes to their operations, however, they should not have to submit an entirely new application with the same information originally provided.

Response to Key Themes and Specific Issues outlined in the discussion paper

Key Themes

Does the *Narcotics Drugs Act 1967* establish a suitable framework for ensuring both a sustainable supply of safe medicinal cannabis products for therapeutic purposes, and the availability of cannabis products for research purposes?

As suggested above, because medicinal cannabis is treated as an International Schedule 1 drug under the Single Convention, the ND Act is not suitable as a framework for medicinal cannabis. Down scheduling CBD and increasing the number of conditions for which CBD and THC containing preparations can be prescribed are approaches that should be given serious consideration.

Does the Act establish a suitable framework for preventing the diversion of controlled narcotics?

With respect to medicinal cannabis, many of the materials are low THC cannabis strains (and materials derived therefrom). These do not represent targets for illicit recreational use and so the potential for diversion is likely to be an overstated issue.

Is the regulatory scheme efficient and effective?

Anecdotal evidence, along with data available, is indicating a sector that is overwhelmed at every level. Producers, prescribing doctors and legal end users have all been affected by timing issues and uncertainty regarding the respective regulatory and administrative processes. This uncertainty has advantaged importers of medicinal cannabis products, whose product prices put them out of reach of the very patients most in need. While there has been improvement over the last 12 months this is still a major concern for those in the sector, that there is still some way to go before Australia has an efficient and effective regulatory system in place.

Views are also being sought on the regulatory scheme's practical implementation – what issues or challenges arise from the way the scheme is administered?

The organisational units charged with the administration of the scheme are under-resourced and now have a significant backlog that has had a negative effect on the industry at many levels. Recent increases in resourcing may allow the scheme to be managed effectively at steady state but the backlog remains.

Is an appropriate regulatory burden imposed on those making licence and permit applications and supplying information?

LeafCann acknowledges that the regulatory burden is generally commensurate with the activities that the licence and permits allow for an international Schedule 1 drug. However, it is the duplication in the application process and the way some information is collected that needs to be improved. Some examples include:

- The difference between a research licence and other licences means a company can't provide the same medicinal cannabis to research facilities and analytic facilities unless they have both been added to a licence. Merging research and cultivation licences provides an option to cultivators who may choose to do some research. Research should be encouraged and not be prohibited by unnecessary application processes.

- In cases where the Therapeutic Goods Administration already has requirements, the ND Act serves as a duplication. The duplication between Acts needs to be reviewed.
- The requirement to specify exact numbers on a permit (eg. numbers of seeds, numbers of tissue culture samples) is limiting research and development. If ODC requires such detail, an estimated range would be a better option with actual numbers provided in regular reporting and audits. This would still give ODC an expected minimum and maximum range, and final figures to allow international reporting, while also allowing companies flexibility in their operations.

Does the Act interact suitably with other Commonwealth, State and Territory legislation relating to the import, export, distribution, trade, possession, use and supply of cannabis products?

There is still a layer of unneeded complexity in Australia and for companies working in multiple states this adds a regulatory burden that is unnecessary and counterproductive. Improved coordination between the States and Territories with Commonwealth legislation can clarify areas of confusion and duplication.

One area that LeafCann would bring to the attention of the review panel is the issue of testing drivers for cannabis use. While it is not specifically covered in this review, the interaction of the ND Act with other Acts will become important in the near future with more and more people using prescribed medicinal cannabis. There is recent evidence that shows the current roadside test can detect salivary THC long after impairment of driving competence has ceased. The second step, a blood test similarly detects circulating THC after ingestion but, because it is a more sensitive assay, the period could be even longer.

LeafCann believes that this is an area that the ODC, through the ND Act, can take a proactive approach and review the situation that currently exists. Solutions such as giving medicinal cannabis patients a letter from a GP waiving the requirement to submit to a roadside test, could eventually be implemented. Scientific evidence has shown that unlike alcohol, there is no linear relationship between blood THC levels, intoxication and driver outcomes. In addition, current roadside testing does not occur for other prescription narcotics including opiates. Removing THC from roadside testing would mean legitimate patients would not be at risk and only those drivers whose driving showed intoxication, would be required to undergo a blood test.

Specific Issues

Are key terms appropriately defined in the *Narcotic Drugs Act 1967* having regard to Australia's obligation to adhere to the requirements and terms of the Single Convention – noting that among the terms defined in the Act and that are important in the operation of the medicinal cannabis scheme are 'cannabis', 'cultivate', 'handling', 'premises', 'production' and 'supply'?

LeafCann supports clarification of nomenclature in the medicinal cannabis sector. A glossary of terms which defines each term, both by what it means and what it doesn't mean, will allow smoother operation of the ND Act.

The *Narcotic Drugs Act 1967* establishes a licensing and permit scheme that rests on three categories - medicinal cannabis licences and permits, cannabis research licences and permits, and manufacture licences and permits. Is that an appropriate structure, having regard to Australia's obligation to adhere to the requirements and terms of the Single Convention? Is there a need to examine options

for greater flexibility, for example, as to the activities (such as research) that can be conducted under a licence, or the uses that can be made of cannabis product that is covered by a licence and permit, or the 'demonstrated supply arrangement' that must form part of an application for a medicinal cannabis licence? Have the requirements of the Act been appropriately interpreted and applied by the Office of Drug Control?

As stated above, merging research licences with other licences will provide flexibility to the sector and encourages research and innovation.

The *Narcotic Drugs Act 1967* does not specify the period for which a licence or permit can be in force. Nor is there a procedure for renewal of an existing licence or permit. Should this be changed?

LeafCann suggests licences operate in perpetuity. However, a licence holder could still be subjected to re-accreditation every 4-7 years using an independent accreditation body in much the same way that occurs in health and aged care, and registered training organisations. Where a risk is identified (for instance a change in a company's executive profile) the ODC has the option of an unannounced visit to conduct a spot audit. Where there are some low risk issues identified, the licence holder should be given a defined period to remedy the situation; where there is major risk, their licence might be suspended or revoked. A cost-recovery model could be used to ensure the ODC is able to investigate any areas of concern without delay. The criteria for risk would need to be developed to facilitate this but useful examples exist in the health and aged care sector.

The *Narcotic Drugs Act 1967* provides an extensive list of matters that must and can be considered in deciding whether to grant a medicinal cannabis, cannabis research or manufacture licence. The requirement that a licence applicant and business associates meet a 'fit and proper' standard is of central importance. Extensive guidance is provided on those matters in the Regulations and by the Office of Drug Control. Does the *Narcotic Drugs Act 1967* appropriately frame the list of relevant matters? Is appropriate guidance provided in the Act, the Regulations and by the Office of Drug Control? Have the requirements of the Act and Regulations been applied appropriately by the Office of Drug Control?

As stated earlier, the fit and proper person requirements are excessive to both applicant and the ODC. Merging Sections 8 and 8B in the ND Act will remove the requirement to provide duplicate applications that are essentially treated as the same.

Overall, there is a lack of clarity around the fit and proper person test requirements and policy in general. It does not seem overly clear what level of employee these need to be applied to. For example, is it required for everyone, even those who cannot access secure areas? Current and future applicants would benefit from more policy direction and guidance on this, particularly relating to the minimum requirements to ensure currency.

Under s 11K of the *Narcotic Drugs Act 1967*, a licence to manufacture a drug derived from the cannabis plant can be granted only if the intended use of the drug falls within one of the categories in s 11K. Does s 11K impose appropriate restrictions on the grant of manufacture licences?

LeafCann would argue that Section 11K(2) and its equivalent under Regulation 7B in the Narcotic Drugs Regulation 2016 be removed. The relationship with the TGA in this instance is not needed. Additionally, this would open a pathway to provide medicinal cannabis for pets.

An applicant can be required under s 14J of the *Narcotic Drugs Act 1967* to provide additional information in support of an application. Is this information gathering mechanism being appropriately managed by the Office of Drug Control? Is the information that applicants are required to provide excessive?

LeafCann would argue that there is an excessive amount of detail required. This includes the duplication in fit and proper applications for individuals and company.

There have been occasions when the information requested had already been provided in the original documentation submitted. This might point to a need to review the current filing and access system of the ODC.

To improve efficiency and relevance of the application process, we would recommend that the application template be simplified and with more specific guidance regarding amount and type of information required. Similarly, with the permit process.

A licence or permit may be varied either on the application of the licence holder or at the initiative of the Office of Drug Control. Has this power been appropriately managed?

Changes to licences either during or after assessment have resulted in even advanced licence applications having to be withdrawn and resubmitted, even when 75% or more of the details were identical and the changes improved the safety, efficacy and security of the proposed operations. This has resulted in delays exceeding 12 months. The excessive application assessment times have meant that companies either cannot respond to market forces or must resubmit their licences, usually both. Either of these situations puts Australian licensees and applicants at a distinct disadvantage to importers.

We would propose that if a change to a licence can be shown to improve the safety, efficacy or security of operations then the variation should be assessed within the scope of the existing licence. If the change is minor, but does not reduce the safety, efficacy or security of operations then it should also be assessed within the scope of the existing licence. Where the change proposed is likely to have a material impact on the existing safety, efficacy and security measures and policy, then the variation be treated as a new application.

The Office of Drug Control can exercise a range of compliance and enforcement powers to ensure compliance with the *Narcotic Drugs Act 1967* and with licence and permit conditions. Have those powers been appropriately exercised? Do licence holders receive adequate guidance about the security standards they are expected to meet for premises and goods and the level of scrutiny that will be undertaken by the Office of Drug Control?

Although we have not been subjected to any compliance or enforcement action, LeafCann suggests the ODC look at establishing an independent compliance audit team, either within or outside the ODC. Having a specialised team would ensure that resources are not diverted away from application assessment and processing. It would also be more effective to provide adequate training to specialised staff performing the audit function.

The Act and Regulations implement a cost recovery scheme, through which fees and charges are imposed on licence applicants and holders. Is the scale of fees and charges appropriate? Should the fee scale apply also to manufacture licences and permits?

LeafCann acknowledges that the fees were set some time ago before the influx of applications put immense pressure on the ODC's assessment team. However, the fees are not currently set to

appropriately cover the cost of administering the ND Act – as evidenced by the slow progress of applications currently in the system. Therefore, it is recommended that fees be increased substantially, and that the revenue goes directly to the ODC assessment team rather than general revenue.

Additionally, LeafCann suggests that the timing of fee payments be changed. Currently, there is a relatively small fee charged upon application and then a larger fee upon issue of the licence. In order to reflect the timing of effort undertaken by the ODC consideration should be given to higher costs up front. This would assist the ODC to recoup its cost in a more timely manner.

Are there any concerns about the interaction of the Act with other Commonwealth laws, including in relation to the Therapeutic Goods Act 1989 (Authorised Prescriber and Special Access Schemes?)

While the ND Act licencing scheme requires higher levels of security for the production of THC containing materials when compared to CBD only materials, the TGA Act makes it difficult for medical practitioners (especially GPs) to prescribe CBD only medications for many conditions. It is also known that there is a strong demand for CBD in the patient population due to the growing evidence of its efficacy in the treatment of chronic pain, inflammatory conditions such as Crohn's Disease, IBD, migraine or arthritis. Aligning the TGA Act to the production skew in the ND Act would result in more Australian produced CBD rich product available for prescription, reducing the cost to patients and steering them away from the black market, where products very rarely contain what is described.