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# Submission for the Review of the *Narcotic Drugs Act 1967*

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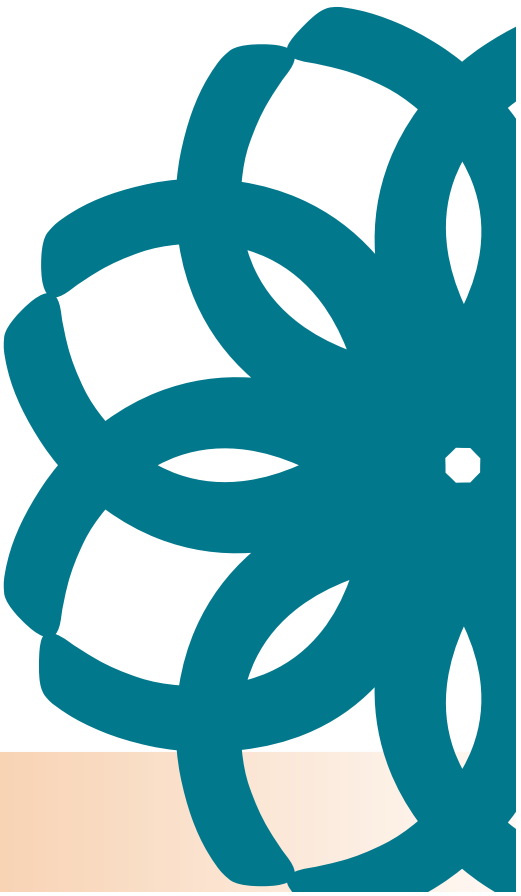

## Background Summary

Cyrelian is a licenced manufacturer, with a board and management team experienced and knowledgeable with the Single Convention, Australian law and the TGA requirements of cultivating, manufacturing and supply of Narcotic Drugs.

Cyrelian congratulates all Commonwealth agencies and associated staff in creating an in-principle suitable framework for the regulatory scheme of medicinal cannabis. We appreciate this formal opportunity to offer feedback, in concert with our ongoing discussions with ODC staff.

We hereby offer the following suggestions for your consideration, regarding practical continuous improvement opportunities for the *Narcotic Drugs Act 1967* and associated regulations.

## Key Themes

1. Does the *Narcotic Drugs Act 1967* establish a suitable framework for ensuring a sustainable supply of safe medicinal cannabis products for therapeutic purposes?

The *Narcotic Drugs Act 1967* (ND Act) does provide a suitable framework in line with international commitments, Commonwealth, State and Territory laws.

The terminology regarding supply for therapeutic purposes should not be overlooked. With the majority of states and territories already having a legislative framework in place for the commercial production of hemp, governments at all levels are highly encouraged to continue to regulate the cultivation of *Cannabis sativa* in line with the sentiments of the Single Convention. That is according to Article 28 of the Single convention; paragraph 2 'the convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes'. Cyrelian strongly encourages all government agencies to maintain clear and defined legislation regarding the cultivation, production and manufacture of *Cannabis sativa* for the purpose of all therapeutic applications to be governed only by the framework set out in the ND Act.

Others in the industry have suggested that the ND Act is superfluous to the requirements under the TG Act; we do not support this view and consider the remit of the TG Act is to ensure quality products for consumers are available in the market. The chief mandate for the ND Act is to ensure Australia's compliance with the Single Convention.

2. Does the *Narcotic Drugs Act 1967* establish a suitable framework for ensuring the availability of cannabis products for research purposes?

The term 'research' is highly problematic as included in the ND Act, associated licence and permits (the Cannabis research licence and permit). Firstly the term 'research' is not adequately defined in the definitions of the Act or regulations. Section 9D of the ND Act does define activities pertaining to a research licence. However Cyrelian suggests that the definition of research versus commercial improvement activities is ill considered.

In consideration of activities as research we present the AusIndustry R&D Tax Incentive definition of those activities as Core R&D:

> a. whose outcome cannot be known or determined in advance on the basis of current knowledge, information or experience, but can only be determined by applying a systematic progression of work that:
>
> 1. Is based on principles of established science; and
> 2. proceeds from hypothesis to experiment, observation and evaluation, and leads to logical conclusions; and
>
> b. that are conducted for the purpose of generating new knowledge (including new knowledge in the form of new or improved materials, products, devices, processes or services)

Ergo, we put forward that any activities pertaining to commercial improvement activities would not meet the definition of generating new knowledge as defined in 2b above. The delineation between commercial improvement activities and true research activities has ramifications for the cost competitiveness of the industry, given the long time frames for issuance and variations of licences and permits and the associated high cost of fees and charges.

We are pleased the ND Act and regulations under the conditions for a manufacturing licence and permit, consider the supply of a drug for the purpose of research relating to medicinal cannabis products and for clinical trials. We do not support academic institutes being subjected to an unnecessary regulatory burden associated with undertaking research activities on drugs when appropriate mechanisms are already in place at a Federal, State and Territory level to manage research involving S8 and S4 products.

3. Does the *Narcotic Drugs Act 1967* establish a suitable framework for preventing the diversion of controlled narcotics to illegal uses?

Cyrelian would agree that the ND Act establishes a suitable framework for the prevention of diversion. The provision of comprehensive guidelines were welcome reference documents for expectations regarding physical security, but not for an adequate risk based assessment of business associates further discussed in point 10.

4. Has the Commonwealth (and in particular the Office of Drug Control) implemented an efficient and effective regulatory scheme for medicinal cannabis? Is an appropriate and proportionate regulatory burden placed on those applying for or holding licences and permits? As to medicinal cannabis licences, is there duplication in the processes and information required in applying for a licence and a permit?

The system has deficiencies in both efficiency and effectiveness. There are many things that can be improved to streamline both the administrative burden and impact on ODC resources, and ultimately benefit industry as the end users.

When an entity holds a licence and applies for another type of licence there should be consideration given to the amount of documentation that has already been supplied for the existing licence. This does not seem to be the case, as it appears the MCS and DCS act independently. This results in unnecessary duplication and unwarranted time penalties for the

applicant. If an entity already has a licence it should not be put to the end of the queue for assessment of other licence applications.

The permit system needs a significant overhaul to be able to respond to industry nuances and changing environments in a more timely and seamless fashion. Not having this in place causes unnecessary angst to industry and may result in an internationally uncompetitive industry. Furthermore specific changes that constitute a variation are not clear.

5. Has an appropriate compliance and enforcement regime been implemented, both in the *Narcotic Drugs Act 1967* and administratively? Are risks being appropriately managed? Is there excessive risk aversion?

Yes, there is excessive risk aversion. Whilst we can understand this is a topical industry, with an established illicit market there is too much administrative burden placed on the assessment of business associates, see point 10 for more detail.

6. Does the Act interact suitably with other Commonwealth, State and Territory laws relating to the regulation of cannabis products and narcotic drugs? Are the intersection points clear? Is there evidence of duplication?

The Tasmanian system under which we operate is relatively harmonious with the ND Act in terms of the scope of this review. There are other areas where the State legislation is stymying the industry generally.

**Specific Issues**

7. 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'?

Mostly this is satisfactory, however there are significant issues with the terminology associated with Relevant Financial Interest, Relevant Position and Relevant Power (discussed further in point 10) and Research (as described already in point 2).

8. 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?

Improvements to the clear delineation between research and commercial improvement activities should be consider, as described in point 2.

The requirement for a demonstrated supply arrangement is sufficiently fluid to respond to the evolving industry demands, but rigid enough to contemplate adherence to the Single Convention, particularly for restricting diversion.

9. 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?

Yes, the process for renewal should be formalised and proceduralised, but no more than already considered with the questionnaire associated with licence renewal.

10. 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?

No, this is one area that we feel needs significant improvement to remove the unnecessarily protracted timeframes and administrative burden associated with assessment and renewals of licences and permits.

Whilst shareholders (as a demonstration of 'business associates') do hold relevant financial interest and to a lesser degree relevant power, the administrative burden of having them screened as fit and proper persons is far in excess of the actual risk potential. If the purpose of this activity is to enable the exclusion of criminal elements, including organised crime, who may otherwise be tempted to use a cannabis licence as cover for illicit activities then it is not proportional to the burden. For example, most shareholders do not have any opportunity to make business decisions outside the remit of voting at shareholder meetings on activities put forward by the board. Shareholders do not automatically have opportunity to enter the facility and access any cannabis material, without the appropriate security screening applied to all employees, contractors and visitors to the site. Ergo the risk to activities associated with diversion are minimal. Whilst not experienced directly by Cyrelian, there is the possibility that the unnecessary screening of business associates through the Informed Consent process may lead to potential investors not pursuing investment in the industry. We suggest that the screening of business associates is wound back to a more proportional risk level, which would also alleviate pressure from ODC staff and resources.

Improvements should also be made to the definition of who should represent a company or trust holding relevant financial interest in the company, to remove ambiguity and potential for excessive paperwork being submitted and reviewed by the ODC.

Furthermore if the screening of business associates (and this equally applies to those persons holding a relevant position) remains as is, then there needs to be significant improvement from external agencies screening of these people/entities. In the current form it is not fulfilling

expectations by industry and is unnecessarily holding up commercial activities, which consequently may lead to a longer-term negative impact for the fledgling industry.

11. 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?

This requirement is satisfactory but could be streamlined by issuance of a template to record all relevant information.

12. 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?

Where additional information has been sought by the ODC this has largely been due to incorrect interpretation of the legislation, guidance documents or other channels of information flow from the ODC.

14. The *Narcotic Drugs Act 1967* lists the standard conditions that apply to all licences, and other conditions that may be imposed on licences and permits. Does the Act provide an appropriate list of relevant conditions? Has the Office of Drug Control appropriately managed these provisions of the Act?

Yes, this appears sufficient.

16. 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?

If fees are applied to manufacturing licences and permits, these should be applied to all sectors across the whole remit of the ND Act.

The research licence costs to commercial entities should be significantly reduced if that entity also holds a manufacturing or medicinal cannabis licence (even if applied for after these licence applications have been submitted).

Licences charges (aside from discussed above) are considered acceptable, the application fees for variations are considered disproportionate as a cost recovery exercise.

*Thank you for the opportunity to provide feedback on the ND Act and associated regulations. We look forward to the implementation of suggestions to ensure Australia has an internationally competitive industry, servicing our patient's needs.*