[redacted]

Professor John McMillan AO
C/- Narcotic Drugs Act Review Secretariat
Health Products Regulation Group
Australian Government Department of Health
PO Box 100
Woden ACT 2606

28.03.2019

Via: ReviewNarcoticDrugsAct@health.gov.au

Dear Professor McMillan,

RE: Written Submission regarding the Review of the Narcotic Drugs Act 1967

Thank you for the opportunity to provide a written submission to this independent review of the medicinal cannabis regulatory scheme (amongst other things) under the Narcotic Drugs Act (NDA).

I wish to expressly endorse and incorporate by reference a submission by and titled: "United in Compassion - Review of the Narcotic Drugs Act 1967 – Submission to the Review" (hereafter the UIC Submission).

That UIC Submission should be seen and acknowledged by the Review for what it is: strong evidence of the 2016 NDA legal-medico-microeconomic reforms having manifestly failed to deliver a suitable framework for sustainable supply of safe medicinal cannabis products for therapeutic purposes.

I plan to expand upon that Submission and place it in a global policy context – that of course being that the World Health Organisation recently recommended to the UN Director General that Cannabis be materially reformed with regard to Scheduling and therefore broader access under the framework of the Single Convention on Narcotic Drugs 1961 (as amended) be undertaken as expeditiously as possible. With those amendments likely to occur in March of 2020, Australia should be aiming to now produce a better framework that aligns with our key ally's and trading partners so as to ensure a *sustainable supply of safe medicinal cannabis for ill Australian's as the current regime does not achieve this.*

Regards

[redacted]

[redacted]

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

Answer:

No - because on the 24th January 2019, Dr Tedros Adhanom Ghebreyesus (Director General , World Health Organisation) wrote to the Secretary General of the United Nations, his Excellency, Mr Antonio Guterres recommending that with reference to Article 3, paragraphs 1, 3, 5 and 6 of the Single Convention of Narcotic Drugs (1961) (as amended by the 1972 protocol, and Article 2, paragraphs 1, 4 and 6 of the Convention on Psychotropic Substances (1971)), that with respect to cannabis and cannabis-related substances:

1) Cannabis and cannabis resin – should be deleted from Schedule IV of the Single Convention on Narcotic Drugs (1961).
2) Dronabinol (delta-9-tetrahydrocannibinol)
    - To be added to Schedule 1 of the Single Convention on Narcotic Drugs (1961)
    - To be deleted from Schedule 2 on the Convention of Psychotropic Substances (1971), subject to the CNDs adoption of recommendation to add dronabinol and its stereoisomers delta-9-tetrahydrocannibinol to Schedule 1 of the Single Convention on Narcotic Drugs (1961)
3) Tetrahydrocannibinol (Isomers of delta-9-tetrahydrocannibinol)
    - To be added to Schedule 1 of the Single Convention on Narcotic Drugs subject to the CNDs adoption of the recommendation to add dronabinol and its stereoisomers to Schedule 1 of the Single Convention on Narcotic Drugs (1961)
    - To be deleted from Schedule 1 on the Convention of Psychotropic Substances (1971), subject to the CNDs adoption of recommendation to add Tetrahydrocannibinol and its stereoisomers delta-9-tetrahydrocannibinol to Schedule 1 of the Single Convention on Narcotic Drugs (1961)
4) Extracts and Tinctures
    - To be deleted from Schedule 1 of the Single Convention on Narcotic Drugs (1961)
5) Cannabidiol preparations
    - To give effect to the recommendation of the 40th meeting of the WHO Expert Committee on Drug Dependence that preparations considered to be pure cannabidiol (CBD) should not be scheduled with the International Drug Control Conventions by adding a footnote to the entry for cannabis and cannabis resin in Schedule 1 of the Single Convention on Narcotic Drugs (1961) to read: "Preparations containing predominantly cannabidiol and not more than 0,2% delta-9-tetrahydrocannibinol are not under international control".
6) Preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that delta-9-tetrahydrocannibinol (Dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health
    - To be added to Schedule III the Single Convention on Narcotic Drugs (1961)

While the adoption of these recommendations by the UN Commission on Narcotic Drugs was expected for March 2019, the Commission decided to postpone *sine die* the vote on the WHO Expert Committee's final recommendations. It is now likely that the Commission only takes action on the WHO recommendations in March 2020 during its 63rd session. **This should not hold us up though here in Australia...!**

The practical effect and impact of this/these inevitable re-scheduling(s) (the most significant since 1961) should be to give Australia significant pause and cause <u>immediately</u> to consider the wholesale removal of cannabis (and its derivatives) as described above at (1) to (5) from the Narcotic Drugs Act 1967 altogether as it no longer provides a suitable framework for ensuring a sustainable supply of safe medicinal cannabis products for therapeutic purposes. It was never intended to be a licensing statute and the interaction of Cth and State laws in this space simply results in inequity, inefficiency in government and medical cannabis stakeholders left in a 'state of limbo.'

Such comments must be seen in a global context of the Convention's future place in International Law and by implication Australian domestic law *(if at all in a Cannabis context) given:*

- ***Canada*** *– a key Australian trading partner, ally and fellow Commonwealth jurisdiction and economy legalising Cannabis subject to provincial and/or other domestic territorial restrictions, for adults who are 18 years of age or older. They are now legally able to:*
    - *possess up to 30 grams of legal cannabis, dried or equivalent in non-dried form in public*
    - *share up to 30 grams of legal cannabis with other adults*
    - *buy dried or fresh cannabis and cannabis oil from a provincially-licensed retailer*
    - *in provinces and territories without a regulated retail framework, individuals are able to purchase cannabis online from federally-licensed producers*
    - *grow, from licensed seed or seedlings, up to 4 cannabis plants per residence for personal use*
    - *make cannabis products, such as food and drinks, at home as long as organic solvents are not used to create concentrated products*
    - *Cannabis edible products and concentrates will be legal for sale approximately one year after their Cannabis Act came into force on October 17th, 2018.*
- ***United States of America*** *- another key Australian trading partner and ally: a significant degree of latitude regarding the International Narcotics Control Board's enforcement mechanisms has been shown to the USA. This Review should be far more cognisant of this in determining a new recommended more open, expansionary framework in Australia.*
    - *For example, the United States of America is considered in 'good standing' regarding the treaties/Conventions above despite the fact that more than 40 of the country's States now permit at least legal medicinal marijuana and it is fully legal in 9 US States. This so-called 'good standing' is because marijuana remains illegal at the national government level.*
- These two countries (and 16 others around the world) have between a 5 year and 16 year medical cannabis policy head-start over Australia in providing better frameworks for access to this plant medically whether inside our outside the Convention. This is causing Australia's health, legal and economic systems to suffer and fall behind unnecessarily.
- ***More broadly though, by implication, these two ally's/key trading partners (along with many other countries) will face a short to medium term prospect to either (a) remain in the treaties but openly violate them, (b) exit the treaties (and then rejoin with reservation) or (c) attempt to reform the treaties - ostensibly by organising a group of like-minded countries to remove cannabis from the list of banned substances.***
    - ***Australia should be positioning (c) to support our ally's and key trading partners in any policy framework reform settings with sensible alignment as this is in the interests of (i) safe reliable supply chains (ii) international trade, finance and administrative law flow on impacts (e.g. matters including as varied as taxation and intellectual property law etc) all of which will (iii) help to ensure safe, more affordable, medicinal cannabis supply to sick Australians.***

In summary (Q 1):
The cannabis plant has up to 144 different cannabinoids (beyond the two mainstream well known ones in THC and CBD) and potentially millions of strains each with varying cannabinoid ratio compositions ultimately that can be used to treat multiple different parts of the human endo-cannabinoid system for numerous medical ailments that afflict our people. *The World Health Organisation Expert Committee reviews outcome referred to above backs this statement and thus should inform a revised policy and legislative framework for Australia the background of which should and can be stated as:*

- *Cannabis is legitimate in medicine – arguably a new official WHO position that should be followed by and expanded upon by Australia sooner rather than later.*
- *Globally renowned experts consider herbal Cannabis less dangerous than Schedule I substances.*
- *Countries such as Australia should be encouraged to provide access to a variety of formulations.*
- *Countries such as Australia should have a broad choice and flexibility of policies on preparations.*

The UIC submission makes clear the 2016 reforms to Act are not and will not deliver such a framework.

The solution in my personal opinion is the removal of Cth oversight of cannabis from this Act with the current licensing framework carved out and transitioned to something more akin/aligned with the Regulator of Medicinal Cannabis Bill – which was passed by the Australian Senate in October 2014 and/or pure state based regulatory regimes.

The conclusion therefore to Q 1 is "no" – the Narcotic Drugs Act 1967 does not establish a suitable framework for ensuring a sustainable supply of safe medicinal cannabis products for therapeutic purposes.

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

[redacted] Answer:

No.

A crimino-legal Act is not the framework for research. An agrarian-medico-pharma research framework is required such as that deployed in Israel.

Quite simply – the Commonwealth and the States needs to adopt / incorporate the Israeli research models into broader system reforms (via models linked/supported by Medicare and Private Health Insurers to bring down the cost, encourage research and to fight the black market). Then we can have collaborative research like what has/is being done at/by:

- Dr Dedi Meiri Principal Investigator, Technion Israel Institute of Technology, Laboratory of Cancer Biology and Cannabinoid Research.
- Raphael Mechoulam from Hebrew University.

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

[redacted] Answer:

No.

I would broadly refer you to the UIC submission in this regard.

In general I am not in a well placed position to accurately comment on the diversion framework of legal medical cannabis to illegal markets. To the extent it works for Cannabis it should be transitioned out into the alternate 2014 legislation mentioned above .

What is clear is that the Convention and the Narcotic Drugs Act 1967 have failed to deter illegal cannabis use since inception and the 2016 medical licensing environment reforms have not changed that: patients by behaviour continue to exhibit demand from illegal markets in preference to legal medicinal markets due to pricing, supply and a generally restrictive access regime at various points of the current framework. A multi-billion dollar illegal market continues to exist with no taxation, no quality control standards nor health monitoring/transparency of what is being taken and what for.

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?**

[redacted] Answer:

I would broadly refer you to the UIC submission in this regard. Anecdotally 200+ license applications outstanding... I mean really...

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?**

[redacted] Answers:

I would broadly refer you to the UIC submission in this regard.

I would add as answers to each question:

- No.
- Yes. Although by all accounts over zealously.
- Yes. Australians are smarter than you give them credit for. Stop the nanny state mentality .

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?**

Interaction suitable? No. Intersection points clear? Somewhat. Duplication and inconsistency? Yes.

Australian adults should be free to make their own choices as long as they do not harm others. Limiting people's liberty is only justifiable to prevent harm to other people. The drug's prohibition at international , national and state level has failed to deter its use and caused more harm than it has prevented. Treating cannabis use as a criminal rather than a health issue has resulted in drug users gaining criminal records, not seeking help with drug-related problems when they need it, and being exposed to the black market and other, more harmful, drugs. Its limbo treatment across the Cth and the States creates deadweight loss in the economy and an administrative and criminal law burden on the court system unnecessarily. Dual regulation is causing economic loss often in the poorest socio-economic communities that use cannabis illegally.

More fundamentally: Sick Australians with a legal right at federal law for safe access to medicinal cannabis essentially have to give up their rights under State law to use a license to drive/control motor vehicles and machinery as there is no current valid test to measure "impairment". State road side testing regimes can result in criminal charges and/or loss of license *by simply detecting the existence of restricted substances in saliva on a per se basis*. There is no measure of impairment. Forcing someone to give up a driving license (which the vast majority of Australians use to travel to and from work via driving their car) effectively engages the right to freely choose and accept work under Article 6(1) of the International Convention on Economic, Social and Cultural Rights. On that basis, the Narcotic Drugs Act interactions with various State regimes governing restrictions on driving where cannabis is detected in saliva are assessed to be incompatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Response to Issues and Key Themes addressed pertaining to The Review of the Discussion Paper: Review of the Narcotic Drugs Act 1967 (4 March 2019)

Key Themes	Response
1. Does the Narcotic Drugs Act 1967 establish a suitable framework for ensuring a sustainable supply of safe medicinal cannabis products for therapeutic purposes?	No comments nor variation proposed for this discussion point
2. Does the Narcotic Drugs Act 1967 establish a suitable framework for ensuring the availability of cannabis products for research purposes?	No comments nor variation proposed for this discussion point
3. Does the Narcotic Drugs Act 1967 establish a suitable framework for preventing the diversion of controlled narcotics to illegal use	No comments nor variation proposed for this discussion point
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 licenses and permits? As to medicinal cannabis licences, is there duplication in the processes and information required in applying for a licence and a permit?	No comments nor variation proposed for this discussion point
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?	Emerging illegal grows can have a significant impact to this relatively infant industry. Further enhancement on law enforcement is recommended to achieve the fundamental principles on efficacy, quality and safety of therapeutic goods.
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?	No comments nor variation proposed for this discussion point
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"?	No comments nor variation proposed for this discussion point
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	No comments nor variation proposed for this discussion point

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?	
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 – an update should be implemented in consideration to the current industry environment to allow for enhanced control.
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 comments nor variation proposed for this discussion point
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 impose appropriate restrictions on the grant of manufacture licences?	No comments nor variation proposed for this discussion point
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?	No comments nor variation proposed for this discussion point
13. 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?	No comments nor variation proposed for this discussion point
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?	No comments nor variation proposed for this discussion point
15. 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	No comments nor variation proposed for this discussion point

expected to meet for premises and goods and the level of scrutiny that will be undertaken by the Office of Drug Control?	
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?	Adequate fee scale should also be applied to manufacture licences and permits. Annual licence renewal fee for current licence/permit holder should be reduced appropriately so to ensure additional funds can be reinvested and utilised effectively pertaining to industry's sustainable growth.
17. 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)?	No comments nor variation proposed for this agenda

Hemp products would greatly add to the tax base. Keep hemp products forbidden and no tax revenue will be received.

Country Women's Association of NSW

Incorporated in 1931 by an Act of NSW Parliament
Constituent Society of the Associated Country Women of the World

ABN 82 318 909 926

02 April 2019

Narcotic Drugs Act Review Secretariat
Health Products Regulation Group
Australian Government Department of Health
PO Box 100 WODEN ACT 2606

Sent via email: ReviewNarcoticDrugsAct@health.gov.au

Review of the *Narcotic Drugs Act 1967*

The Country Women's Association is the largest women's organisation in Australia. It aims to improve conditions for country women and children. The CWA does this by advocating for its thousands of members, helping local communities, creating a network of support and meeting together in towns and cities across Australia.

The CWA of NSW has thousands of grassroots members and hundreds of branches across the state. Our members have a strong interest in policy decisions that affect communities, families and country people and can be viewed as an important stakeholder of government at both state and national levels. A key aim of the CWA of NSW is to improve the conditions of families especially in country areas, as well as enhance the value of country living focusing mainly on health and educational facilities.

The CWA of NSW is also NSW's largest rural issues advocacy group. With well over 8000 members and close to 400 branches across NSW, there is no other member-based organisation that has the breadth and depth of membership on matters affecting country people. Our policy positions and prioritised advocacy areas are determined by our grassroots members, via a democratic process.

In 2015 the CWA of NSW generated policy supporting the use of medicinal cannabis, specifically to support the legalisation of the growing, manufacture and distribution of cannabis, for medicinal purposes only.

We welcome the opportunity to provide input into the review of the *Narcotic Drugs Act 1967* (NDA). This submission will raise at the outset some limitations on the review itself, and then raise some of the problems as we see it with the legislation. The CWA of NSW appreciates that steps are being taken to introduce the use of medicinal cannabis into a complex pharmaceutical management scheme in Australia. However overall, the system created by the NDA is not achieving this objective effectively. We recommend a simplification and rationalisation of the parts of the Act relating to its use and associated Acts, regulations, registers and the like.

Limitations of the review of the NDA

We note in the Discussion Paper there is a series of items that are explicitly not included in this review. We understand the requirement for statutory review and the limitations inherent in this. However, there are features to every legislative framework that if not reviewed, in effect make the process futile.

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By not including the issues of: patient access to medicinal cannabis, the costs (or subsidisation of costs) of medicinal cannabis products through the PBS, and the scheduling of cannabis products through the TGA and ARTG, the review team are side-stepping the review of fundamental functions of the 2016 amendments to the legislation. Whilst it is appreciated that there is legislative overlap in many cases with other regulatory frameworks, to specifically rule out these items significantly hampers real, worthwhile outcomes in terms of improving the legislation, and makes the review a largely academic and legalistic exercise in legislative interpretation.

Improve the policy objectives of the *Narcotic Drugs Act 1967*

CWA of NSW submits that the legislation ought to be amended to include specific objectives, along the lines of managing and regulating the safe use of medicinal cannabis to ease suffering and reduce symptoms of those with a terminal illness or chronic pain and/or treatment of side effects significantly reducing a patient's quality of life.

It is our understanding that these objectives should have been included into the NDA when the 2016 amendments were made. The current review presents the perfect opportunity to amend the objectives so as to include a measurable benchmark to review the effectiveness of the legislation. If the legislation does not set out what is trying to be achieved, it is impossible to effectively measure whether the legislation is achieving any desired outcomes.

We understand a need to move cautiously and conservatively. We believe that policy objectives are of fundamental importance when navigating through this untested field of regulation, and will assist the process.

Cumbersome regulation is resulting in very limited access to medicinal cannabis

Whilst the TGA does not release the complete data in terms of patient numbers, we do know that there are approximately 4500 approvals to access medicinal cannabis currently. Given that we cannot determine repeat patients the number of actual patients is likely to be much less than that. There are reportedly tens of thousands of patients sourcing it illegally. This does indicate policy failure, and does not align with the purposes of the introduction of the 2016 amendments.

We understand that the procedure for the manufacture and distribution of medicinal cannabis is flawed in that the compliance standards GAP and GMP, and the Therapeutic Goods Order 93 and 100 combined with the fact that medicinal cannabis is not included on the Australian Register of Therapeutic Goods (ARTG) places this product in perpetual regulatory limbo. The *United in Compassion* (UIC) submission goes into a great deal of detail on the cumbersome regulatory requirements, and the CWA of NSW refers to that submission, and supports the statements put forward by the UIC.

We also understand that the number of state and territory approvals varies drastically. Again, without the full release of the data it is difficult to properly assess the impact, however it is clear that some states are far more able to obtain access than other states/territories. This is disadvantageous to those living in those states or territories where access is seemingly extremely exceptional.

The UIC use the example of Germany as a comparison – where medicinal cannabis legalisation legislation was introduced one year after Australia's. Germany has approximately 50,000 patients currently accessing medicinal cannabis.

Lack of commercial incentives and opportunities for agriculture

The CWA of NSW further submits that there is market failure as well as policy failure happening. Presumably because the cannabis plant is not patentable, the commercial incentive for the production of the medicine is significantly reduced. In such a scenario it is the responsibility of the Government to intervene and ensure the regulatory system is designed in such a way as to stimulate market participants.

Australian farmers are known for their clean green approach to primary production, there is an immense potential here to allow farmers to diversify whilst also adding to the Australian GDP. This could all be happening with the knowledge that pain and suffering of our sickest community members will ultimately be reduced. The case is strong for a win-win scenario.

Further information

We commend fully to the Review Team the UIC submission which explains in further details the failings of the current policy framework. We implore the review team to look closely at the current legislative settings as there is a potential to significantly improve the current commercial market and policy framework, and to properly give effect to the purposes of the 2016 amendments.

Our policy manager, Adair Garemyn can be reached on (02) 8337 0200 to further discuss the issues raised in this submission. We appreciate the opportunity to provide input into this important review.

Yours sincerely

Danica Leys
CEO

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4 April 2019

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Review of the *Narcotic Drugs Act 1967*

The Country Women's Association of Australia (CWAA) appreciates the opportunity to provide input into the Commonwealth Government's Review of the *Narcotic Drugs Act 1967* (NDA) and the Discussion Paper released by the review secretariat and Professor John McMillan AO.

The CWAA is supportive of the legalisation and effective management of the use of medicinal cannabis for terminally ill patients and chronic pain sufferers. The Association's current policy on the matter was passed at its 2006 conference and reconfirmed in February of this year, and is extracted below for the review secretariat's reference.

> *That the CWA of A requests the Federal Government to consider the legalisation of cannabis for medical purposes, for the relief of pain in the terminally and chronically ill.*

The NDA is an important piece of legislation in that it contains the framework for the management of the cannabis plant for medicinal use by state and territory governments. The relevant parts of the Act are those that were inserted by the *Narcotic Drugs Amendment Act* (February 2016) (the 2016 amendments), the subject of this review. It is our view that since those amendments a rather unworkable policy framework has formed Australia wide, which we trust is able to be rectified following this statutory review.

Patient access (and the PBS)

The CWAA believe that it is imperative to consider the fundamental issues of patient access to medicinal cannabis as well as the potential for cannabis medicine to be listed under the Australian Pharmaceutical Benefit Scheme (PBS). Despite the Discussion Paper explicitly ruling out these matters, we believe these matters are central to the test as to whether the legislation is achieving its desired effect as per the objectives of the 2016 amendments. This review should examine whether the legislation in fact does provide for the management and safe use of this medicine in Australia.

As mentioned in the Discussion Paper, this is an untested field of regulation for Australia, and so we appreciate many matters are still in the formative stages. However, the unworkability of the register and approvals process, coupled with the fact that it is estimated there are in excess of 100,000 of patients accessing medicinal cannabis on the illegal (unregulated) market, indicates that the legislation is sub-par.

A messy commonwealth system paired with ad hoc state/territory approval processes

The legislation at a Commonwealth level should provide for a streamlined means for state and territory governments to enable access to medicinal cannabis. The Commonwealth system is not only cumbersome but nonsensical in that the medicine is simultaneously approved and not approved. This occurs because of the requirement of compliance with production standards (GAP/GMP, TGO 93 and 100), and yet it remains unregistered by not being included on the Australian Register of Therapeutic Goods. This also means it is not able to be recognised through the PBS system and treated like other conventional medicines.

Depending on the regulatory system of the individual state or territory , will really determine whether proper access is able to be achieved for patients in that state or territory. CWAA advocates for equal opportunity for all patients be they in regional rural or remote areas, or metropolitan, for all states and territories of Australia.

We understand through data obtained by the advocacy group *United in Compassion* that there are a number of states/territories with less than 13 approvals , whereas the collective number for Australia is over 2000, showing a huge discrepancy in regulation across the states and territories. The NDA needs to enable *equivalent* State and Territory legislative arrangements for approvals and ultimately, equality of access for patients.

What's more, the current scheme only permits prescriptions by specialists rather than general practitioners (GPs). This is not the case for conventional medicines. This is a significant issue for CWAA as this is particularly disadvantageous to those patients in regional, rural and remote Australia, where specialists are very rare if at all existent. For the chronically ill or chronic pain sufferers, travelling hundreds or even thousands of kilometres to see a specialist is going to be extremely difficult if at all possible.

GPs are the ideal professional to prescribe this medicine. Not only are they the first point of call for patients involved in chronic health management, they are accessible for patients in regional, rural and remote Australia.

The big picture

The legislative controls of medicinal cannabis in Australia have really resulted in very limited patient access to this medicine. The CWAA believe there is a huge potential for this product to relieve suffering and pain of terminally and chronically ill patients. Just as the cannabis plant is unique in its ability to ease pain and suffering, and reduce symptoms, the medicine requires a unique policy approach. There is also a unique opportunity for industry and the supply chain in Australia. We implore the Review Team to look at all available options that will increase patient access to the medicine across all States and Territories.

I would be pleased to discuss further the recommendations raised in this letter with the Secretariat. Again, we are appreciative of the opportunity to provide input into this important review.

Yours sincerely

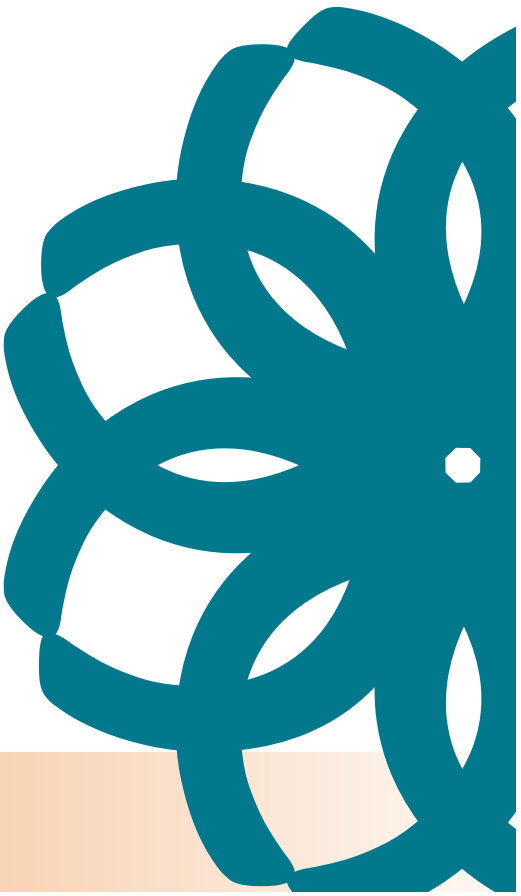
Tanya Cameron
National President

cyrelian

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

Prepared by:
Davina Gregory-Dunsmuir, BSc Hons, PhD, MBA
CEO, Executive Director
On behalf of Cyrelian Pty Ltd

29th March, 2019



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.

DELTA TETRA CONSULTANCY
SPECIALISED PROFESSIONAL MEDICAL CANNABIS MANAGEMENT

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Date: 28 / 03 / 2019

Review of the Narcotic Drugs Act 1967

Scope:

Delta Tetra Consultancy and its core management team have been actively engaging with the Australian medical cannabis industry and its associated regulatory nuances since the conception of the sector.
Having played a key role as principle representative for a number of active cannabis companies and individuals, Delta Tetra has been privy to a wide range of exposures with regard to engaging with the current regulatory framework and associated regulatory bodies.

Delta Tetra finds itself in a position to offer unique pieces of feedback around the Narcotics Drugs Act and the Medical Cannabis framework that has been placed within it.
Moreover, we have direct and ongoing operational experience in terms of consistent engagement with the Regulatory bodies such as the ODC & TGA.
These sets of experiences allow Delta Tetra to offer an informed and refined viewpoint regarding the effectiveness and efficiency of the current sector and its associated regulations.

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

- While the NDA 1967 has, in theory, created a federal framework for the safe production and supply of medical cannabis products, in reality this has yet to come to fruition.
- Slow and cumbersome regulatory requirements have enforced stagnation on an aspirational and vibrant sector.
- The current framework was developed with minimal involvement from industry experts, thus creating a regulatory system that has been forced to 'learn on the go'.
- The framework's chief and principle concern is 'Risk of Diversion' – this overzealous approach has created an inflated sense of risk.

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

- The framework has encouraged clinical trials on internationally imported products.
- Hypocrisy between imported products and Australian manufactured product standards, allows for concerns in moving forward with research initiatives.
- The framework has resulted in a strong clinical trial culture within Australia, with clinical data a pre-requisite to product development.
- However, the unwillingness to accept international trial data to support product development has resulted in an inordinate amount of data recreation, seemingly arbitrarily.

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

- Seemingly, the NDA 1967 was drafted with the exclusive concern for Risk of Diversion in mind.
- From an operational stand point, the broad-stroke terminology utilised within the NDA 1967 creates an ultimately endless barrage of roadblocks through 14J processes.
- Allowing the regulations to be open to interpretation creates a 'one up' culture within the ODC and the nascent industry.
  Each company presents a new and potentially improved solution to a security concern, the ODC then accepts this solution as the 'new standard' and requests that all other applicants in the queue meet this newly imposed standard.
  One company improves on that solution and becomes the 'new new standard' and so on and so forth.
  This will invariably create a never-ending feedback loop for the industry as it attempts to play catch up with an ever-shifting regulatory goal post.
- From a security perspective the framework presents, clearly, the importance of securing your cannabis site against all and any risk factors.

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 ODC has left the burden of context and application to the nascent industry. This has allowed for the effective manipulation of the system through poorly compiled applications and poor revision processes.
  This has created a 'slip stream' for early applicants, applicants whom had they submitted the same application now would receive lengthily 14J requests. However, as the submitted while the ODC was still learning they have had licenses approved that may not meet requirements.
- The disparity between the ODC issued 'Guidelines' and the regulations as stipulated in the NDA 1967 must be resolved. The observation of what must be legally addressed in an application vs the observation of what is expected as per the ODC guidelines is significantly varied.
- Delineations between the License phase and the Permit phase have not been adequately observed. It was expected that the License phase would cover a range of details relating to the applicant and the associated business activities and the Permit phase would then provide operational, mechanical, engineering & build-out stages of the application process – clarity around this would benefit industry stakeholders and regulatory bodies.
  This has not been the case; Permit level information is routinely requested throughout Licensing phase – creating ambiguity with regard to what level of information is actually required.
- License processing should be contained to a single case manager, familiar with the applicant and the relevant details of the case.
  In reality, every interaction is with a different individual. Each 14J is handled by a separate and potentially new assessor, this is creating a double-handling culture within the ODC. Our clients are routinely having to re-supply information and documentation that has been previously submitted. This creates confusion in both camps.
- For those applying for a suite of licenses (Cultivation & Manufacturing) there is the double up of dealing with both the MCS & DCS.
  The two departments operate independently of one another, as such there are separate 14J systems relevant to the Cultivation

License (MCS) and the Manufacturing License (DCS).
The lack of transparency and contact between the two departments results in two 14J processes that have no relation or cohesion with one another – often these two departments will be months apart from one another in terms of the processing times.
This leads to significant changes in information being supplied to one arm without the other knowing

- Time frames.
  The time frames currently being supplied to industry are incorrect.

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?

- Given the scheduling of THC and CBD, it could be sensibly argued that the Risk of Diversion considerations are justified. However, in reality, there is an excessive focus on risk aversion.
- It would be fair to consider that the broad-stroke nature of the regulations itself creates a risk.
  Early approved licenses were approved at a much lower standard due to the ODC's knowledge base and standards being effectively lower.
  We have seen a stark difference in the 14J's of 2018/2019 compared to 2016/2017.
  Licenses that were approved early in the process would gain far greater scrutiny than that of what they actually received prior to approval. This has, as mentioned previously, created a slip-stream for numerous first movers. As well as an industry with dual-standards.
- By utilising a non-cannabis industry specific regulatory body to approve and enforce all applications and regulations, time-frames are significantly blown out due to the ODC being up to date with cannabis specific nuances as well as a rigorously enforced focus on the security of product. The combination of these two things creates a system overly concerned with risk that it stagnates the whole process.
  There needs to be some faith placed in industry that assumes industry wants to be the most efficient, effective and secure version of itself.
- The ODC should be looking to play a more collaborative position with applicants. If applicants had a dedicated case manager, there would be nuanced understanding of the applicant at their aspirations from the regulators. Vice versa, the applicant would understand the regulators focus and be able to find a

solution that appeases the assessor. As things stand, both sides are consistently attempting to infer from one another. The 14J's are purposefully vague as to stimulate a transparent response from the applicant, which in turn encourages the applicant to over-share for fear of not addressing the concern of the assessor.
This then provides more information for the assessor to review and question, causing the issue to compound. In our experience, this can be put down to inefficient and inconsistent communications, as well as lack of transparency in the assessing process.

In summary, Delta Tetra Consultancy has had an hands-on set of experiences with the regulations and associated departments.
Our feedback is rooted in our experience and is of course objective and is offered with the view to help allow for an informed review process.

I would also like to note, we have great admiration for the work the ODC has and continues to do.
We understand the complexities and challenges of this industry better than many. I hope the recipient of this feedback is understanding of the spirit in which this feedback has been offered.

We would like to extend the offer to support the ODC throughout this review process should it be required.
If your office would benefit from further context around some of the points stipulated above, please don't hesitate to contact us to do so.

Warm Regards
Tim Oates
CEO
Delta Tetra Consultancy

Review of the *Narcotic Drugs Act 1967*

Submission

I am a Veterinarian and Biochemist in Sydney, NSW. I am writing a submission to support and encourage a sustainable supply of safe medicinal cannabis products for therapeutic purposes in animals, and the availability of cannabis products for veterinary research purposes in Australia.

Evidence of possible therapeutic benefit in animals

There have been controlled clinical trials conducted, which have investigated the use of cannabinoids in humans and reported positive effects in respect of pain, nausea, vomiting, inflammation, cancer, asthma, glaucoma, spinal cord injury, epilepsy, hypertension, multiple sclerosis, Parkinson's disease, Alzheimer's disease, or loss of appetite.

However, quality research involving cannabis for therapeutic purposes in animals is limited.

Initial studies suggest that cannabis may promote comparable therapeutic outcomes in animal patients as those observed in human patients. For example, a researcher from Colorado State University recently reported findings from a small pilot study involving 16 epileptic dogs. She observed that 89 percent of the dogs had fewer seizures when taking chicken-flavoured CBD oil, compared to approximately 20 percent in the placebo group.[1] Another project, a randomized, placebo-controlled, double-blind crossover study conducted at Cornell University, demonstrated that dogs treated with CBD oil experienced a clinically significant reduction in pain and increase in activity.[2]

Nevertheless, the therapeutic use of cannabis in animal patients cannot be entirely based on the results of human studies as evidence, specifically for cannabis[3] and professional experience, has shown that the different metabolic processes can result in different clinical outcomes.

Separately, evidence of the safety and tolerance profile of cannabis in dogs and cats has been encouraging.[4]

Overall, therefore, the preliminary findings in humans and animal patients warrant further investigation into the veterinary applications of medicinal cannabis in Australia.

Proposed changes to the legislation

In my view, subsection 11K(2) of the *Narcotic Drugs Act 1967* (Cth) should be changed to include, apart from the present wording of that provision, the possibility of the Office of Drug Control granting a manufacture license if it is satisfied, on reasonable grounds, that a person will be manufacturing a medicinal cannabis product for the treatment of animals. This would be the first step toward facilitating more widespread use of cannabis in research and therapy involving animal patients. Notably, however, corresponding changes to the relevant State and Territory legislation would also be required because the possession, use and supply of cannabis other than for human therapeutic use is prohibited at that level.

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[1] Guiden M. Preliminary Data From CBD Clinical Trials 'Promising' (2018). Available online at: https://cvmbs.source.colostate.edu/preliminary-data-from-cbd-clinical-trials-promising/ (Accessed October 4, 2018).
[2] Wooten SJ. Cornell Takes the Lead in Cannabidiol Research (2018). Available online at: http://veterinarynews.dvm360.com/cornell-takes-lead-cannabidiol-research (Accessed October 4, 2018).
[3] D. J. HARVEY, E. SAMARA AND R. MECHOULAM, Comparative Metabolism of Cannabidiol in Dog, Rat and Man, *Pharmacology Biochemistry & Behavior*, Vol. 40, 523-532.
[4] See, for example: B Whalley, H Lin , L Bell, T Hill , A Patel *et. al.* Species-specific susceptibility to cannabis induced convulsions (2018) *British Journal of Pharmacology*; and A Brutlag, Toxicology of Marijuana, Synthetic Cannabinoids, and Cannabidiol in Dogs and Cats (2018) *The Veterinary clinics of North America. Small animal practice* [0-323-64270-5] 1087 - 1102.

In my view, veterinary practitioners should be able to use medicinal cannabis in special cases, in the way that medical practitioners are able to supply unapproved medicinal cannabis products through the Authorised Prescriber or Special Access Schemes. A similar framework, facilitated either under the current exemption for medicines extemporaneously prepared by veterinary surgeons, or new provisions of the Agricultural and Veterinary Chemicals Code, could enable this.

Presently, anyone wishing to investigate the effects of cannabis or cannabinoids, whether in humans or animals, must navigate a challenging legal and financial process.

Despite some confusion around the legal status of cannabis in the USA, which has made it challenging to study its effect, demand for medicinal cannabis continues to grow, with sales in 2018 having generated $4.5 billion in revenue.

In light of all the above, it is my view that the potential for medicinal cannabis to make a positive contribution to the treatment and quality of life for many animals, in Australia and internationally, is significant. However, progress requires substantial changes to facilitate access to safe cannabis products for a variety of uses, across a variety of industries, including but not limited to therapeutic and research purposes. In particular, I hope that this review sees changes made that improve access to cannabis by veterinary surgeons and other professionals, so that formal and comprehensive research can be conducted and so that the treatment of animals can benefit from what emerging evidence suggests cannabis has to offer.

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.

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.

Medical Cannabis Council

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 intregrity, standards and public health and saefty.

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 cultivation 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 the 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.

Medical Cannabis Council

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

Medicinal Cannabis Industry Australia

Medicinal Cannabis Industry Australia Submission to the Review of the Narcotic Drugs Act (Cth) 1967 (ND Act)

April 2019

1.0 About Medicinal Cannabis Industry Australia (MCIA)

Medicinal Cannabis Industry Australia (MCIA) welcomes the opportunity to make this submission to the Review of the *Narcotic Drugs Act (Cth) 1967* (ND Act).

MCIA is the peak industry organisation for Australia's licensed medicinal cannabis industry. This encompasses all activities of medicinal cannabis licence holders across research, cultivation and manufacturing and interaction with patients, the medical profession and communities.

MCIA's focus is on building an industry that enhances wellbeing through facilitating access to quality Australian medicinal cannabis products for Australian and global patients.

MCIA is providing stewardship for an economically sustainable and socially responsible industry that is trusted and valued by patients, the medical community and governments. The Australian industry and its products are built on sound science and underpinned by industry processes and standards that ensure patients, the medical community and governments have confidence in the sector and its products.

2.0 Introduction

The ND Act was amended in February 2016 to establish a regulatory framework that would enable a sustainable supply of medicinal products for therapeutic purposes and facilitate scientific research.

MCIA welcomed these amendments and is supportive of a framework that enables the development of a medicinal cannabis industry in Australia and the access for patients to this product that has potential to positively contribute to a broad range of conditions.

With the framework now in place and operating for a couple of years, it is timely to review the administrative and operational aspects of the framework to ensure it is meeting the objectives and operating efficiently and effectively.

MCIA recognises that there is frustration within the community that patient access has been limited to date, and while outside of the scope of this review, we believe that by improving and streamlining some of the processes in relation to the ND Act that this will also assist to facilitate patient access to timely, cost effective and quality Australian product.

MCIA recognises the need for a framework and is pleased to provide this submission that highlights some current challenges with the framework and offers suggestions for improvement and streamlining.

This will assist to deliver MCIA members' objective of ensuring medicinal cannabis products meet the highest standards and that patients in Australia and internationally benefit from research and product development. Within the short time since the Australian Parliament passed legislation (29 February 2016) to enable the cultivation of cannabis for medicinal and research purposes, the industry has already progressed significantly towards being a world leading supplier of medicinal cannabis products. MCIA believes that the industry has significant growth potential and estimates that it could become a $10billion industry in Australia by 2025.

3.0 Background and context

The therapeutic benefits of medicinal cannabis have been informally recognised for decades and medicinal cannabis is now becoming recognised worldwide as a natural and effective medicine to treat a growing number of conditions. With the scientific evidence still evolving, there is an increasing use of CBD (cannabidiol) and other constituents within medicinal cannabis in treating a wide range of ailments.

There is significant and increasing public support for the use of medicinal cannabis; in 2016, 85% of Australians supported a change in legislation to permit the use of cannabis for medical treatment.[1]

[1] https://www.aihw.gov.au/reports/phe/221/alcohol-tobacco-other-drugs-australia/contents/drug-types/cannabis

To date, the major active constituents of the cannabis plant that have proven medicinal properties are THC (delta-9-tetrahydrocannabidiol) and CBD (cannabidiol). The cannabis plant however, contains about 400 different components (including 80 to 100 cannabinoids) that may contribute to its therapeutic benefits. As global and local research develops scientific evidence to support the role of these components, or combinations of components in delivering therapeutic benefits, the patient-driven market will expand. Reported effective therapeutic uses for cannabis include the management of chronic pain, epilepsy, inflammatory conditions, antispastic, analgesic, palliation, as an anti-emetic and many others. In countries where medicinal cannabis is available, some medical practitioners prescribe it as an alternative to opiate-based medicines due to the risks associated with developing opiate dependency.

The amendments to the ND Act in 2016 enable the cultivation and manufacture of medicinal cannabis in Australia in a manner that is consistent with Australia's international obligations under the UN Single Convention on Narcotic Drugs 1961 (UN Single Convention). Australia has a well-established track record in relation to management of regulated industries (e.g. the poppy industry), being one of the world's leading producers and exporters of opiate based medicine.

Patient access to medicinal cannabis however remains limited and as end of March 2019 there were only 56 authorised prescribers of medical cannabis in Australia and 5000 medicinal cannabis product prescriptions approved under the Special Access Scheme (SAS).[2]

4.0 Key Issues for MCIA

This submission addresses the specific questions raised in the Review's discussion paper in the following section. There are however, a few additional key issues that MCIA believes would assist to improve the efficiency of the ND Act implementation and support the growth of the industry and consequently availability of safe, quality and affordable Australian product for Australian and international patients. These issues relate to the more seamless linkage between the Office of Drug Control (ODC) and Therapeutic Goods Administration (TGA) activities in particular, as they relate to manufacturing and understanding of research requirements.

Issue 1: Manufacture licensing

Under the current regulatory framework, there is a lack of clarity across regulatory authorities (specifically, the TGA and ODC) and subsequently duplication in relation to a licensed medicinal cannabis manufacturer. This can hamper regulatory activities and creates significant inefficiencies for both the ODC and the TGA licensed manufacturer.

While article 29 of the UN Single Convention requires that the manufacture of cannabis is undertaken by a licenced entity, it does not however, require that the licence is granted under the same legislative instrument as cultivation licences.

Medicinal cannabis may only be legally supplied to Australian patients as a therapeutic good, placing manufacture under the control of the Therapeutic Goods Administration (TGA) via the Therapeutic Goods Act 1989 and its regulations. The TGA regulatory framework and structures successfully manage the safe and compliant manufacture of all controlled drugs.

As a TGA *Licence to manufacture therapeutic goods* and corresponding *Certificate of Good Manufacturing Process compliance of a manufacturer* (together, a 'GMP Licence') is an absolute requirement for the manufacture of medicinal cannabis for therapeutic supply to patients, it would be possible to remain compliant with the Single Convention through medicinal cannabis manufacturing licences being granted solely through existing TGA licencing processes, including without limitation controls relating to the facility and processes implemented by the GMP certificate/licence holder to mitigate the risk of diversion (which we note has been successfully managed by the TGA in respect of the manufacture on numerous drugs of dependence). Thus, the current requirement for an additional ODC Manufacture Licence granted under the ND Act is not necessary.

[2] Note this figure is for number of approved prescriptions not the number of patients receiving a prescription, nor Sativex medical cannabis prescriptions.

Recommendation 1:

Clearer delineation around roles of the relevant regulatory bodies involved in relation to a manufacture licence for medicinal cannabis and in delivery of these responsibilities would significantly improve the efficiency and effectiveness of the ND Act, namely:

- **ODC has responsibility and oversight for all cultivation operations and supply pathways to suitable operators and appropriate controlled areas;**
- **TGA has responsibility and oversight for manufacture in compliance with GMP certification and manufacture licence; and**
- **States through State/Territory laws (medicines and poisons legislation) have responsibility and oversight for the site security.**

Issue 2: Product development/R&D

The current ODC process for a manufacture licence (and R&D licence) requires the end product to be defined when this is part of the product development and/or R&D process.

The operation of the ND Act is inconsistent with the development of medical and agricultural science and the associated necessities of research. Specifically, this inconsistency occurs in respect of the cultivation and supply limitations imposed under the current Licence and Permit system, under which a licence holder is required to forecast a number of research outcomes before the research commences, which is generally not possible given the investigative nature of scientific research.

For the current ODC issued manufacture licence (for medicinal cannabis) an applicant is required to define the end finished product attributes such as strength/concentration and quantity which at the stage of initial application may not be known as medicinal use of cannabis is still an emerging field. The TGA recognises the necessity of drug development and product validation before a final dose can be established and released to the market.

In fact, international standards (ICH Guidelines) require that a therapeutic good is underpinned by quantitative and qualitative data substantiating all aspects of the good and the process to achieve the good, meaning that neither product nor process should be defined in advance of the systematic development program.

Similarly, for product development work undertaken under the cannabis research cultivation licence and permit as currently regulated by the ODC, the end product also needs to be defined. This is fundamentally different to the way medical research or product development is undertaken. The TGA regulatory framework understands the life-cycle of pharmaceutical product development and effectively and safely manages the regulation of the pharmaceutical industry working with high-risk, dangerous, restricted and/or regulated compounds. Cannabis plants however, produce comparatively low-risk pharmaceutical compounds.

A regularly audited Poisons register is already an absolute requirement on organisations dealing in poisons/ controlled goods (under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) and provides the risk management protocols and practices for industry compliance.

MCIA believes that this issue could be addressed through a change to the licence and permit application form. Thus, rather than a prescriptive permit that requires the exact levels of cannabinoids to be stated, which cannot practically be predicted by licence holders in all circumstances, latitude in the permit application (e.g. specification of a range) should meet requirements for reporting to relevant international bodies through statistical averaging. Licence holders can subsequently provide actual amounts in reporting.

Recommendation 2:

The ODC move away from a prescriptive permit that states the exact levels of cannabinoids to one that allows specification of a range. Licence-holders would subsequently provide actual amounts in reporting.

Issue 3: ODC operation efficiency and effectiveness

The current delivery of the regulatory framework has significant operational inefficiency due to both lack of resources for ODC and inefficient processes and interpretations that are hindering innovation and development.

MCIA member companies have identified a number of issues regarding the ODC operational activity including lack of transparency, significant delays with licence and permit review turnaround times and lack of a triaging approach to applications (refer Q4A below). Further, the currently regulatory framework for the medicinal cannabis industry contains imprecise definitions and/or reflects a lack of understanding of those definitions.

MCIA contends that while resources are part of the problem, they are not the whole problem. Additional resourcing will not of itself address all of industry's concerns. Processes and interpretations are key factors hindering innovation and development.

Policy Circulars from the ODC have attempted to provide clarity and guidance as to the interpretations of the ND Act. These interpretations however, have on occasion, demonstrated a lack of comprehension of the pharmaceutical and industrial context of the manufacture and research processes. This can have adverse consequences for our industry.

By way of example, in Policy Circular #01/17 the ODC stated that it was their interpretation that analytical testing processes conducted on cannabis constituted manufacture and placed a unilateral maximum sample size under which no licencing would be required. This sample size relates solely to cannabis, has been introduced to deal with medicinal cannabis, and ignores the potential impact of the firmly established analytical framework supporting policing activities. This approach is inconsistent with established processes for other regulated and pharmaceutical industries.

Recommendation 3:

That the application and review process for Licences and Permits can be enhanced through implementation of improved processes and Guidance documents, a fully integrated and efficient portal and application of triaging for existing licence holders.

5.0 Specific issues raised in the discussion paper

The following section addresses the specific questions posed by the Review.

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

   While recognising the need for a framework that enables the development of a medicinal cannabis industry in Australia, MCIA considers that the burden on licence holders through the current framework and the operational inefficiencies are preventing cost effective and highly effective medicines reaching patients.

   MCIA considers that particularly as currently interpreted by the ODC, there is an overemphasis on the mitigation of diversion to the detriment of industry development and innovations that would ensure an appropriate supply of safe, high-quality and effective cannabis-based therapeutic products for patients.

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

   As highlighted above, there are some inconsistencies in relation to R&D activities. Specifically, this occurs in respect of the cultivation and supply limitations imposed under the current Licence and Permit system, under which a licence holder is required to forecast a number of research outcomes before the research commences, which is generally not possible given the investigative nature of scientific research.

   In addition, the scope of research activities (development activities, analytical testing and validation) able to be carried out under a Cannabis Research Licence/Permit and Medicinal Cannabis Licence/Permit are not clearly defined. As an example, cannabis crops grown under a medicinal cannabis licence/permit also has requirements for testing and validation in order to release a quality end product to patients.

Moreover, the industry is essentially prevented through the existing processes, from enabling the provision of cannabis (in plant, extract, or finished dose form) to third party researchers (such as NGOs, universities, research hospitals) for the purpose of investigator-initiated (non-company controlled) research. This engagement of the pharmaceutical industry with the research industry is pivotal to Australia's knowledge base and international research and pharmaceutical standing, and it must be noted that existing Poisons Licences currently enable this for all non-cannabis controlled goods.

As industry leaders, MCIA members seek to develop guidelines into research and build a consistent safety profile encompassing all cannabis forms from the seed to end product, enabling clarity and evidence-based decision making for policy and legislation coherency, medical practitioners, pharmacies and the public.

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

MCIA recognises the critical importance of anti-diversionary requirements. Although certain features of the ND Act do assist in reducing the risk of diversion of cannabis for illegal use, these provisions operate in concert with existing controls, such as criminal codes, poisons legislation and import/export laws.

Given the diversity of business models within the industry, a great number of anti-diversionary responsibilities are self-imposed by the applicant for a cannabis licence at the time of filing an application. In this way, the industry itself through a collection of independent risk-assessments, completes the anti-diversionary requirements of the framework.

4 A. Has the Commonwealth (and in particular the Office of Drug Control) implemented an efficient and effective regulatory scheme for medicinal cannabis?

As noted above, while MCIA recognises that a framework is required, this is currently not effective or efficient in achieving the objectives of the ND Act.

MCIA contends that while resources are part of the problem, they are not the whole problem. Additional resourcing will not of itself address all of industry's concerns.

Processes and interpretations are key factors hindering innovation and development, along with the lack of clarity in the demarcation of activities across authorities involved.

A number of key issues in relation to resourcing and ODC systems have been identified by MCIA member companies including:

- A lack of transparency;
- An inability to track the progress of a submission;
- The lack of an integrated and effective portal for online applications and management of the process for tracking, variations and notifications;
- The absence of legislated timelines and mandatory reporting, which apply in established TGA regulated areas; and
- Little or no triaging of applications (or if such a process does exist, it is not obvious or transparent).

The application and review process for Licences and Permits is convoluted and drawn-out, which (once issued) presents a set of operating conditions and restrictions incompatible with fostering a successful new medicinal industry.

The Department of Health's internal review concluded that the ODC is under- resourced[3] . MCIA understands that this has been recognised and additional resources have been allocated, although the industry may continue to see restrictive operational practices until the new resources are adequately trained. However, as noted above additional resourcing will not of itself address all of industry's concerns.

[3] '*Department of Health, Internal Audit of Regulation of Medical Cannabis'* Final Report September 2017 (accessed 21 February 2019. http://www.health.gov.au/internet/main/publishing.nsf/Content/45516859A754C637CA25837C000C4F4E/$File/Document%201.pdf

By way of comparison, MCIA acknowledges the practice of the Australian Taxation Office in providing official rulings on matters which requires legislative interpretation and determination from a body of authority. In respect of the medicinal cannabis industry, and given the relatively recent status of the ND Act, we suggest that similar process could be implemented by the ODC to provide clarity and consistency in their determinations as issues are raised by Licence holders and other stakeholders.

4B. Is an appropriate and proportionate regulatory burden placed on those applying for or holding licences and permits?

The seriousness of dealing with a drug of dependence is accepted and recognised. Accordingly, MCIA accepts that sufficient information needs to be provided to the regulator to ensure that an applicant can be properly and equitably assessed as suitable. Therefore, duplication notwithstanding, specific to the initial application for licences and permits, an appropriate and proportionate regulatory burden is placed on new license applicants.

A disproportionate burden is placed however, on existing licence holders. Re-application processes should be restructured and streamlined a part of an effective risk management process. A process of licence renewal should focus on the historic compliance by the Licence holder and the operational changes (if any) of the business.

Additionally, we have concerns that the inability of the current regulatory system to properly capture the proposed business operation of the applicant results in inappropriate application questions that appear to be more investigative than pertinent.

There is also the need to delineate where the ODC's responsibility sits in terms of commercial business models. If risk of diversion, accountability, record keeping and fit and proper person requirements are adequately addressed, it is the applicant that accepts the risk of commerciality.

4C. As to medicinal cannabis licences, is there duplication in the processes and information required in applying for a licence and a permit?

To an extent, yes. More often however, the duplication occurs when applying for multiple Licences (i.e. Medicinal Cannabis Licence, Cannabis Research Licence and Manufacture Licence) or when applying for multiple permits.

5A. Has an appropriate compliance and enforcement regime been implemented, both in the Narcotic Drugs Act 1967 and administratively?

The ability to update the regulator on non-critical changes is currently not provided for outside of variations to Licences. For example, there is an expectation that changes in shareholdings is communicated to the regulator. In a publicly-listed company, this occurs hourly and so there is the need for the company to define, in consultation with the regulator, what constitutes a reportable change. The ability to submit changes in these sorts of non-critical company information through an online portal, would be helpful and preferred.

In addition, best practice dictates that a company ensure all policies/procedures undergo continuous improvement. TGA audits under GMP expect procedures to be updated between audits and focus on the requirement for a robust review-modify-approve process as part of quality management system. The overemphasis by the ODC on procedural control at the operating (SOP) level stifles continuous improvement which does not aid compliance and enforcement. Therefore, the current requirement to submit SOPs for review and approval by ODC should be instead be revised to enable companies to supply the required information in the application. Thus allowing company controlled documents (SOP's) to be managed under the company's quality management system and are available during audit/inspection as required.

There are some industry concerns related to the obligations of the licence holder to ensure that they employ suitable persons at all times. Whilst recognising the importance of this, on a practical level the mechanism for this relies heavily on a criminal check for each new employee. After the initial check companies have to rely on self-reporting of any criminal status change by an employed staff to ensure the licence holder maintains compliance with their licence obligations.

MCIA suggests the wording is changed from 'must ensure' to 'must take all reasonable steps to ensure'.

MCIA members have also observed that in contrast with the well-established rules relating to the storage and supply of scheduled poisons, the compliance measures in respect of cannabis under the ND Act are somewhat tailored to the applicant. This is not necessarily a bad thing, but may lead to inconsistencies for example, with respect to transactions between two licence holders who have incompatible transportation procedures.

MCIA members also identify the potential for impact on the ability to meet future workforce demands due to inconsistency in the regulations, for example, Section 39(2)(a) of the ND Regulations that provide that a person is taken not to be suitable to carry out manufacture activities if they have, "during the period of 5 years before that time, used illicit drugs". The restriction on employing such persons seems unduly onerous, particularly given then in-and-of-itself, a person ***convicted*** of a cannabis related offence can be licensed by the ODC if the conviction is disclosed and the Secretary otherwise considers it appropriate.

5B. Are risks being appropriately managed? Is there excessive risk aversion?

The assessment of risk is reasonable when the risk of diversion is considered in isolation. When consideration is given to the less obvious risks however, such as risk of overcomplicating the supply pathways, risk of discouraging participation in this industry, etc. The current system risks could ultimately lead to a lack of supply for Australian patients.

Accordingly, it is MCIA's view that currently, the balance of risk is not appropriately managed, as the weight of diversion of product is overshadowing what should be the key consideration, i.e. enabling the thriving development of an Australian medical cannabis industry capable of managing the treatment demands of Australian patients.

The ND Act is also being operationalised in isolation. There is no recognition that the industry operates in a well-established regulatory framework which is proficient in dealing with controlled good phyto pharmaceuticals (e.g. poppies and thebaine).

Again, we refer to the need for recognition and application of demarcation of responsibilities across ODC, TGA and State/Territory laws (medicines and poisons legislation).

6A. Does the Act interact suitably with other Commonwealth, State and Territory laws relating to the regulation of cannabis products and narcotic drugs?

MCIA considers that generally, the interaction is mostly complementary and without direct conflict. For example, the restrictions relating to how cannabis can be supplied under the Act are similar to the restrictions in place at a State level when controlling the supply of controlled substances. We highlight however, that existing Commonwealth (Therapeutic Goods Act) and State/Territory laws (medicines and poisons legislation) competently control activities such as manufacture, transport, analytics and research associated with controlled substances, including non-cannabis narcotic drugs. Cannabis-specific incorporations within the ND Act that cover (manufacturing) or have been interpreted (analytics) to overlap with this existing regulatory framework, have introduced confusion and conflict.

6B. Are the intersection points clear? Is there evidence of duplication?

There needs to be further exploration of this to ensure a stream-lined approach. Sometimes the points of intersection between Commonwealth and State requirements and jurisdictions are not clear. At some points medicinal cannabis is solely the responsibility of Commonwealth and at other points in its production cycles it is the responsibility of Commonwealth and State legislation (e.g. State level poisons requirements related to safe storage). As an example, in respect of waste management there needs to be greater clarity in respect of whether the ND Act can be relied on exclusively, or if State requirements (in respect of the destruction of controlled poisons) needs to be taken into consideration and followed and the extent that State laws are inconsistent with Federal requirements (i.e. Scheduled poisons facilities are to date not licenced under the ND Act).

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'?

MCIA considers that the current definitions are not clear and further terms should also be included and defined. The current interpretations have not been applied through the lens required for commercial industry. Broad definitions lead to confusion for both licence holders and regulators.

Key definitions required include:

- *Manufacture / Manufacturing* – including what exactly is a 'transformation in form' that triggers an activity as being manufacture instead of production (e.g. is conversion from THCA to THC via decarboxylation, a transfer in form), and whether analytical services and/or research activities that would otherwise be defined as 'manufacture' should be excluded.
- *Plant* – there is confusion as to whether tissue culture is a plant or not.
- *Research* – definition and additional amendments to the Act to reduce the regulator burden of suppling to parties who undertake defined research.

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.

A. Is that an appropriate structure, having regard to Australia's Review of the Narcotic Drugs Act 1967 obligation to adhere to the requirements and terms of the Single Convention?

It is the opinion of MCIA that Australia can both adhere to its obligations under the UN Single Convention and greatly improve the current licencing and permit system. The Single Convention does require licences and permits but does not specify the required licence categories or which specific mechanisms or authorised office must be responsible for their administration.

MCIA is broadly supportive of the existing framework, noting improvements identified above.

MCIA notes the current review of cannabis being undertaken by the United Nations/World Health Organisation and believes that the outcomes of this review should be considered by the Government once available. MCIA would welcome consultation on the outcomes of any international adaptations to the rescheduling of cannabis by the UN Single Convention.

B. Is there a need to examine options for greater flexibility, e.g., 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?

MCIA would welcome greater flexibility, recognising that it is important to minimise the risks of diversion and to ensure an accountable system. There are however, inhibitions to industry innovations through the current permit system which for example, insists on accurate forecasts of the cultivation, production, manufacture and supply amounts and profiles.

In key areas, the ND Act does not align with the Therapeutic Goods Act. As indicated above, there are areas of the current regulatory system under the ND which are in conflict to the well-established requirements for therapeutic drug preparation under the Therapeutic Goods Act.

C. Have the requirements of the Act been appropriately interpreted and applied by the Office of Drug Control?

It has been the industry's experience that in some cases, requirements have been interpreted in a manner that has been a significant contributor to the very slow uptake of medicinal cannabis. In turn, this has caused of growing frustration and resentment from consumer and patient bodies.

To some extent, it is understandable that a new regulator will take an extremely cautious approach to the regulation of a new product. The ODC does understand this and does have insight into the matter. The Act as it is currently operating and being interpreted however, does not meet what legislators originally intended.

It appears that the ODC does not have a standardised view of where extraction processes sit – whether encompassed under the term 'Production' or 'Manufacture'. It is the position of MCIA that Production definition includes the separation of cannabis resin from the plants from which they are obtained, which clearly defines extraction.

As addressed previously in this submission, the interpretation that analytical activities solely applied to cannabis are encompassed within the definition of manufacture, and a cannabis-only sample maximum is imposed, is out of step with an established regulatory framework successful governing analysis of all controlled (and prohibited) goods servicing policing, pharmaceutical and research activities.

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?

MCIA recommends that the ND Act contains a provision for a licence term of 5 years' duration, renewable on fee payment. Due to the significant investment requirement for establishment of medicinal cannabis facilities and other restrictions associated with a licence, this will provide appropriate investment certainty. A renewal process is appropriate on fee payment, and the ND Act already addresses reasons for cancellation of licence for non-compliance with the ND Act

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.

10A. Does the Narcotic Drugs Act 1967 appropriately frame the list of relevant matters?

The list is sufficiently appropriate. As mentioned in response to Q5A however, it is difficult for a Licence holder to be certain that the criteria has been met for each employee as it this is reliant upon Criminal History Check and self-reporting by the employee.

Further, MCIA notes that the ODC has requested AFP checks as compared to criminal history checks from an accredited CrimTrac provider. AFP checks can take weeks to process compared to CrimTrac reports which in some instances have a 24-hour turn around. This creates barriers to efficient and effective recruitment processes given that this presents significant delays before employment can commence.

The requirement for Criminal History Checks carried out by Australian Federal Police (AFP) or State Police checks compared to police checks carried out by third party providers has not been made clear to industry.

MCIA members consider the higher level of criminal history checks is appropriate for Directors and senior management. Other employees however, should be able to be assessed as fit and proper through a standard efficient CrimTrac check.

10B. Is appropriate guidance provided in the Act, the Regulations and by the Office of Drug Control?

As identified above, MCIA considers there should be further definitions provided within the Act that will assist with guidance. Our members consider that the guidance provided by the ODC is clear. The subject matters however, are currently very limited and it would be helpful if more guidance was provided across the scheme.

There are exceptions to the helpfulness of the guidance provided by the ODC, for example relating to the guidance on testing bodies and their ability to receive material for testing and hold up to 200g of material at any time.

This guidance and the chosen quantity seem unclear and the artificial limit appears to have been selected without a proper understanding of the practical requirements of the industry. There are very few testing bodies and they need to have the necessary flexibility to service multiple batches from multiple licence holders simultaneously. We propose that the quantity of supply to testing bodies could be better managed by setting against the quantities listed in a permit held by a Licence holder.

10C. Have the requirements of the Act and Regulations been applied appropriately by the Office of Drug Control?

MCIA notes a concern in that the guidance note mentioned above appeared to amend the laws by introducing a supply limit which was not set out in the Act or its Regulations.

As an industry we should expect to rely on the Act, the Regulations and the conditions of the Licences/Permits held to create the formal requirements that must be adhered to. It is inappropriate for the regulator to introduce additional restrictions through publications made on its website.

11. Under s11K 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 11K impose appropriate restrictions on the grant of manufacture licences?

Improved and extended definitions as suggested in response to Q7 would enable the extension to cover product development.

12. An applicant can be required under s 14J of the Narcotic Drugs Act 1967 to provide additional information in support of an application.

12A. Is this information gathering mechanism being appropriately managed by the ODC?

MCIA recommends that there be statutory response times imposed on the ODC in relation to application processing and queries related to applications to ensure an efficient and effective regulatory system. We suggest a portal system should be introduced to allow potential licence and permit holders to track the progress of their applications.

A formal mechanism for requests to extend the Section 14J due dates should be implemented.

12B. Is the information that applicants are required to provide excessive?

This is a very broad provision which allows the ODC to ask questions which satisfy them on reasonable grounds. Accordingly, the level of questioning will be related to the level of concern from the regulator. MCIA notes that some questions appear to be asked for the comfort or background knowledge of the regulator and are not questions which go towards the appropriateness of the activities being proposed under an application. Specifically, we refer to the ODC's interest in understanding the reason and potential outcomes of scientific research, instead of restricting its questions to the control measures in place to allow supply to research bodies. The regulator's key concern should be about measures to prevent diversion rather than the merits of a research approach or validity of a hypothesis.

13. 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?

The variation process takes much too long, and the matters that require variation are too many and often not substantial enough to warrant undertaking a full variation application process (i.e. adding new staff to a list of authorised persons, new analytical laboratory). This impedes the industry and should be managed more in line with ASIC registration amendments.

Again, if this is aligned to the relevant areas of responsibility, then ODC should only be directly involved where variations relate to the operator. Variations where the relevant activity is related to TGA or States, it could be by notification.

The ODC process would be improved by clearly defined major and minor variations and timelines.

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?

MCIA suggests an electronic portal to provide notifications when such notifications are listed as condition of a licence or permit. Currently, this is provided by way of email.

We suggest the standard conditions need to be supplemented with a list of standard authorities, including the ability to conduct research and the ability to supply material to testing bodies.

15. 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.

15A. Have those powers been appropriately exercised?

Yes, so far in MCIA members' experience.

15B. 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?

MCIA recognises that matters such as site security must be considered in respect of the specific site and therefore there is a level of 'self-regulation' by the applicant when proposing the specific security measures that they will have in place. We see this as necessary and appropriate.

16. *The Act and Regulations implement a cost recovery scheme, through which fees and charges are imposed on licence applicants and holders.*

The fees are appropriate, but in light of fees being based on a cost recovery model, the service must be present from the Office of Drug Control.

17. 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 recognising that this is somewhat out of the scope of this review, MCIA considers the industry is hampered by the category of medicines cannabis is designated under and that there may be value in consideration of a new TGA regulatory category of 'Aust-C. MCIA would welcome the opportunity to work with the ODC and TGA to explore this.

MCIA is supportive of the ODC's efforts to support this emerging industry. There are however, some challenges for commercial medicinal cannabis industry. By way of example:

- The TG Act demands that material is certified under relevant Therapeutic Goods Orders and in comparison, the ODC as regulator of the ND Act then imposes requirements that stand in the way of this certification. Specifically, a 200g limit on the quantity of cannabis which can be held at any time by a testing body who does not hold a Licence under the ND Act; making it extremely difficult to analyse a crop and meet the requirements of the TGA;
- Lack of clarity around definitions make it unclear whether a testing authority is/could be undertaking a manufacturing process; and
- We understand, that on current timelines a fully licenced Schedule 8/9 facility will still take in excess of 6 months to achieve approval.

MCIA is of the view that there is substantial opportunity for streamlining the existing processes, particularly in relation to third party services. Presently, licence holders are restricted because third party services e.g. labs, analytical services and research and development providers need to be accredited and approved for each licence. Evidence of laboratory testing is required, prior to distribution of a manufactured product by a vertically integrated licensed facility, under the existing regulation.

Proper checks and balances already exist within the Pharmaceutical industry with respect to Schedule 8/9 poisons and the hemp industry has operated successfully for decades. It is not clear why additional burdens are imposed with respect to cannabis. Indeed, we have the unequitable situation whereby there are more impositions on local production of cannabis than importation of cannabis.

Medigrowers PTY LTD

Date: 2nd April 2019

To whom it may concern

Re: Consultation Submission for Review of the Narcotic Drugs Act 1967

Below are the queries submitted by Medigrowers Pty Ltd for the Review.

- With the high increase in license applications being received by the ODC & the current lengthy turnaround times being experienced with applications, how are current License Holders going to be prioritised for Permit Applications, License Renewal Applications & additional License Applications?
- There is a high value of investment required to enter into this industry. License Holders therefore require clarity around the License Renewal Process & how certainty will be given that Licenses will continue to be renewed.
- After being awarded a License, the maximum period given before the License Fee is payable is 12 months from the date the License was awarded. On receipt of the License, there are still a number of things that need to take place before the business will be operational in this industry, including but not restricted to Development Application approval, building of the facility, finalising Permits etc., which could take considerably more than 12 months to finalise. It is requested that the period given for the License to be payable be extended to at least 24 months after the License has been awarded.
- Throughout the application process, a number of different ODC representatives are giving feedback or making requests in regards to the application. Would the ODC consider the allocation of a dedicated case representative to a company applying for a License, Permit or License Renewal, ensuring that the dedicated person has a clear understanding of where the application or renewal is up to & can clearly communicate what is still required for the successful completion of the application
- The ODC representative working on an application is currently responsible for ensuring that the latest versions of documents relevant to the application are being reviewed. To improve efficiencies & to ensure that the control of the latest versions of the documents is the responsibility of the applicant, would the ODC consider the implementation of a Web Portal where license applicants can upload the latest documents, replace older versions & ensure the ODC is reviewing the correct documentation throughout the application, especially when requests for updated documentation & processes are required by the ODC.
- Once a License has been awarded, is there a possibility for the license holder to be allocated a dedicated liaison with the ODC, who would be able to respond to queries as soon as possible & ensure that everything is being done correctly & in line with ODC expectations & guidelines.

- Cultivation License holders that are wanting to apply for Manufacturing & Export Licenses should be given priority over non-license holders. Information submitted for the Cultivation License should also be used for the Manufacturing & Export License Applications wherever possible, rather than the current requirement of all documents having to be resubmitted & then re-reviewed, such as Fit & Proper Persons reviews etc.

- Clarity is required around the options of being able to negotiate & supply cultivated products to alternative licensed manufacturers, other than those stipulated on the cultivation license.

- There are currently only a limited number of Manufacturing Licences that have been issued, leading to a highly restricted market for cultivators to supply. In the event that approved Manufacturers are not willing to engage with approved Cultivators to purchase Australian cultivated product, approved cultivators will require other avenues to enable them to sell cultivated product, either locally or to export markets. Cultivators are embarking into considerable investments with what is currently very limited channels to sell product, which in essence is anti-competitive. What other alternative channels is the ODC working on to ensure that approved cultivators are able to operate in a less restricted market?

In the event that further discussions are required in regards to these submissions, please feel free to contact the author, as per details below.

Kind regards

[redacted]

Medigrowers Pty Ltd

Medigrowers Pty Ltd
Sydney, Australia

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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

Tasmanian Alkaloids (TasAlk) is one of the world's largest producers of alkaloid raw materials established in Tasmania for over 40 years. It employs over 180 Tasmanians consisting of scientists, engineers, technicians, marketers and administrators. The team can also include over 500 farmers throughout Tasmania. It's flexible and modern manufacturing facility is fully compliant with Good Manufacturing Practice (GMP) and can easily adapt to the production of new products including Medicinal Cannabis.

Following the amendment of the Narcotic Drug (ND) Act in February 2016 TasAlk made the decision to enter the medicinal cannabis industry and have had experience in applying for and receiving approvals for licences and permits under the Act. This has involved applications, site inspections, requests for additional information including numerous meetings in person and by telephone.

The amendment of the ND Act has allowed TasAlk to progress to a position of being able to offer medicinal cannabis products both within Australia and overseas as the demand increases. TasAlk have considered both the terms of reference (key themes and specific issues), their combined experience of working within the poppy industry for over 40 years and the emerging medicinal cannabis industry.

The review undertaken by TasAlk centred on recommendations to increase efficiencies and reduce the regulatory burden while still preserving the effectiveness of the Act. This has been presented as key recommendations, the critical area for Tasmanian Alkaloids however is the availability of large scale biomass from low Tetrahydrocannabinol (THC) crops grown on a broadacre basis.

Tasmanian Alkaloids has extensive experience in contracting growers to provide large scale biomass currently within the poppy industry. This model could be used effectively for the hemp industry, with access to the leaves and flowering heads (licensed manufacturers only) after the seed or other parts of the plant are utilised for the hemp food industry.

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Summary of Recommendations

In this submission, TasAlk have addressed both key themes and specific issues from the Review of the Narcotic Drugs Act 1967 Discussion Paper. To ensure ease of cross referencing the individual themes and issues will be reproduced in italics and use the same sub headings as the discussion paper.

Key Recommendations

1. Instigate a pre-screening system for the submission of application forms for licences and permits to increase the effectiveness of the application process.

2. Instigate a risk based assessment system to allow classification and acceptance of minor changes to licences and/or permits which are classified as not material in nature to reduce the regulatory burden to a level proportionate to the risk.

3. Implement a system with a single 'Medicinal Cannabis' licence with authority granted as required within the licence to remove duplication of processes and information submitted for individual licences.

4. Remove the requirement to record number of plants including the identification of individual plants by strain name and source and replace with the amount of active ingredient contained in the plant to allow transparency of reporting across all licence holders.

5. Allow the cultivation of certified cannabis seed varieties (with not more than 1% of THC contained in the plant) to be grown under an Industrial Hemp Licence but allow access to the leaves and flowering heads to entities holding a medicinal cannabis manufacturing licence.

6. Allow an avenue for licensed manufacturers to apply for approval to hold Schedule 9 materials where there is clear evidence of a link to medical research and potential commercial opportunity.

7. Apply a risk based approach to information required in support of an application or variation submission, if it is not critical to the approval of the application then a period of 10 business days should be allowed without incurring the 30 days reset before any further review.

8. Once an entity has shown adherence to monthly reporting for a trial period, allow an option to move to quarterly reporting.

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Key Themes

Key Theme 4

Has the Commonwealth (and in particular the Office of Drug Control) implemented an efficient and effective regulatory scheme for medicinal cannabis?

a. Is an appropriate and proportionate regulatory burden placed on those applying for or holding licences and permits?

There is an appropriate level of regulatory burden placed on those applying for or holding licences and permits, the permit application process needs to be addressed to allow it to be proportionate.

The existing licence application and approval system would benefit from a pre-screening process. The pre-screen would ideally incorporate specific questions that could be completed on-line that would trigger an approval process to allow the applicant to progress to the next level. This system would allow the Office of Drug Control (ODC) to set minimum requirements before applicants could access the application process.

In regards to permit application and variations this should be more proportionate. The permit variation process needs to be based on a risk assessment model. As an example, if an entity is issued a Medicinal Cannabis permit there is a requirement to list specific strains by name, source, THC/CBD % & quantity of plants. If, during the time taken to issue a permit any of these criteria change then a variation is required which can take 6 to 9 months. Commercially, these time frames are not feasible when the changes are not material to the permit. A risk based approach would allow non-material changes to be approved as a permit attachment to allow commercial operations to proceed without any regulatory concerns. If the risk assessment classified the change as not materially affecting the decision to originally grant the licence and/or permit, then written notification of the variation would be deemed sufficient.

Recommendation 1

Instigate a pre-screening system for the submission of application forms for licences and permits to increase the effectiveness of the application process.

Recommendation 2

Instigate a risk based assessment system to allow classification and acceptance of minor changes to licences and/or permits which are classified as not material in nature to reduce the regulatory burden to a level proportionate to the risk.

b. As to medicinal cannabis licences, is there duplication in the processes and information required in applying for a licence and a permit?

Under the current system with three licences there is excessive duplication if an existing business on a single site needs to submit the same information three times.

The system should be changed to issue a single generic 'Medicinal Cannabis' licence with authority for research, production & manufacturing as required. This would allow the generic information to be submitted once and allow for additional information required for each specific authority.

The individual permits could still be retained, allowing the amounts of cannabis to be managed and transparency between research, production and manufacturing as they would be linked to a single licence.

The information required in permits and licences related to cannabis plant identification and quantity needs to be simplified to create efficiencies. The individual identification of plants is a good system for small areas with minimal number of plants but as the industry matures, an alternative system will be required.

The ND Act establishes a suitable framework to prevent diversion through licensing, inspections and the permit system. The use of individual plant identification within permits is cumbersome and does not add any further level of control. If an assay of THC or CBD is known, plant weights are recorded (wet & dry) and then extraction of active ingredient is known then this is sufficient for control. The information required should focus on the active ingredient in the plant based on recorded weights, assay and yield.

Recommendation 3

Implement a system with a single 'Medicinal Cannabis' licence with authority granted as required within the licence to remove duplication of processes and information submitted for individual licences.

Recommendation 4

Remove the requirement to record number of plants, including the identification of individual plants by strain name and replace with the amount of active ingredient contained in the plant to allow transparency of reporting across all licence holders.

Key Theme 5

Has an appropriate compliance and enforcement regime been implemented, both in the Narcotic Drugs Act 1967 and administratively?

a. Are risks being appropriately managed?

b. Is there excessive risk aversion?

Excessive risk aversion applies in that the fundamental issue with cannabis is that the diversion concern should be directed at the management and control of THC as the active ingredient and not CBD.

Cannabis (including seeds, extracts, resin and the plant) and THC (a psychoactive cannabinoid) are listed in Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), which is scheduled to the current Poisons Standard.

Schedule 8 informs State and Territory drugs and poison legislation that restricts the manufacture and availability of cannabis and THC to reduce abuse, misuse and physical or psychological dependence. CBD, a non-psychoactive cannabidoil, is listed in Schedule 4 of the SUSMP as a prescription only medicine.

The different Scheduling of both CBD and THC are inconsistent with the risk management under the ND Act. Medicinal cannabis or an Industrial Hemp crop containing predominantly CBD with low levels of THC currently has the same implied security & compliance requirements under the Act.

The Industrial Hemp Act 2015 (Tas.) defines Industrial Hemp as any plant of the genus Cannabis that has been grown from certified hemp seed; and has a concentration of THC in the leaves and flowering heads of not more than 1%.

Certified Cannabis seed varieties with not more than 1% of THC should be able to be grown as Industrial Hemp varieties on a broadacre basis with the same licensing requirements as Industrial Hemp is, but left for States to licence as per Industrial Hemp.

It is not the intention of TasAlk to vary the Scheduling of CBD or THC but to allow cultivation on a broad acre basis and allow harvesting of Industrial Hemp leaves and flowering heads. This allows cultivation of Industrial Hemp for food products to continue but would allow the leaves and flowering heads to be made available to licensed manufacturers under the ND Act. This still allows protection for leaves/flowering heads as farmers could continue to grow the crop for food related hemp products but also allow them to contract separately to licensed medicinal cannabis manufacturers for the remainder of the crop.

Recommendation 5

Allow the cultivation of certified cannabis seed varieties (with not more than 1% of THC contained in the plant) to be grown under an Industrial Hemp Licence but allow access to the leaves and flowering heads to entities holding a medicinal cannabis manufacturing licence.

Key Theme 6

Does the Act interact suitably with other Commonwealth, State and Territory laws relating to the regulation of cannabis products and narcotic drugs?

a. Are the intersection points clear?

b. Is there evidence of duplication?

In relation to Narcotic Drugs, TasAlk recommend that a mechanism be created to allow manufacturing licence holders, under the Narcotic Drugs Act 1967, to be able to research and manufacture drugs (or intermediates) that are specified on the Poisons Standard (SUSMP) as Schedule 9 substances.

Where TGA approved medical research in Australia or an overseas INCB signatory country e.g. NIH in the USA has the need for a Schedule 9 drug which can be manufactured in Australia by existing licence holder, the licence holder is currently unable to make a “bid” for the manufacturing element, due to manufacturing licence holders not being public institutions at a State level and thus not being able to hold the material is the first place.

This would potentially enable the assessment of new business opportunities, which Australian manufacturing licence holders are unable to participate in. The interaction would also need to be linked with the Therapeutic Goods Act 1989.

Recommendation 6

Allow an avenue for licensed manufacturers to apply for approval to hold Schedule 9 materials where there is clear evidence of a link to medical research and potential commercial opportunity.

Specific Issues

Issue 9

The Narcotic Drugs Act 1967 does not specify the period for which a licence or permit can be in force.

c. Nor is there a procedure for renewal of an existing licence or permit.

d. Should this be changed?

In general, the emphasis of any changes to licence or permit periods, or the need for a renewal procedure for permits and licences, should be on efficiency and reducing the regulatory burden (and cost) while preserving the effectiveness of the information used to approve the licence or permit.

Applying long term licences e.g. 5 years, with updates for business changes made that could materially impact the licence conditions (onus on licence holders updating the ODC), would minimise the regulatory burden. There should not be a need to submit an additional application to renew a licence unless there are substantial changes or personnel identified as either authorised or fit and proper person have changed.

Issue 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?

The information collection under s14J is relevant to the application process and forms part of any regulatory scheme. The information gathering should be subject to a risk assessment process however as an application can be held up for 30 days once a request is made under s14J. If the request for additional information is not assessed to be critical to the approval of the application, then it should proceed if information is returned by the applicant within a set period.

Issue 13

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?

In regards to licence or permit variations this should be more proportionate. The permit variation process needs to be based on a risk assessment model. As an example, if an entity is issued a Medicinal Cannabis permit there is a requirement to list specific strains by name, source, THC/CBD % & quantity of plants. If, during the time taken to issue a permit any of these criteria change then a variation is required which can take a further 6 to 9 months for approval.

Commercially, these time frames are not feasible when the changes are not material to the permit. A risk based approach would allow non-material changes to be approved as a permit attachment to allow commercial operations to proceed without any regulatory concerns. If the risk assessment classified the change as not materially affecting the decision to originally grant the licence and/or permit, then written notification of the variation would be deemed sufficient and could be granted within 10 business days.

Recommendation 7

Apply a risk based approach to information required in support of an application or variation submission, if it is not critical to the approval of the application then a period of 10 business days should be allowed without incurring the 30 days reset before any further review.

Issue 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.

e. Does the Act provide an appropriate list of relevant conditions?

f. Has the Office of Drug Control appropriately managed these provisions of the Act?

The conditions on reporting would benefit from a change to quarterly reporting as a month in a commercial business is often too short and creates overlapping information. An example of quarterly reporting used by other Government agencies could be followed, e.g. Business Activity Statement (BAS) reporting.

Recommendation 8

Once an entity has shown adherence to monthly reporting for a trial period, allow an option to move to quarterly reporting.

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Conclusion

Tasmanian Alkaloids appreciate the opportunity to take part in this review and have provided key recommendations that we believe would increase the efficiency of the Act whilst still maintaining public health and safety.

As part of this submission TasAlk management welcome further discussion on any points raised and extend an invitation for representatives to visit the site. This would give TasAlk the opportunity to present an overview of the submission, the poppy crop from broad acre to customer supply chain and the medicinal cannabis systems already in place.

Kind Regards

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TheraCann International
https://.theracann.solutions

Submission on Review of the Narcotic Drugs Act 1967

[redacted]

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ABOUT THERACANN INTERNATIONAL

Theracann International is a global leader in providing high quality and in-demand cannabis services and products. We offer unique technology and managed services to clients across the globe in the medicinal cannabis industry, and currently operate in over 10 countries on more than 200 projects.

We are dedicated to providing an innovative and adaptable solution that is reliable, economic, practical, safe and secure while setting he gold standard in cannabis quality, tractability and regulatory compliance.

Theracann is currently partnered with Canngea Pty Ltd in Australia in its application to construct a medicinal cannabis cultivation facility in the New South Wales Hunter Valley region.

The current licensing and permit regimes

The current application system has similar failings to those in other jurisdictions, in our experience. Limited information is requested from applicants at the initial stage of the process, with supporting documentation not requested in a standardised manner. We understand that significant processing time is spent by staff assessing whether supporting documentation satisfies the requirements of the Act and Regulations. We suggest that improvements could be made to this process, with standard forms prepared for each piece of information required of applicants, with applicants required to supply that information at the initial stage of the application process. A detailed application process with standardised forms for the provision of information would lessen the burden on processing staff, and reduce the time spent assessing each application. Certainly, the initial effort required of applicants may be increased; however, we anticipate that requests for further information should correspondingly decrease.

Track and Trace

Cannabis regulations worldwide are evolving rapidly. Regulatory Agencies must combat the problem of diversion using technology for full traceability, to create legal export markets, patient safety and economic opportunity.

The importance of tracking cannabis cannot be overestimated. The integrity of any cannabis regulatory framework is built on the premise that only legally produced, processed or distributed grams come from a licensed location. That such a framework is capable of discerning "white" (legal) from "black" (illegal)

cannabis. Cannabis regulatory frameworks that permit black market cannabis to enter a licensed facility such that it processed and sold as "gray" market cannabis completely undermines the credibility and enforceability of the cannabis domestic and international supply chain. Yet many jurisdictions have permitted and continue to permit this to happen. As a result, those jurisdictions have demonstrated their inability to fully recall cannabis products that have caused harm. Further they are not able to provide the necessary level of certainty to domestic and international banks that every gram is a clean gram, and that every penny associated with the sale of those grams is a clean penny. As a result, those jurisdictions have been, and will continue to be, singled out by international law enforcement, international banking, and international quality assurance associations as being too "weak" to be included in a robust, repeatable, reliable, economical, scalable, safe and secure cannabis supply chain.

Full tracking is the only way to prevent the diversion of illegal cannabis and its funds. The legally produced product that meets health standards must not be diverted into a situation of misuse, but also important is that uncontrolled product does not make its way into facilities, and become "gray market" packaged product that poses a hazard to patients. Both Black Market and Grey Market situations must be curtailed in order to have successful medical cannabis successfully implemented in a country and to comply with international legal, banking and quality assurance conventions related to the international export of food, herbal and medical products.

Ignoring the fact that technology ***does exist*** which can safely, securely, economically track cannabis could risk the integrity of the Australian market. The Australian Government should adopt the available technology to protect the security of consumers and producers alike. Technology that has been successfully approved and used in other related sectors has made it possible to have full traceability of cannabis from seed to consumption, recall and/or destruction. The ETCH Biotrace (SigNature®) molecular tag technology is the application of a food-safe molecular tagging system, where a tiny amount of DNA material, chemically identical to that already present in cannabis, is applied to the plant to form a DNA "bar-code" that survives processing. The tagging can be applied in a dry fog for indoor production, processing and/or distribution of cannabis. The tag can also be applied to hemp, grown in open-air fields. The molecular taggant can also be added to processed cannabis extracts, thereby identifying the processor or brand associated with the product.

A full explanation of the safe and digestible nature of the DNA tag is attached(1). Please note that this technology has been developed for introduction to the U.S. pharmaceutical market, with a Drug Master File on file with the FDA for its use in

pharmaceutical coatings to be taken by mouth. It is categorized under an excipient as per the 2011 FDA Guidance for Physical-Chemical Identifiers in Drugs (2). The DNA contained in the molecular tag is chemically identical to the DNA already in cannabis. It is not a gene and metabolizes like all other cannabis DNA. This is not a genetic modification of the cannabis gene and therefore leaves the product non-GMO (3). A white paper outlining the safety of the ETCH Biotrace (SigNature molecular tag by Applied DNA) is attached (1), written by Joseph V. Rodricks, PhD, DABT, Chair of USEPA Board of Scientific Counselors and founding Principal of Environ-Ramboll, after a 15 year career at the FDA. Dr. Rodricks is an internationally recognized expert on toxicology and human exposure to chemical substances and noted author on the topics.

As noted, the ETCH biotrace taggant can be applied to plants, cuttings or to chemical extracts of the plant matter to allow a full trace of the material from harvest, through processing and post processing phases.

The ability to track every gram of medical cannabis to its source, to the licensed location, and even to the room, or when needed, to even the row or shelf from which it was derived can also then be compared to the production capability of a facility and to its financial records. When ETCH biotrace is combined with Sprout AI (indoor computer controlled aeroponic vertical grow technology) and OS2 (secure web based enterprise resource planning and compliance software integrated to secure payment gateway and blockchain supply chain) additional mass balance calculations can be provided to match data recorded for consumables of the operations (e.g. power, water, worker gloves etc.) to the recorded amount of raw, produced and waste product inventory. To further assure that diversion into or out of the facility is not occurring, OS2 when combined with ETCH Biotrace and Sprout AI will provide enough data for an independent auditor to do apply financial tests for diversion. In addition, in the case of recalls, the ability to trace precisely will protect public health with more surety than previously possible.

Both the New York and Californian jurisdictions have enacted track and trace legislation, leading the way in medicinal cannabis regulation worldwide. Whilst commendable, it is essential to note that neither of these jurisdictions provide for the full DNA tagging technology that Theracann International has developed. Furthermore, DNA taggants can work to provide the ability to fully track and trace each gram of medicinal cannabis, but ***only*** in conjunction with the corresponding software. As explained above, DNA tagging is comparable to a barcode system – without barcode reading software and proper inventory management, it is simply a collection of numbers and lines. Used together, they offer a world-class system of diversion control in the medicinal cannabis industry.

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CONCLUSION

Governments around the world are now learning about this readily available technology and we anticipate it will become the standard for tracking and tracing cannabis and revenue from resulting sales of cannabis. We recommend this as the technology that should be mandatory to provide the highest confidence in Australia's medicinal cannabis products.

ADDITIONAL RESOURCES

1. APDN-Ramboll-Environ-GRAS-Report-Final-03-13-19: White Paper by Joseph V Rodricks
2. FDA Guidance for PCID
3. APDN-GMO-Whitepaper-Signed 07-11-18

FOR MORE INFORMATION

For more information, please contact [redacted]@theracanncorp.com

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Safety and GRAS Determination of the ADNAS DNA-based Physical-Chemical Identifier (PCID)

Prepared for:
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Prepared by:
Ramboll Environ US Corporation
Arlington, Virginia

Date:
May 2016

Project Number:
2434814A

Contents

Acronyms and Abbreviations

A	Adenine
C	Cytosine
DNA	Deoxyribonucleic acid
FDA	Food and Drug Administration
G	Guanine
GRAS:	Generally Recognized as Safe
KCl	Potassium chloride
MgCl	Magnesium chloride
PCID	Physical-Chemical Identifier
PCR	Polymerase Chain Reaction
T	thymidine
Taq Polymerase	DNA polymerase originally isolated from bacterium, *Thermus aquaticus*
UV	Ultraviolet (light)
VIS	Visible (light)
WHO	World Health Organization

1. Introduction

1.1. Identity of Substance

The subject of this dossier is a set of short, synthetic DNA fragments which are not of human, viral, or bacterial sequence origin, to be used as Physical-Chemical Identifiers (PCIDs). As described below and in the supporting documentation, these DNA fragments are synthetic, free from chemical modification of the polynucleotide chain, purified by chromatography, shorter than 500 base pairs (bp) in length, and designed to be devoid of any known human gene regulatory sequence. Based on the short length and lack of biochemically active DNA sequence, such DNA fragments are not capable of genetic function.

1.2. Intended Use

This set of DNA fragments will be used as a PCID to be incorporated into high-value food products. These DNA based PCIDs will be analyzed by chemical extraction of the DNA from the food, followed by isothermal amplification, PCR, or sequencing of the extracted PCID. The DNA PCID will be administered at less than 1.0 ng per label (in the ink or varnish or other excipient). The reason to apply these DNAs as a PCID is that they provide an additional level of authentication, to be used to deter the counterfeiting of high-value foods, and to detect such counterfeits once in the market, so that the criminal source of a counterfeit product may be found and subjected to legal action. The overall goal is to protect the integrity of the product supply chain, and to protect the consumer.

1.3. Basis for Determination of Safety and GRAS

In the area of orally-delivered vaccines and other orally delivered biologics, the FDA (2010) and WHO (2007) have already determined that intact gene-sized (functional) human DNA may be included in oral dosage formulation at levels as high as 100 µg per dose. In that guidance, FDA notes that this allowance is conservative and that if the DNA were applied as fragments that were smaller than gene size (i.e., much less than 1,000 bp) and if the DNA lacked functional human DNA sequence elements, then the 100 µg standard would be seen as even more conservative than the case obtained for long, functional, human DNA.

The above-mentioned set of synthetic DNA PCIDs for administration at less than 1.0ng per label represent 100,000-fold less than the 100 µg limit designated by the FDA and by the WHO as safe for ingestion, even if the entire fruit label was ingested. Given that the FDA and WHO have viewed the 100 µg limit as being conservative, we suggest that as a PCID, an additional 100,000-fold margin of safety is additionally conservative.

In addition, since the PCID is composed of short chains of unmodified DNA, it is identical in chemical composition to the DNA found in foods of animal, plant, and fungal origin and, therefore, qualifies as GRAS through "experience based on common use in food" since before January 1, 1958 (21 CFR 170.30), or in this case, since before recorded history.

6. Summary and Conclusions

The ADNAS DNA-based PCID consists of short (100 – 500 bp), unmodified DNA molecules generated biochemically and is chemically identical to the DNA complement of food. Because of their short lengths, the sequences contain no gene function, but serve simply as a DNA-based barcode. The ADNAS DNA-based PCID is stable under normal storage conditions for fruits and vegetables and can be reliably detected and sequenced to confirm the identity of the product to which it is affixed.

Because the ADNAS DNA-based PCID consists simply of normal DNA bases with no biochemical function or pharmaceutical activity, is chemically identical to the DNA found naturally in food, and is applied at very low levels (< 1 ng/label), it presents no health risk to humans who may either accidentally or intentionally ingest it in products utilizing the PCID, particularly as a label for fresh foods.

Safety testing of the ADNAS DNA-based PCID reveals, as expected, no indication of genotoxic or cytotoxic activity, and confirms the safety of the PCID.

Trace levels of PCR reactants used in the production of ADNAS DNA-based PCID molecules are themselves GRAS and/or are at levels too low to present any health risk to consumers.

Based on an evaluation of relevant data, the ADNAS DNA-based PCID is considered to be safe for its intended uses and generally recognized as safe (GRAS) based on scientific procedures, and based on its chemical identity to molecules that have been safe components of the human diet at much greater levels for millennia.

Furthermore, we believe that other "experts qualified by scientific training and experience to evaluate the safety of food and food ingredients" would agree.

Joseph V. Rodricks, PhD, DABT
Principal, Ramboll Environ US Corporation

Duncan Turnbull, DPhil, DABT
Senior Science Advisor, Ramboll Environ US Corporation

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GRAS status for trace contaminants:
General: 21 CFR 170.30
MgCl: 21CFR184.1426
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Guidance for Industry

Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
October 2011
CMC

Guidance for Industry

Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting

Additional copies are available from:
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
October 2011
CMC

Contains Nonbinding Recommendations

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Contains Nonbinding Recommendations

Guidance for Industry[1] Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This document is intended to provide guidance to pharmaceutical manufacturers who want to use physical-chemical identifiers (PCIDs) in solid oral dosage forms (SODFs). A PCID is a substance or combination of substances possessing a unique physical or chemical property that unequivocally identifies and authenticates a drug product or dosage form.

This guidance provides recommendations to pharmaceutical manufacturers on (1) design considerations for incorporating PCIDS into SODFs, (2) supporting documentation to be submitted in new drug applications (NDAs) and abbreviated new drug applications (ANDAs) to address the proposed incorporation of PCIDs in SODFs, (3) supporting documentation to be submitted in postapproval submissions to report or request approval to incorporate PCIDs into SODFs, and (4) procedures for reporting or requesting approval to incorporate PCIDs into SODFs as a postapproval change.

The incorporation of components or features used in radiofrequency identification for drug products is outside the scope of this guidance. In addition, this guidance does not apply to manufacturing or formulation changes, made in conjunction with the addition of a PCID, that go beyond simply inserting the PCID into a blending or mixing operation (e.g., adding a PCID to a non-functional tablet film coating is covered by this guidance, but adding a non-functional film coating that contains a PCID to a previously uncoated tablet involves manufacturing changes that are not covered by this guidance). The incorporation of a PCID into the packaging or labeling is not covered in this guidance.

Other guidance documents, which may be applicable to proposed changes outside the scope of this guidance, are located on FDA's guidance Web site[2] and should be consulted to help to

[1] This guidance has been prepared by the Office of New Drug Quality Assessment, Office of Pharmaceutical Science in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

[2] CDER guidance documents can be found on the Internet at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm. We update guidances periodically. To make sure you have the most recent version of a guidance, check the CDER guidance Web site.

determine whether additional reporting or approval procedures may apply to proposed changes outside the scope of this guidance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in an Agency guidance document means that something is suggested or recommended, but not required.

II. BACKGROUND

Pharmaceutical manufacturers aiming to thwart drug product counterfeiting have been investigating readily available technologies that may make drug products more difficult to duplicate. One approach that pharmaceutical manufacturers appear to be considering involves adding a trace amount of an inactive ingredient(s) to an existing *section*[3] of the dosage form. A unique physical-chemical characteristic of that ingredient makes it possible to detect and authenticate legitimate dosage forms, and to identify counterfeits.

Examples of substances that may be incorporated into SODFs as PCIDs include inks, pigments, flavors, and molecular taggants. Such PCIDs may allow product authentication by their presence alone or may be used to code the product identity into or onto the SODF.

There are various available means for presentation and detection of PCIDs (e.g., photolithography, holography, optical microscopy, laser scanning devices, excitation/fluorescence detection). Some identifying characteristics, such as pigments or flavors, could be easily observed by patients, healthcare practitioners, and pharmacies. Others could require the use of a detection instrument (e.g., a scanner, photometric detector, mass spectrometry).

FDA anticipates that many of the ingredients that will ultimately be employed as PCIDs are already used as food additives, colorants, or excipients with established safety profiles.

III. DESIGN CONSIDERATIONS FOR INCORPORATION OF PCIDs IN SOLID ORAL DOSAGE FORMS

A. Pharmacological and Toxicological Considerations

If an applicant incorporates a PCID into a solid oral dosage form, we recommend that the ingredients comprising the PCID be pharmacologically inactive so the ingredients can be treated as excipients.

To minimize toxicological risk, FDA recommends using permissible direct food additives,[4] food substances that are generally recognized as safe (GRAS) (including direct food substances

[3] *Section* is the term used for a discrete, contained solid or a layer in a solid oral dosage form. Any section can be described by its composition, the functional characteristics that distinguish it from other sections in that dosage form, and its position relative to other sections that may be present (e.g., coatings, capsule shells, encapsulated particles, a layer in a bi-layer tablet, and compressed powders).

[4] See 21 CFR parts 172.

affirmed as GRAS),[5] or those ingredients listed in the FDA Inactive Ingredient Guide (IIG) that have been used in SODFs.[6]

Certain substances could present a toxicological risk when used as a PCID in a SODF if the substance is:

- Used at a level in excess of the limitations provided in the relevant IIG listing or Code of Federal Regulations (CFR) chapter for direct food additives
- An ingredient that has never been used in an SODF or as a direct food additive
- An ingredient that poses risk of adverse reaction (e.g., allergic reaction or irritation), including an ingredient derived from a major food allergen (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat and soybeans)[7]

We recommend that applicants contact the appropriate clinical review division for more information on how to assess the safety of such proposed PCIDs.

B. Other Design Considerations

A substance employed as a PCID should not adversely affect the identity, strength, quality, purity, potency, or bioavailability of the SODF. To minimize the risk of adverse effects on these characteristics, FDA recommends that applicants add a PCID to an SODF at the lowest level that ensures identification of the dosage unit. Applicants also can minimize the potential for adverse interactions by using a PCID that is relatively inert (i.e., unreactive). Applicants also should consider the potential effect of a PCID on the quality, performance, and stability of the SODF both during the selection of a PCID and during the design of an SODF that will include a PCID.

Another factor that applicants should consider is the location of the PCID within the drug product. When considering where to place a PCID, the applicant may find it helpful to conceptually subdivide an SODF into sections that differ in composition that may or may not contain active drug substance. For example, a core section in an SODF is likely to contain one or more drug substances,[8] while the external sections of the SODF may not. If an applicant places a PCID inside a core section of the SODF, that placement may increase the chances of interactions with the drug substance that could result in degradation. If the applicant is concerned the PCID will interact with core components, incorporating the PCID into an external section of the SODF (e.g., in a coating or an ink-imprinted logo) may reduce the possibility of such interaction.

The applicant should also consider whether the presence of the PCID might interfere with control of the release rate of modified-release SODFs (SODF-MRs), including extended-release and delayed-release dosage forms. Thus, FDA recommends that the applicant consider incorporating the PCID into a section of the SODF-MR that does not contain any *release-controlling excipient*.[9] Since the mechanisms that impart modified-release characteristics are varied, the

[5] See 21 CFR parts 182 and 184.
[6] See http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm.
[7] See section 201(qq) of the Federal Food, Drug, and Cosmetic Act.
[8] The term *drug substance* is defined in FDA's regulations at 21 CFR 314.3.
[9] A *release-controlling excipient* is any ingredient in the SODF that controls the rate at which a drug substance is made available for absorption in the gastrointestinal tract after it is administered.

potential impact on drug product release rate and stability should be evaluated by the applicant prior to incorporating a PCID into an SODF-MR, regardless of the location of the PCID relative to the drug substance and release-controlling excipients.

IV. SUPPORTING DOCUMENTATION TO ADDRESS THE PROPOSED INCORPORATION OF PCIDs IN SOLID ORAL DOSAGE FORMS

Section A below describes FDA's recommendations for documentation to be submitted both by applicants proposing to incorporate PCIDs into new SODFs in an NDA or ANDA for initial approval of a drug product and by applicants proposing to incorporate PCIDs into SODFs as a postapproval change. In addition, as described in section B below, FDA recommends that applicants proposing to incorporate PCIDs into SODFs as a postapproval change submit certain additional documentation.

A. Documentation Regarding Incorporation of PCIDs into Solid Oral Dosage Forms to be Included in any Premarketing or Postapproval Regulatory Submission

FDA recommends that applicants include the following information in appropriate sections of any premarketing or postapproval regulatory submission proposing the incorporation of a PCID in a SODF:

1. Chemical composition (names and relative amounts of each component) of the PCID.
2. Rationale for selection and incorporation of the PCID and description of how the PCID is integrated into the design of the SODF.
3. An illustration showing the location of the PCID in the SODF, unless the location can be easily explained without the use of an illustration.
4. Relevant physical-chemical attributes of the PCID (e.g., those relating to identity, strength, quality and purity) including those attributes that make the material useful as a PCID.
5. Specification[10] for the PCID.
6. Information on the impurities that may be present in the PCID.
7. Justification for safety of the PCID including any toxicological assessment.
8. Information on product development pertaining to incorporation of the PCID. (This information should include any study conducted during development to assess compatibility of a PCID with other formulation components.)
9. Description of manufacturing steps and controls associated with the incorporation of the PCID in the drug product.
10. Assurance and verification of quality, performance, and stability of the drug product containing the PCID.[11]
11. A summary of a product quality and performance risk assessment associated with the incorporation of the PCID.

The amount of information provided for a PCID will depend on its pharmacological and toxicological characteristics as well as the design of the SODF. For example, less

[10] The term *specification* is defined in FDA's regulations at 21 CFR 314.3.
[11] See also section IV.B. regarding postapproval regulatory submissions.

information would be expected for a PCID, which is a permissible direct food additive, a food substance that is GRAS, or listed in the IIG, than for a novel PCID.

B. Documentation Regarding Incorporation of PCIDs into Solid Oral Dosage Forms to be Included in any Postapproval Regulatory Submission

When an applicant proposes to incorporate a PCID into an SODF that has already been approved and marketed without the PCID, we expect that the applicant will be able to conduct certain assessments comparing the product without the PCID and with the PCID. Assessments of impurity profile, stability, and dissolution data as described below may be sufficient to address item 10 in the list in section IV, A above. We recommend that such applicants provide documentation regarding the assessments described below in the appropriate section of any postapproval regulatory submission proposing the incorporation of a PCID in a SODF:

- The applicant should perform analyses to determine whether the impurity profile of the drug product has been altered by the addition of the PCID, either through the presence of new impurities or increased levels of previously detected impurities. To prepare your submission in accordance with 21 CFR 314.70, FDA suggests that applicants follow the recommendations in the International Conference on Harmonisation guidance entitled "Q3B(R2) Impurities in New Drug Products"[12] regarding the reporting, identification, and qualification thresholds, even if the PCID is a permissible direct food additive, a food substance that is GRAS, or listed in the IIG.

- If the addition of the PCID to the SODF has the potential to significantly affect drug release rates, FDA recommends that applicants conduct evaluations of dissolution profiles. The applicant should perform dissolution testing using methods and apparatus specified in the approved application. Where applicable, the submission should include a statistical comparative assessment of multipoint dissolution profiles for the prechange and postchange batches obtained in one or more dissolution media simulating physiologically-relevant conditions.

- The applicant should use long-term and accelerated stability studies to evaluate impurity formation and the effect of the PCID on the dissolution profile. One should conduct such stability studies through the drug product expiration date, although the studies need not be completed prior to submission of the change. The initial report of the change, whether in an annual report or supplemental application, should include the most current stability data, and the applicant should continue to provide updated data in subsequent annual reports.

The applicant should also ascertain whether any analytical procedures should be revalidated as a consequence of adding the PCID.

V. DETERMINING REPORTING CATEGORY FOR POSTAPPROVAL CHANGES TO INCORPORATE PCIDs INTO SOLID ORAL DOSAGE FORMS

Applicants that propose to incorporate a PCID into a SODF as a postapproval change should report the change in a prior approval supplement, a changes being effected (CBE-30)

[12] This guidance is available on FDA's website. See footnote 2.

supplement, or an annual report according to the recommendations described in section A below.[13] Section B below describes our recommendations regarding revising the labeling of the SODF to indicate that a PCID has been incorporated.

A. Reporting Categories

The applicant should perform a risk assessment to determine the appropriate reporting category and type of drug product testing needed to evaluate the proposed change on a case-by-case basis, regardless of previous use of the same PCID in other SODF drug products.

1. Prior Approval Supplement

If the incorporation of a PCID in a SODF would have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product, the applicant may not market the drug product with the PCID unless a prior approval supplement is submitted and approved.[14] Examples of situations in which an applicant should submit a prior approval supplement include, but are not limited to, when a substance in a proposed PCID is not a permissible food additive, a food substance that is GRAS, or an inactive ingredient used in a CDER-approved SODF (as indicated by IIG), or if it poses the risk of an adverse reaction in patients. In such circumstances, FDA encourages the applicant to contact the appropriate clinical review division for guidance on how to provide a toxicological assessment to the Agency.

2. Changes Being Effected Supplement

If the incorporation of a PCID in a SODF would have a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product, the applicant should submit a CBE-30 supplement at least 30 days before distribution of the drug product made using the change.[15] Examples of situations in which an applicant should submit a CBE-30 include, but are not limited to, a situation in which the applicant proposes to add a PCID (which is not a PCID for which a prior approval supplement should be submitted) to a core section of the SODF or to a section of an SODF-MR that contains a release-controlling excipient.

3. Annual Report

If the incorporation of a PCID in a SODF would have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product, the applicant should describe the addition of a PCID to the drug product in its next annual report.[16]

B. Labeling

Applicants should review the statute and all regulations to determine how the incorporation of a PCID may impact the labeling of their drug. FDA does not intend to object if ingredients used as PCIDs are not included in the list of ingredients in a drug's labeling. If the incorporation of a PCID changes the identifying characteristics (e.g., color) of the SODF, then the labeling must be

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[13] See 21 CFR 314.70.
[14] See 21 CFR 314.70(b)(1)
[15] See 21 CFR 314.70(c)(1) and 314.70(c)(4).
[16] See 21 CFR 314.70(d)(1)

revised in accordance with 21 CFR 201.57(c)(4). All labeling changes are subject to the submission and approval requirements under 21 CFR 314.70.

RAMBOLL

ENVIRONMENT
& HEALTH

Mike Hogan, PhD
Vice President, Life Sciences
Applied DNA Sciences
50 Health Sciences Drive
Stony Brook, NY 11790

GMO WHITE PAPER

Date July 11, 2018

Dear Mike,

Attached is our White Paper. As explained there:

- SigNature DNA is not itself a genetically modified organism (GMO) because it is too short to carry any functionality associated with a gene or an organism;
- The use of SigNature DNA applied to other organic products does not make the other products genetically modified (GMO) because SigNature DNA is not inserted into the gene of the other product by Applied DNA Sciences and SigNature DNA has no ability to insert itself;
- SigNature DNA does not fall within the accepted definition of "Synthetic Biology" as it does not encode a transcribable protein and contains none of the control elements required to do so;
- If SigNature DNA was released from products on which it was used, its fate would be like that of the millions of tons of DNA that are released annually in plant pollen, leaves, feces, and dead organisms it would simply be broken down and used as food by environmental micro-organisms (bacteria and fungi).
- Our full analysis is in the July 2018 report, attached, entitled, *"Does the Use of Applied DNA Sciences' DNA Tags Make Products "GMO"?"*

Yours sincerely

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Prepared for
Applied DNA Sciences

Date
July 2018

DOES THE USE OF APPLIED DNA SCIENCES' SIGNATURE® DNA MAKE PRODUCTS "GMO"?

RAMBOLL

DOES THE USE OF APPLIED DNA SCIENCES' SIGNATURE® DNA MAKE PRODUCTS "GMO"?

Date **July 11, 2018**

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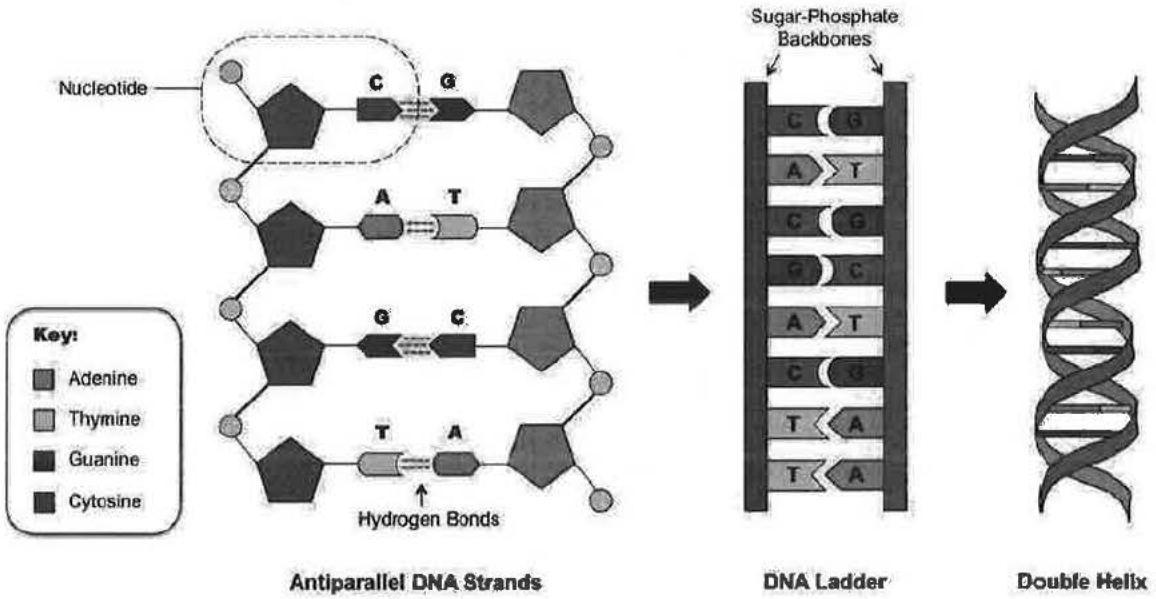
CONTENTS

Does the Use of Applied DNA Sciences' SigNature® DNA Make Products "GMO"?

What is DNA?

DNA is a special kind of polymer – a material made up of long chains of repeating units. Unlike the repeating units in a simple polymer, like polyethylene (the stuff plastic grocery bags are made from), in which all the repeating units are the same, DNA is made up of four different repeating units (nucleotides). Each nucleotide contains a phosphate group, a sugar molecule (ribose), and one of four different organic bases (adenine, guanine, thymine, or cytosine – A, G, T, or C). The structure of these bases and of the polymeric chain of DNA is such that DNA normally occurs as a double-stranded chain in which a base in one strand is complemented by a different base in the other strand – A is always opposite T, and G is always opposite C, and vice versa, as shown below.



(from http://ib.bioninja.com.au/standard-level/topic-2-molecular-biology/26-structure-of-dna-and-rna/dna-structure.html)

This pairing of bases in the two strands in this way serves to stabilize the structure, making it resistant to degradation. This is why it has been possible to recover intact DNA from the remains of mammoths frozen in the arctic tundra for 10,000 years, or even from older fossils.

The sequence of these bases in the DNA molecule can be read by forensic techniques. When the DNA comes from a person, this forms the basis of use of DNA in crime investigation, to determine if the DNA comes from a specific individual. The DNA strands in a human, or other living creature, are millions of base-pairs long, and contain the coded genetic information needed by the organism to produce proteins, though only if they have a "promoter" region at the beginning can they be translated by the cell's machinery to produce a protein. By comparison, the SigNature® DNA strands used by Applied DNA Sciences (ADNAS) as identification tags are just a few hundred base pairs long, contain no genetic information, and do not contain promotor sequences, so even if they somehow avoided the normal defense mechanisms of the body and

reached a cell, they could not be translated into any protein, or have any other effect in the cell. This is rather like the comparison between the very specific sequence of letters, spaces, and punctuation needed to make up a book, and a short random sequence of letters that conveys no meaning, except, perhaps, as a security code, which is precisely the function of the SigNature® DNA tag.

Where is DNA found?

If TV shows like *CSI: Crime Scene Investigation* and other crime dramas have taught us anything, it is that DNA is everywhere. You only have to drink from a glass, brush your hair, or go to the bathroom, and you leave behind a trail of DNA. DNA is part of every living thing on the planet (except for RNA viruses). Landenmark et al. (2015) estimated that the total amount of DNA on the planet is approximately 50 billion tonnes (about 100 trillion pounds). Every spring, trees and other plants release tons of DNA in their pollen (Doerfler and Schubbert 1998; Jonas et al 2001), and virtually everything you eat, if it comes from a plant or an animal, contains DNA.

It is estimated that a typical human diet provides 0.1 to 1 gram of DNA/person/day (Jonas et al. 2001). Because the DNA content is higher in meats, particularly organ meats, than in plants, DNA intake is higher in meat-eaters than in vegetarians (Jonas et al. 2001). In addition. Our entire body, particularly our lower gastrointestinal tract, is home to a variety of commensal microorganisms. It has been estimated that the human body contains about 38 trillion bacteria (mostly in the colon) (Sender et al 2016), each of which would contain about 4-5 fg of DNA.

What does "GMO" mean?

Genetically modified organisms (GMOs) are living organisms whose genetic material has been artificially manipulated in a laboratory through genetic engineering. This creates combinations of plant, animal, bacteria, and virus genes that do not occur in nature or through traditional crossbreeding methods.[1] The first type of GMO to be introduced commercially involved the extraction of a gene from one type of organism, and insertion of that gene into another organism to supply a desirable feature.

More recently, techniques have been developed by scientists so that rather than transferring an existing gene from one organism to another, scientists synthesize an artificial gene and introduce that into the host organism so that it produces a desirable product that it does not normally produce. This technique, called "synthetic biology," is defined as "*the design and construction of new biological parts, devices and systems that do not exist in the natural world and also the redesigning of existing biological systems to perform specific tasks.*"[2] Another type of modern GMO technology is a gene editing method called CRISPR. This enables scientists to directly edit parts of the genome by removing, adding, or altering sections of the DNA to activate or deactivate genes within a living organism to produce a desired effect.

Whichever method is used, the production of genetically modified organisms involves the deliberate alteration of the genetic material within the cells of an organism using sophisticated technology.

[1] https://www.nongmoproject.org/gmo-facts/
[2] http://non-gmoreport.com/articles/gmos-2-0-new-technologies-new-risks-no-regulations/

Is a SigNature® DNA tag GMO?

As noted above, SigNature® DNA tags are just a few hundred base pairs long and contain no genetic information. They are not organisms, and are not produced by organisms; so, by definition, they cannot be GMO.

Does adding a SigNature® DNA tag to something make it GMO?

As the term, "genetic engineering" implies, it takes more than adding a fragment of DNA to an organism to make it a GMO – it requires sophisticated technology to manipulate the genes of an organism. This may involve use of a specially modified virus to transport the DNA extracted from one organism and insert it into the nucleus of the cell being modified. Some viruses are capable of incorporating their own DNA into the cell's DNA, but they have evolved this ability over millennia, and do so with the aid of specific DNA sequences in their own DNA that have evolved to match sequences in their host's DNA. They also require a specific viral protein (integrase) that catalyzes the insertion of the viral DNA sequences into the host DNA (Hindmarsh and Leis 1999). Without these prerequisites, a piece of DNA, like a SigNature® DNA tag could not become integrated into a cell's DNA, even if it could evade the body's defense mechanisms, and make its way into the nucleus of a cell. Other genetic engineering methods by which foreign DNA can be made to enter a cell involve using a powerful electrical field to force the DNA into the cell nucleus, or even a "gene gun" or "biolistic particle delivery system," which fires particles of a heavy metal (e.g., gold or tungsten) coated with DNA into the target cell (Sudowe & Reske-Kunz 2013). These forms of complex technology are absent in the case of the SigNature® DNA tag. There is no "artificial manipulation" of the genetic material of any organism, no "genetic engineering" of any organism, and no "synthetic biology."

Because the SigNature® DNA tag is not incorporated into an organism's DNA, and does not have the ability to do so itself, its use does not make anything it is used with GMO. If it did, we would all become GMO every time we ate anything that came from a living organism, or breathed in a pollen grain, since each of those events exposes us to much more DNA than is present in the SigNature® DNA tag. That would be like expecting that a scrap of paper with a few letters scribbled on it and placed inside a book would change the text of the book. It is simply not physically possible without complex technology – a word processor in the case of the letters and the book, or a laboratory with sophisticated genetic engineering technology in the case of the DNA, whether from a SigNature® DNA tag, or a tomato or a pollen grain.

Could SigNature® DNA tags be released from the products to which they are applied and have adverse effects in the environment?

As described above, the small fragments of DNA that comprise SigNature® DNA tags are specifically designed to have no genetic function, and are not capable of affecting the genetic material of organisms. As a result, they present no risk to the environment. Also, as described above, the organisms in the environment contain about 50 billion tonnes (about 100 trillion pounds) of DNA. If SigNature® DNA tags did become released, the few micrograms of non-functional DNA would join the millions of pounds of DNA released every spring in tree and other plant pollen, every fall in fruits, and every day in human and animal feces, none of which presents any hazard, except the small fraction that occurs in the form of self-replicating,

infectious organisms. SigNature® DNA tags are not self-replicating, are not infectious, and are not organisms. Any such fragments of DNA that were released would simply be broken down and used as food by environmental micro-organisms (bacteria and fungi).

Conclusions

While the SigNature® DNA tag is itself artificially synthesized to contain a specific short DNA sequence, that scrap of DNA has no ability to affect the genetic material of any organism it comes in contact with. As a result, its use does not make any product it is used with GMO, and it presents no risk to product users or to the environment.

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Professor John McMillan AO
C/O Narcotic Drugs Act Review Secretariat
Health Products Regulation Group
Australian Government Department of Health
PO Box 100 Woden ACT 2606

1 April 2019

Dear Professor McMillan,

I am writing in response to your request for comments from interested parties on the terms of reference for the Review of the *Narcotic Drugs Act 1967* (the Act).

OVERVIEW OF TILRAY:

Tilray is a global leader in medical cannabis research, cultivation, processing and distribution. We aspire to lead, legitimise and define the future of our industry by building the world's most trusted cannabis company. A proud pioneer, we are the first GMP-certified medical cannabis producer to supply cannabis flower and extract products to tens of thousands of patients, physicians, pharmacies, hospitals, governments and researchers on five continents.

Tilray's experience is unmatched worldwide. Our team of professionals on the ground in 7 countries serves thousands of patients around the globe. Our flagship cultivation facility is among the most advanced in the world. As laws regarding medical cannabis evolve in different jurisdictions, we are actively seeking to expand our operations.

Tilray is the first GMP-certified medical cannabis producer to supply cannabis flower and extracts. All our products are produced with meticulous care to ensure the highest quality, consistency and purity for our patients.

We are committed to scientific research that leads to an improved quality of life for patients in a time frame that matters. We partner with leading hospitals and universities to advance the clinical applications of cannabinoids.

Tilray takes tremendous pride in our customer service, patient outreach, and physician interaction. We recognise the importance of tracking potential adverse events as well as therapeutic benefits to ensure the safety of our patients.

TILRAY AUSTRALIA & NEW ZEALAND:

Tilray was the first company to legally export medical cannabis from North America to Australia and New Zealand. Today, Tilray is one of the leading providers of medical cannabis in Australia and New Zealand for commercial, compassionate access and research purposes.

BEST PRACTICE REGULATION:

The Australian Council of Australian Governments (COAG) has agreed that all governments will ensure that regulatory processes in their jurisdiction are consistent with the following principles:

1. establishing a case for action before addressing a problem;
2. a range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;
3. adopting the option that generates the greatest net benefit for the community;
4. in accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:

    a) the benefits of the restrictions to the community as a whole outweigh the costs, and

    b) the objectives of the regulation can only be achieved by restricting competition;
5. providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear;
6. ensuring that regulation remains relevant and effective over time; and

7. consulting effectively with affected key stakeholders at all stages of the regulatory cycle; and government action should be effective and proportional to the issue being addressed.[1]

The Act was passed in 1967. Endnote 3 of the Act indicates that the Act has been extensively amended since 1967. Notwithstanding, the Act does not articulate any clear policy objectives and fails to meet the best practice regulatory principles adopted by COAG.

Manufacturers, suppliers, and medical professionals (including doctors and pharmacists) currently must meet multiple sets of Australian, State and Territory standards, depending on the products or services that they deliver. This creates barriers to market entry and an unnecessary regulatory burden. It also produces excessive complexity and does not meet the needs of patients who are entitled to a quality framework that they can understand and use.

INTERACTION OF THE ACT WITH OTHER COMMONWEALTH, STATE AND TERRITORY LEGISLATION:

Page 6 of the Discussion Paper indicates that one of the major issues raised in public forums includes whether the Act interacts suitably with other Commonwealth, State and Territory legislation relating to the regulation of cannabis products and narcotic drugs. It is submitted that there is poor interaction between the Act and other Commonwealth laws and State and Territory laws, including the *Therapeutic Goods Act 1989* (Authorised Prescriber and Special Access Schemes).

In 2018 an online system was introduced to enable the lodgement of SAS applications and notifications. The TGA worked in collaboration with the State and Territory Health Departments to streamline the application processes pertaining to the prescription of and subsequent access to unapproved medicinal cannabis products in Australia.

The SAS online system includes functionality that now allows prescribers in certain (not all) States and Territories to submit an application to both the Commonwealth and the relevant State/Territory Health Department simultaneously. Prior to the introduction of this system, prescribers of unapproved medicinal cannabis products were required to complete and separately submit paper forms to the TGA and relevant State Health Department.

The TGA and relevant State and Territory Health Departments should be commended for this approach. Notwithstanding, it is submitted that dual application processes constitute an unnecessary level of red-tape which significantly impedes the independence of medical practitioners to exercise a clinical decision to prescribe medicinal cannabis under appropriate circumstances.

This red-tape is contrary to the principle that doctors are the gateway to the Australian health care system which should focus on the health of the whole person combining physical, psychological and social aspects of care.

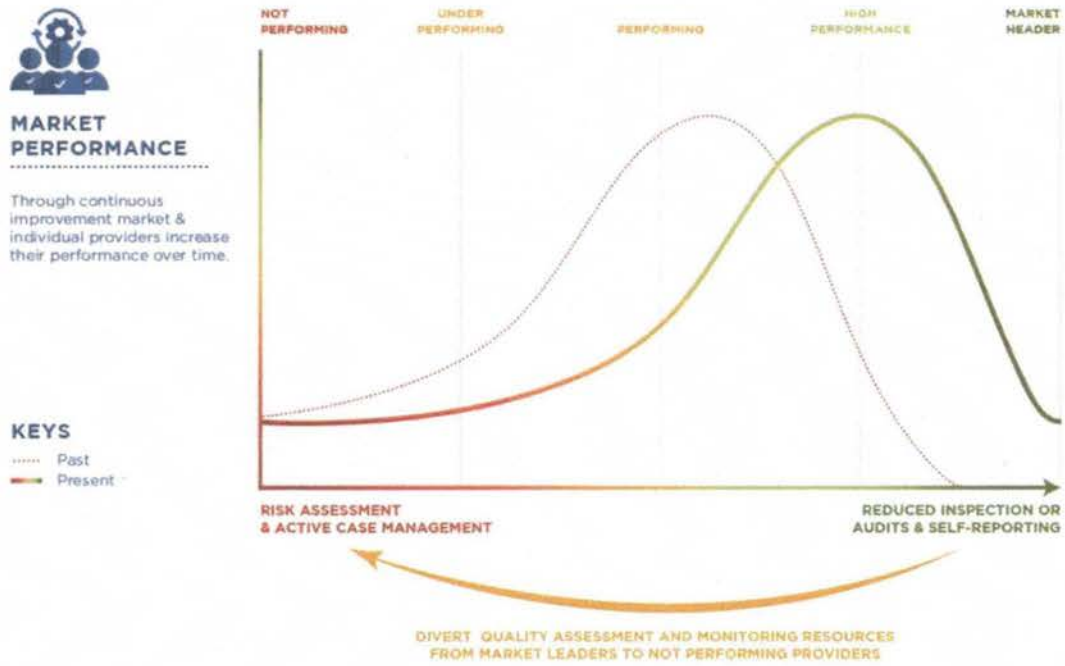
REGULATORY ROAD MAP:

In general, regulatory interventions are considered along a continuum from prescriptive command and control based regulation at the one end, towards self-regulation at the other. Traditional command-and-control based regulation does not acknowledge or reward high performance. Consequently, operators with high performance are often treated the same way as operators who are not performing.

It is recommended that the Australian Government, in consultation with the States and Territories (through COAG), develop a roadmap outlining an incremental approach to regulatory reform which is reflected in the regulatory approach/continuum below. The speed of this regulatory reform will depend upon the maturity and sophistication of the medical cannabis market and the extent to which it meets relevant standards.

REGULATORY APPROACH/CONTINUUM

Consideration should therefore be given to risk-based approaches that are less onerous for low risk operators, while focusing education, and compliance activity on high risk operators. Under this approach, organisations that show a consistent record of compliance and continuous improvement need less assurance by government. As outlined below, a risk based approach would enable these services to have less oversight and quality assessment, freeing up government resources to focus on the underperforming market segments who are struggling to meet expected standards of care and services.



CBD PRODUCTS:

CBD is a substance found in cannabis that has potential therapeutic value, with little or no psychoactive properties.

It is noted that CBD is no longer a class B1 controlled drug under the New Zealand *Misuse of Drugs Act 1975*. It is a prescription medicine under the New Zealand *Medicines Act 1981*.

Approval by the New Zealand Ministry of Health is not required to prescribe, supply or administer products for medical purposes if they meet the definition of a CBD product.

It is anticipated that the World Health Organisation will recommend that CBD be removed from the *Single Convention on Narcotic Drugs 1961*.

It is recommended that Australia follow New Zealand's lead and enable medical practitioners to prescribe products for medical purposes (without TGA or State or Territory approval) if they meet the definition of a CBD product.

Thank you for the opportunity to respond to the Discussion Paper.

Yours sincerely,

[redacted]

Ryan Fletcher
Government Relations Director

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[1] *Best Practice Regulation: A guide for ministerial councils and national standard setting bodies* (October 2007) @ 4.

United in Compassion

Review of the Narcotic Drugs Act 1967

Submission to The Review

Foreword / Note To Review Secretariat

This submission was, for the most part, authored in January 2019 before the Secretariat published it's 'Discussion Paper' of the Review.

UIC notes the following remark within that Discussion Paper:

> *This Review is restricted to a review of the operation of the ND Act. It is not a review of cannabis regulation in Australia more broadly. Matters that do not fall directly within the scope of the review are the operation of Commonwealth, State and Territory laws dealing with:*
>
> - *patient access to medicinal cannabis – for example, under the Special Access Scheme, the Authorised Prescriber Scheme and the Personal Importation Scheme established under the Therapeutic Goods Act 1989 (Cth) (TG Act);*
> - *subsidising the cost of medicinal cannabis products through the Pharmaceutical Benefits Scheme;*
> - *scheduling of cannabis products by the Therapeutic Goods Administration (TGA) and adoption of scheduling decisions by State and Territory health departments;*
> - *registration of cannabis products as prescription medicines on the Australian Register of Therapeutic Goods (ARTG); and*
> - *decriminalisation of cannabis possession and for recreational uses.*

This we believe to be nonsensical - and an attempt by officials to limit the damage and embarrassment such a Review Process may cause by casting light upon what has been, from the outset, disastrous legislation and execrable public policy causing untold damage to sick Australians.

One of the key documents we feel the Review will have need to consider is the Explanatory Memorandum of the Narcotic Drugs Act Amendments Bill which can be viewed at the below link:
http://classic.austlii.edu.au/au/legis/cth/bill_em/ndab2016250/memo_0.html

As the Memorandum makes perfectly clear, the legislation in question was designed with all or most of the issues identified in the above bulleted list in mind, thus they absolutely *do* fall into purview and operation of the Narcotic Drugs Act Amendments of February 2106. To argue otherwise would, we feel, be tantamount to an admission that legislators were being misled when asked to consider and vote on the relevant Bill.

On this basis then, we trust every issue raised by this Submission will therefore receive due deliberation and consideration in the course of your duties.

United in Compassion
March 2019

About UIC

United in Compassion is Australia's Peak Medicinal Cannabis advocacy body which helped bring about the 2016 legislative changes this Review is tasked with exploring. Founded in 2014 by Lucy Haslam and her late son Daniel, UIC's main functions since then have been to promote education and knowledge around clinical uses of cannabis as well campaigning for improved patient access to what, for many, can be a life-saving medicine. We welcome the opportunity to contribute to this Review process.

Executive Summary

This Submission posits that the 2015 Federal Department of Health Regulation Impact Statement for Medicinal Cannabis (MC) did not meet the Standards of Best Practice as stipulated by Office of Best Practice Regulation within the Department of the Prime Minister and Cabinet (see Section 3.2 of this document).

Such a failure in turn resulted in legislative and regulatory change (the 2016 Amendments to the Narcotic Drugs Act and Re-Scheduling of cannabis in the Poisons Standard) which placed the medicine into permanent 'regulatory limbo', making it available only through a pathway designed for 'exceptional clinical circumstances.' This pathway moreover usually involves the support of a medical specialist (inexpert in cannabis) and comes with the additional need for additional State & Territory approval, issues explored in the Submission's Section 3.9.2.

Further, from the outset – aside from compliance to the 1961 UN Single Convention on Narcotic Drugs - no real policy aims were identified in terms of what the legislation set out to achieve, thus *no benchmark exists against which its 'success' or 'failure' may be measured.*

The result has been that only a comparatively small number of patients (out of many tens, even hundreds of thousands sourcing illicit products) have been able to access such medicine legally and then only at significant expense. Attrition among these is reportedly high.

Additionally, the Submission also points out (Section 3.5.3) that the Federal Government's intent has never been to make 'medicinal cannabis' available to sick Australians. Instead Ministers and bureaucrats have been quite clear that the only cannabis products they wish generally accessible are those that have undergone the assessment process for inclusion on the Australian Register of Therapeutic Goods (ARTG). But they have done so without acknowledging that the financial incentives are not in place for this to occur, causing a misalignment of policy and commercial objectives.

A successful and vibrant domestic industry has failed to emerge as a consequence, further hindered by lack of resource and poor management practice within the Office of Drug Control, a point also discussed

We therefore argue only a complete overhaul of the current system – which demands will at the political level – can accomplish what UIC has always had as its Mission; that being to advocate for:

'*….patient access to Full Spectrum herbal medicinal Cannabis extracts and dried herb Cannabis in a manner which is safe, effective, affordable, equitable and favourable for patients, for the dignified relief of suffering.*'

Section One: Overview

1.1 The Review & Legislation

On 14th December 2018 Greg Hunt, the Federal Health Minister, announced a Statutory Review of the operation of the 2016 Amendments to the Narcotics Drugs Act 1967 with a report to be tabled in Parliament by 29 October 2019. The public was to be consulted as part of this Review process.

As Minister Hunt said in his announcement, the Amendments in question were intended *'to provide for the regulation of cannabis cultivation and production in Australia (&) to enable a sustainable supply of safe medicinal cannabis products for therapeutic purposes*,' whilst the Terms of Reference of the Review itself were to establish:

> *'.....whether the measures implemented are working efficiently and effectively or could be improved for the benefit of affected parties (being applicants and regulated entities as well as the department administering the Act).'*

Though in and of itself a somewhat weak and equivocal policy objective (in contrast, within Section Five of this Submission) UIC proposes a minimum further *five* such objectives against which any future medicinal cannabis Framework may be more appropriately benchmarked) even this, we suggest, was never really the primary or even secondary purpose of the 2016 legislative change. Instead, we assert it set out, first and foremost, to remain compliant with the UN Single Convention on Narcotic Drugs 1961 and as a response to immense public pressure - which had continued into the start of the 2016 General Election cycle - to 'legalise medical cannabis'.

Whilst the Review may afford some advocates, members of the public and Australia's nascent cannabis Industry the opportunity to catalogue various of the many very real negative outcomes that as a matter of fact and law have their causal roots in the aforementioned 'measures', many of these, we feel are already well documented. Instead then, this document sets out to explore how and why the legislative changes of 2016 have failed - and will continue to fail - to deliver a satisfactory medical cannabis (MC) Framework for Australia, Australian patients and the country's new Industry. Suggestions on how matters might be improved will then follow.

1.2 Overlooking Actual Reality: Illicit vs Licit Medicinal Cannabis Use in Australia

UIC's focus is, and has consistently been through the lens we feel *all* discussion of this and related issues *must* necessarily be viewed: the fact that, currently, *hundreds of thousands of sick Australians needing MC are accessing black market products of unknown provenance and completely without medical supervision, criminalising themselves in the process*. [1] This highly unsafe and grossly unsatisfactory state of affairs represents – presumably - the exact *opposite* of what Governments and medical professionals would have wished to accomplish yet has become exactly the position in which Australia now finds herself, largely as a result of the legislation under review. Failing or refusing to acknowledge this reality and its significance is to overlook arguably the single most important facet of the matter at hand – the context of *things as they actually are*. Without a full appreciation and recognition of these as the circumstances in which the Review and any other discussions take place is therefore likely to render such deliberations purposeless and a misuse of labour and other resource.

1.3 In Brief: Why the Amendments to the Narcotic Drugs Act Have Failed To Deliver A Successful Medicinal Cannabis Framework

With this at the forefront then, and in broadest terms, we would argue passage of the Narcotic Drugs Amendment Act 2016 has been singularly unsuccessful in meeting what Minister Hunt claims were its original objectives (see above) - and this for three basic reasons.

First, and not least among them, is that from the outset, the legislation was based on a Regulation Impact Assessment (RIS) that *failed to meet the Government's own Standards of Regulation Best Practice* - a major factor in the scheme's evolution hitherto overlooked and to which it is hoped the Statutory Review will pay special attention. Indeed, the Government's own 'watchdog' on such matters found the Federal Department of Health's evaluation of how the legislation would play lacked '*analysis of the practical impacts of the measure*' while noting '*more extensive consultation was required*.' This issue is discussed in greater detail within Section Three.

Secondly - we believe as a direct result of this failure - the Framework as it currently stands has served to consign MC to perpetual 'regulatory limbo' destined forever to be 'quasi-approved' (via compliance with production standards like GAP/GMP and TGOs 93 & 100) yet 'unregistered' (not included on the ARTG, thus not perceived - or able to be treated - as other (conventional) medicines). Paradoxically however, exactly this state of affairs exists regardless, and even because of, the fact that, as Australian and other State Governments repeatedly point out, passage of the Narcotic Drugs Amendment Act now supposedly means:

'Medicinal cannabis products are regulated as medicines in Australia, therefore medicinal cannabis is regulated under both state legislation and the Commonwealth's Therapeutic Goods Act 1989.' [2]

Thirdly, we feel strongly that - again from the outset and by ignoring expert advice - policy-writers and legislators, whether wittingly or otherwise, badly misunderstood the nature of 'medicinal cannabis' itself and were *mistaken* in the belief it could properly be regulated - as are conventional medicines - under the Therapeutic Goods Act to begin with. And *this*, we argue, has resulted in the unsatisfactory and troubling situation Australia is now facing.

We suggest moreover a thorough assimilation of each of the above – particularly by those setting policy - is critical for a true appreciation of why the current legal and regulatory framework for MC is – as we believe it to be - irredeemably flawed in Australia for reasons this Submission discusses in detail. Only armed with this understanding, we believe, does it become apparent why a replacement system is felt necessary. Indeed, such a replacement is, we feel, the *only* real option available if cannabis is ever to be seriously and genuinely offered as a legal treatment option for Australian patients. This of course includes the 100,000+ individuals already identified as using unregulated cannabis at present.

Sections Three and Four of this document therefore explore these ‘failure points’ in more detail after having first answered what UIC sees as an equally critical question.....

Section Two: Definition: What is (and is not) 'Medicinal Cannabis'?

Much confusion abounds in the media and the minds of the public about what 'medicinal cannabis' in fact is. This is particularly true in Australia where effort is being made and emphasis placed in transforming (via the (Cth) Therapeutic Goods Act 1989) a phytochemically complex plant into a potential suite of single-molecule therapies using a regulatory system designed for conventional pharmaceutical medicines. Such laboratory-produced, highly standardised, isolated agents, of which only one – Sativex – is currently registered for use in this country, can theoretically and for the purposes of the Act, even include synthetic substances. Importantly however, such drugs are routinely conflated with all and any other cannabis-based products, especially by an ill-informed press. [3] Thus such proprietary medicines (like Sativex and others unregistered here) are (wittingly or otherwise) thrown into the catch-all basket of 'medicinal cannabis' (or 'medical marijuana') along with herbal (i.e. ‘botanical’) cannabis itself and whole-plant oils and tinctures made from it. Conflating these though, we would argue, is extremely misleading.

For the sake of clarity therefore, UIC proposes a definition of MC that we would hope might be commonly agreed and adopted for general use in the future, standing next to the technical and medico-legal meanings found in this country's Poison Standard (SUSMP) and in numerous items of legislation

To this end, and in the avoidance of unwarranted controversy, we commend one such definition provided by two major authorities of unquestionable credibility and repute – Associate Professor Mark Ware of Canada's McGill University and the Encyclopaedia Britannica.

The latter, we hope, needs no explanation, representing arguably the most trusted source of general knowledge anywhere in the English language. Dr Ware meanwhile is among the most prominent researchers in cannabis medicine not just within Canada but in the entire world. [4]

Thus Dr Ware's contribution to Britannica we hope offers sufficient plausibility and weight to satisfy even the most fastidious and exacting of critics and can be read in its full version here:

https://www.britannica.com/science/medical-cannabis

For the purposes of this document however, the salient and defining paragraph is this one, which describes MC as:

> *'….the use of cannabis under ongoing medical supervision, with an established diagnosis of the target symptom-disease complex. Herbal cannabis is used in conjunction with, or in consideration of, other pharmacological and nonpharmacological approaches and with the goal of reaching prespecified treatment outcomes.*'

This, Dr Ware asserts, is because '*there is no inherent difference between herbal cannabis used recreationally and that used medically*' whilst going on to imply a distinction between 'medicinal cannabis' *per se* and the '*several pharmaceutical drugs based on cannabis, in purified and standardized form, (that) have been made available for medical use.*'.

Though later in his Britannica article Dr Ware does add that cannabis '*...developed for medical use.....(is) grown under carefully controlled conditions, and the drug is standardised*' he also insists that it ceases to be 'medical' if used outside of a clinical environment:

> *'Cannabis that is used in an unsupervised manner is not considered medical cannabis. The same is true for cannabis that is authorised by a physician who has not adequately evaluated the patient, who does not prescribe the cannabis as part of a wider care model, or who does not monitor the patient for subjective and objective outcomes or adverse events,'*

Such a distinction between herbal / whole plant cannabis and '*pharmaceutical drugs based on cannabis'* is particularly important, as will become clear in due course.

Section Three: In Detail: Why the current Framework has failed and will continue to fail

3.1 Background to the Narcotic Drugs Act Amendments 2016

Some background and brief history are useful and relevant here.

In February 2016 the Australian Government passed the Narcotic Drugs Amendment Act (NDAA), replacement legislation of an earlier Bill - the Regulator of Medicinal Cannabis Bill – which itself had been passed by the Senate in October 2014.

Both pieces of legislation had been in response to huge public pressure: to make MC available to those sick Australians who needed it – and came at a time when, unlike any other medicine, the fight for access to the drug was - and continues to be - a global phenomenon driven almost entirely by patient lobbying and activism alongside a growing evidence base.

3.1.1 Two Different Bills – 2015/16

The two Bills (as at the beginning of 2016) were however very different nature and in terms of what they set out to achieve. One, (the 'Regulator' Bill) aimed to create - as the name suggests - a stand-alone, specialist Regulator for cannabis while the other sought to make it a prescription medicine governed by the (Cth) Therapeutic Goods Act 1989 and jointly overseen by the Government's Federal Medical Regulator the Therapeutic Goods Administration (TGA) and by individual State and Territory Health Departments.

3.1.2 Public Inquiry – Regulator of Medicinal Cannabis Bill

Prior to enactment of Amendments to the Narcotic Drugs Act, the 'Regulator Bill' had been the subject of an almost year-long Inquiry [5] involving hundreds of public Submissions [6] and three days-worth of Hearings, [7] culminating in a thoroughgoing Report [8] by the Senate's Legal and Constitutional Affairs Legislation Committee which sat to examine the proposal.

During this time, it became clear, the State of Victoria, having run its own 2014-15 Inquiry into MC, [9] would in any case enact its own legislation irrespective of what might occur Federally whilst the Australian Senate Committee recommended that (Cth) 'Regulator Bill' be enacted. The Turnbull Government was thus forced to move since the Victorian legislation may have put Australia in contravention of the UN Convention on Narcotic Drugs, compliance with which was felt necessary to safeguard the country's lucrative poppy straw trade. [10] The Department of Health undertook an assessment of how best to proceed, producing a Regulation Impact Statement on MC [11] in late 2015 as

is required of all Cabinet Submissions.

3.1.4 Government Response

The result was that an alternate arrangement was put forward, one that would place cannabis not in the hands of a specialist Regulator as experts had argued it should, but within TGA's existing regulatory framework by amending the (Cth) Narcotic Drugs Act 1967 so as to permit the cultivation of cannabis for medical and research in purposes in Australia for the first time in over five decades. [12]

At around the same time (with further adjustments to follow) 'cannabis' was rescheduled in the SUSMP, Australia's Poison Standard, bringing CBD products of high (98%) purity into Schedule 4 of the Standard ('Prescription Only Medicines') and those containing THC into Schedule 8 ('Controlled Substances' – requiring State authorisation for use). Non-medical – i.e. unregulated cannabis products – remained within Schedule 9 ('Prohibited Substances').

It was at this point, we would argue, that whatever (if any) plans the Australian Government may have had to make MC available to those Australian patients requiring it were de-railed, as became apparent once the 'system' for MC production and distribution in Australia took effect in November 2016. [13]

3.2 Initial evaluation process of possible outcomes of the 2016 legislative changes did not meet the Government's Regulation Best Practice Guidelines

Reasons for this failure are to be found in two key documents - the Government's own Explanatory Memorandum [14] in relation to the Narcotic Drugs Amendment Bill (later Act) of 2016 and the Regulation Impact Statement referred to above, which itself became incorporated into the Explanatory Memorandum.

As we have noted, producing Statements like these are standard (and compulsory) procedure in Government whenever significant regulatory developments are planned - a process is overseen by the 'Office of Best Practice Regulation' (OBPR) which sits in the Department of the Prime Minister and Cabinet.

As one would expect from an organisation tasked with administering Regulatory Impact Analysis requirements, the OBPR has its own handbook - the 'Best Practice Regulation Handbook' [15] - which sets out the standards and demands placed on Government Departments where the framing of regulation and assessment of its impacts are concerned. Meet those requirements (per the Handbook) and a Department will have achieved the expected Best Practice; failure to do so means it will not.

Unfortunately, the Regulation Impact Statement for Medicinal Cannabis *did not* meet

those standards, with the OBPR commenting that:

> *'The Office...assessed the RIS prepared by the Department Health as compliant with the Government's requirements but not best practice. To achieve best practice more detailed analysis of the practical impacts of the measure and more extensive consultation was required.'* [16]

To this it should be added, the Narcotic Drugs Amendment Act was passed by Parliament in record time making it possible the majority of members of both houses may not have had time to read or fully understand the Explanatory Memorandum or the Regulation Impact Statement it contained. With this in mind, it becomes easy to see why United in Compassion and many others believe Australia's current MC system has floundered: *the 'system' does not, nor ever has, adhered to the Government's own guidelines and prescriptions for achieving best practice in regulation and policy-making*.

It should also be noted in the year 2015-16 when the Regulation Impact Assessment was created, 78% of all such documents submitted to the OBPR achieved the designated Best Practice standards, [17] placing the Department of Health's exercise well into the bottom quartile of Assessments appraised by that Office and among a minority of 'fails'.

Thus from the outset, far from setting any meaningful policy objectives such as those UIC identifies in Section Five and then devising a strategy to meet them, individuals responsible for this country's MC 'system' as it is currently seem to have sought only to keep as tight a rein on the medicine as possible – ostensibly to comply with the UN Convention – and to have had little regard for all else.

3.3 System 'A Basket Case' – RACGP President

The result, which for over two years has been widely discussed and criticised both in the media and within medical advocacy circles, has been – from the patients' perspective – a disaster, one the now-immediate past President of the RACGP Dr Bastian Seidel described (while in post) as a 'basket case'. [18]

3.4 Case Proven: ODC Internal Audit 2017

Such a view of the extent to which substandard management practices have contributed to this present unsatisfactory situation was amply borne out by an Internal Audit of the ODC from 2017 [19] obtained by The Australian Newspaper [20] under a Freedom of Information request this January and seen by UIC.

The Audit and accompanying Report were undertaken and prepared by Protiviti, a Management Consultancy firm, and dealt with the ODC's handling of applications for MC cultivation, manufacture and research licences in Australia, of which there was at the time and remains a considerable backlog.

3.4.1 Findings of Audit, ODC Under-resourced etc.

Among other things, Protiviti found the ODC to be substantially under-resourced, an observation to which the Department of Health replied: '*Given the present financial situation of the Department it is unlikely that the effort in closely mapping the resourcing required would lead to an increase in resources for the medicinal cannabis program*.'

Notwithstanding that comment, the RIS being discussed in this Section originally identified an initial cost of running an MC programme of $407,000 - clearly a gross underestimate subsequently bolstered when '*last month, however, (December 2018) the government quietly allocated a further $4.4 million over two years for "assessment and compliance activities"*,' according to The Australian. In mid-January 2019 the ODC posted advertisements for an extra six staff. [22]

3.4.2 ODC lacking objectives, leadership etc.

Unsurprisingly, given the RIS never met the Government's own Best Practice Standards, Protiviti's Report also appears to identify the fact that the ODC - at the time, and one suspects currently - had no clear policy objectives so was provided with guidance by the Consultancy which identified thirteen characteristics it felt '*effective regulatory arrangements (and regulators) should demonstrate'.* These included having '*clearly defined objectives and a defined regulatory philosophy and approach*' as well as an understanding of '*the complexity of regulation (while striving) to undertake its mandate in the most efficient and effective manner possible*.'

Tellingly, the Consultancy also pointed out such tasks should '*embed the principles of regulatory best practice in all of (their) activities*,' which as we have already established, from the outset they manifestly did not.

3.4.3 Characteristics & Principles of Best Practice in Regulation

Equally, the other twelve 'characteristics' highlighted by Protiviti are precisely what UIC believes Australia's MC 'Framework' lacks as a whole - not just in terms of the administration of licensing matters. Besides these and those of the Office of Regulation Best Practice, Protiviti additionally specify out a further framework also exists for managing regulatory performance – those of the Australian National Audit Office (ANAO) which suggests such practice should focus on:

1. Defining regulatory outcomes and administrative priorities;
2. A risk-based approach to regulatory administration;
3. Effective stakeholder relationships;
4. Effective information management;
5. Transparency and accountability;
6. Managing regulatory capability; and
7. Measuring, reporting and reviewing regulatory performance.

UIC questions whether any evidence exists to suggest those drafting and enacting the Narcotic Drugs Act Amendments now or in the past succeeded or even made efforts to ensure points 1-7 were effected in the course of their work – since we contend they were not. Assuming this to be the case however means *Australia's MC 'Framework' neither currently has - nor has ever had - a clear set of objectives against which progress could or can realistically be benchmarked.*

And such a failure to meet the Government's Best Practice Guidelines on Regulatory Impact or the ANAO framework when creating Australia's cannabis 'policy' was, we feel, the first – and arguably most significant – of many additional errors and provides the context for all else that followed.

With this in mind, it is hardly surprising that the current 'system' has been criticised – and we suggest any future changes in policy, legislation or regulation are undertaken only *after an analysis of their possible impact has met with Government's own Best Practice Guidelines* per the OBPR and the ANAO frameworks.

3.5 An 'Approved Unapproved Medicine': Australia's current Framework consigns cannabis forever to 'regulatory limbo'

In November 2018 the TGA announced that 568 approvals of MC prescriptions had been granted that month, [23] bringing the total number to 2339 for an estimated (though unconfirmed) 2,000 patients. The November approval rate was, the TGA said, its highest ever, though, despite requests, no breakdown of figures on a State-by-State basis has been forthcoming (perhaps unsurprising; in Tasmania, for example, the number of patients in November 2018 totalled seven). [24]

Almost all of the MC products made available had (and have always) been imported from overseas since to date (at time of writing – January 2019) only one Australian company (The Little Green Pharma Co) has succeeded in bringing a domestic product to market. [25] Whilst the apparent inertia and lack of activity in this country's embryonic (legal) cannabis industry may speak volumes about the success or otherwise of the current Australian 'system', perhaps the most significant point to be made concerns the regulatory status these medicines 'enjoy'.

3.5.1 How Cannabis Products Are Currently 'Approved'

The TGA and its recent (2015) offspring the Office of Drug Control have in place (quite correctly) various standards relating to the cultivation and production of cannabis and cannabis medicines whether originating in Australia or overseas. Hence imports and (so far mostly theoretical) locally sourced goods alike must be grown using Good Agricultural Practices (standards laid out by the Food and Agricultural Organization of the United Nations), Good Manufacturing Practice (as stipulated by the PIC/S Guide to GMP) as well as the Therapeutic Goods Orders #93 & #100 – the TGA's 'Standard for Medicinal Cannabis' - and 'Microbiological Standards for Medicines' respectively.

To the extent that *every* cannabis product available here *must* comply with these standards, they can clearly be said, in one sense, to be 'approved for use in Australia' yet none (save for Sativex, already mentioned) has been evaluated for inclusion on the Australian Register of Therapeutic Goods (ARTG) which lists products that can be legally supplied in this country. Thus, in an equally substantive and highly consequential way, are these medicines simultaneously '*unapproved* for use in Australia', leaving them, as we've already argued, in an incoherent state of 'regulatory limbo' – quite literally, simultaneously *'approved unapproved medicines'*.

At this juncture we must turn to the two documents cited earlier – the Explanatory Memorandum of the Narcotic Drugs Amendment Bill 2016 and the Regulatory Impact Statement for MC the Memorandum contains – and which comprises the analysis upon which the Bill's purpose and intent for the most part was fundamented.

3.5.2 By Its Own Admission: How 'Regulatory Limbo' was planned from the start

From the outset, it appears, the Department of Health was not only *aware* that cannabis would be designated 'neither fish nor fowl' from an 'approved medicines' perspective - it purposely designed a system that would ensure that exactly this happened, as the below two quotes from the (non-Best Practice compliant) RIS attest (our emboldenment):

> *'**The option (of regulating MC Federally) will not necessarily bring a medicinal cannabis product to registration on the Australian Register of Therapeutic Goods (ARTG), in the short or medium term,** but will facilitate further clinical trials that may support such a registration in the future. Cannabis material cultivated and manufactured in Australia would be able to be used to conduct clinical trials and **develop therapeutic products to be used in accordance with the Therapeutic Goods Act.'***

And:

> *'Assuming there is a suitable source of cannabinoids available; pathways for lawful access to cannabinoids for medicinal use are:*
>
> 1. *Medicines registered on the Australian Register of Therapeutic Goods (ARTG);*
> 2. *Clinical trials (such as the trials being conducted in New South Wales and Victoria); and*
>
> 3. *The Special Access Scheme (SAS) and Authorised Prescriber Scheme (AP).*
>
> ***Access to cannabis for medicinal purposes through the first pathway, such as occurred for Sativex, requires a robust dossier of clinical trial and other data and is commonly submitted after some years of significant***

commercial investment.' (Our emboldenment).

3.5.3 The Australian Register of Therapeutic Goods: Of no use to cannabis or cannabis products

Leaving aside for now the matter of '*pathways for lawful access to cannabinoids for medicinal use*' other than the ARTG; as the above statements make clear, whilst the *intent* of the legislation has always been to encourage the development of '*therapeutic products to be used in accordance with the Therapeutic Goods Act*', even in 2015 the Government realised this could (and then only might) occur after '*some years of significant investment*'. Thus by its own admission and even in its exact words, the option of regulating MC Federally would '*not necessarily bring a medicinal cannabis product to registration on the Australian Register of Therapeutic Goods (ARTG), in the short or medium term.'*

At the same time however, and crucially, policy-writers had ignored advice handed them by many experts and by the Senate's Legal and Constitutional Affairs Legislation Committee during and after the Public Inquiry into the Regulator of Medicinal Cannabis Bill discussed in Section 3(A). Instead they decided to favour the views of organisations like the Australian Medical Association and others [26] long opposed to the use of medicinal cannabis as such, arguing rather for the development and use only of '*pharmaceutical drugs based on cannabis'.*

3.5.4 Opponents of MC shape policy and legislation

Indeed, quoted within the same Regulatory Impact Statement already cited, the AMA makes its position explicitly clear on the matter, saying:

> *'Smoking or ingesting a crude plant product is a risky way to deliver cannabinoids for medical purposes and other appropriate ways of delivering cannabinoids for medical purposes should be developed.'*

For 'risky' 'completely unacceptable' is actually meant, yet, save for the element of 'smoking' (no clinician in the world known to us recommends ingesting cannabis in such fashion) it needs to be stressed the above statement is factually wrong in several respects – issues discussed in Section Five**.**

Just as importantly though, it is at this point the definition of 'medicinal cannabis' itself takes on appreciable importance, since the Mark Ware/Britannica view of the matter described earlier (and which UIC suggests be adopted as a commonly agreed meaning) differentiates and distinguishes between 'medicinal cannabis' *per se* ('*there is no inherent difference between herbal cannabis used recreationally and that used medically*' Ware says) and '*pharmaceutical drugs based on cannabis'.*

3.6 Legislation (2016) never intended to make MC readily available to sick Australians

The reason we go to such considerable pains to emphasise this is that it is our contention the Amendments to the Narcotic Drugs Act 1967 were *never* intended to make *actual* 'medicinal cannabis' (per the Ware/Britannica definition) available and were *always* in order to create an environment in which pharmaceutical products made from it might be developed. Indeed, these, in practice are the *only* types of product the Therapeutic Goods Act 1989 is capable of regulating save from those within the quite separate realm of complementary medicines (and from which cannabis is excluded because of its Scheduling in the Poisons Standard).

To the counter-argument - that this was always the intention and nothing is wrong since it is done for all other drugs and medicines - we would point out, as discussed further below, neither the commercial incentive nor practical means exists to regulate cannabis in this manner.

3.7 Legislation (2016) enacted against the majority of expert advice after *six* Public Inquiries

Such an intent also flies in the face of the vast majority of evidence presented at the ***six*** Public Inquiries into MC that have occurred in Australia to date [27-32] – including the large Federal Inquiry into the Regulator of Medicinal Cannabis Bill 2014.

A review of these half-dozen Inquiries in general and the Federal Inquiry in particular would, we argue, overwhelmingly demonstrate that, if the Government had been (or is) *genuinely serious about making cannabis available for medical purposes to Australian patients* it would regulate the drug *outside* of the Therapeutic Goods Act 1989.

Such a view was propounded by (among others) Emeritus Professor Laurence Mather of Sydney University in both his Public Submission to that Inquiry [33] and in the oral evidence he provided to the Inquiry's Public Hearing in Sydney (one of three day's-worth of such events that were integral to the proceedings). [34]

Here Professor Mather made clear:

> *Conventional regulatory bodies have no framework for examination and approval of potentially variable mixes of drugs. Conventional pharmaceutical companies have little to gain from investing in natural products that cannot be patented or bear an illegal drug label.'*

3.8 Additional reasons current Framework unsuitable for Medicinal Cannabis: 'Enourage Effect/Personalised Medicine

In addition to this, many clinicians and scientists experienced in cannabis medicine as well as their patients consider that precisely *because* cannabis itself cannot properly be considered a 'single drug' but is rather a natural product composed of a plethora of

disparate compounds, the 'whole plant' is superior in its efficacy to any single-agent derived from it. [35] This is known as the 'entourage effect' meaning, in simple terms, its chemical components act synergistically and perform as a whole – the combined effects of which appear to be greater than the sum of its parts.

As Dr Ethan Russo – among the world's foremost cannabinologists and a recognised expert in this matter in particular recently put it:

> *Although the single molecule synthesis remains the dominant model for pharmaceutical development (Bonn-Miller et al., 2018), the concept of botanical synergy has been amply demonstrated contemporaneously, invoking the pharmacological contributions of "minor cannabinoids" and Cannabis terpenoids to the plant's overall pharmacological effect.'* [36]

While this Submission does not seek, nor is designed to offer any clinical commentary or opinion of its own, next to this we would nevertheless additionally note that many experienced clinicians insist a personalised approach both to the patient and the drug itself is desirable. [37] This is because its effects may vary between individuals while different cannabis cultivars are said to possess quite different qualities. In short, with cannabis medicine one size may not fit all – while products regulated by the Therapeutic Goods Act and which are included on the ARTG absolutely *demand* that they do. Put next to the fact that cannabis is extraordinarily versatile and effective in an uncommonly wide range of clinical settings [38] and two problems more are added as to why, at this stage, attempts, to regulate the drug 'like other conventional medicines' will not deliver good outcomes to patients. They also help explain why the approach has been rejected in all jurisdictions with well-functioning MC programmes. [39]

3.8.1 UIC's Position on the above

None of this is to suggest however that UIC does not advocate further investigation into cannabis or the eventual creation of new, proprietary cannabis-based products. Over 80 years of continued international prohibition have meant research into the plant's therapeutic uses has been exceedingly difficult. It is thus possible – highly likely even – that an entire array of extremely promising and effective new medicines will one day find their way into the market – and onto the ARTG. Herbal cannabis on the other hand cannot and never will join the Register - for reasons touched on above. We contest in the meantime that the latter – *actual* medical cannabis in other words – *should and must* be made available to patients while being *regulated in a logical and reasonable way*. It should not, and never should have been, placed - as it is now - within what is at best an inelegant, self-contradictory legal and regulatory position within which it appears destined to remain in perpetuity unless significant legislative and/or regulatory change is forthcoming.

The above having been said, UIC recognises and fully predicts the TGA and some in the medical profession will argue that the system in place currently is adequate and in fact

working well. They will refer, in all probability, to the approval figures cited at the top of this sub-section and argue this apparent month-on-month increase testifies to the growing success of Australia's existing cannabis 'Framework'.

To such arguments – recalling the entire system and legislation behind it was predicated on an assessment the Government itself said required '*more detailed analysis of the practical impacts of the measure'* and about which *'more extensive consultation'* was needed – UIC would take strong exception: *since no policy objectives appear to exist currently, nor were ever devised to begin with, no benchmark exists against which success or failure may be measured.*

In short then, the regulatory position we describe has created - and will continue to cause - such negative outcomes for any presumed MC 'programme' in Australia that, where patients at least are concerned, in practice, no real or properly designed 'programme' to speak of is actually in operation at all.

The consequences of such a regime on the other hand are readily identifiable.

3.9 Inadequate Pathways to accessing cannabis – the consequences of a failed MC programme

Firstly, the current 'system' ensures access to MC is *only* available (legally) through the 'pathways' outlined above and identified in the Explanatory Memorandum of Narcotic Drugs Amendment Act 2016 and in the Regulation Impact Statement it contains - both cited previously. As a reminder, these pathways are comprised of the following - meaning access to cannabis products can be via:

1. Medicines registered on the Australian Register of Therapeutic Goods (ARTG);
2. Clinical trials; and
3. The Special Access Scheme (SAS) and Authorised Prescriber Scheme (AP).

Looking at each in turn, although doctors are largely unhindered when prescribing drugs listed on the ARTG, issues already highlighted demonstrate a complete absence of any utility for this as a 'pathway' for cannabis or cannabis products now or in the foreseeable future. And where herbal/whole plant cannabis is concerned this is ***forever*** an impossibility, in part because of its scheduling within the SUSMP.

3.9.1 'Pathway' One: ARTG

Thus the ARTG's current (completely aspirational) role in the drug's regulation (the *hope* that 'cannabis-based pharmaceuticals' will one day appear) the Register in fact serves to *impede* access to the products patients have been demanding: that is, herbal cannabis and 'whole-plant' products made from it.

As the primary and official repository of legally available drugs in Australia, the ARTG speaks to how such medicines are evaluated, sold, obtained, perceived, marketed and subsidised so its role and importance cannot be overstated, nor, *in the absence of any alternative*, the ramifications for products *not* listed within it.

While these facts alone should be sufficient to raise serious concerns about the suitability and adequacy of instruments like the Therapeutic Goods Act 1989 and the ARTG properly to regulate cannabis, the other three pathways referred to we find equally unsatisfactory and problematic. This, we argue, is the case *irrespective and regardless* of the TGA's citing of modestly upward-moving approvals figures for November 2018 and onward. These, we would claim, represent little more than an attempt to convey a sort of 'Australian cannabis success story' while – to some extent anyway – bowing to the considerable and unremitting public pressure characteristic of the MC debate in this country since at least 2014.

3.9.2 'Pathway' Two: Special Access Scheme, 'Record Approval Levels' and use of an unsuitable system

The 'record November figures' mentioned earlier are themselves in reference to Federal (TGA) cannabis prescription approvals, all accomplished via use of the second form of 'pathway' identified: the TGA's Special Access Scheme – which, we must begin by making clear, was and is in this instance *being employed in a role for which it was never intended*. The SAS, according to the TGA website, was created ***'for health practitioners who wish to access therapeutic goods that are not in the Australian Register of Therapeutic Goods (ARTG) and are not otherwise exempt from being in the ARTG'***. [40]

This however – and in the TGA's own words – is pathway designed and intended only '***for exceptional clinical circumstances***' (TGA's emboldenment). [41]

As an organisation advocating for medical cannabis, UIC is acutely aware – as we have already made clear - there are currently many thousands of individuals using the drug solely for medical purposes across Australia (and millions doing so worldwide). [42] Whilst it remains true almost all domestic users are obliged to source their medicines from the illicit market for use without clinical supervision (including of children with complex conditions, often rare forms of intractable epilepsy) it cannot realistically be argued these circumstances are remotely 'exceptional'. This situation of course remains true regardless of the extent to which politicians, bureaucrats and elements within the medical profession would like to believe or insist otherwise. The reality is that cannabis *is* widely used and its use (as a medicine) is growing in both popularity and ubiquity. [43]

Thus, regardless of how much the Government and elements within the medical profession wish to view and proclaim use of MC products as appropriate only for these

'*exceptional clinical circumstance*s' the truth of the matter is that they are clearly and obviously far from it – as vast and growing data from across the globe increasingly illustrate. [44] *Any* 'pathway' to a legal MC supply therefore that is for use only in these 'exceptional circumstances' is, we believe, *inherently and, by definition, unfit for purpose*.

Thus, regardless of how much the Government and conservative forces within healthcare wish to view and proclaim the use of MC products as appropriate only for these 'exceptional clinical circumstances', the truth of the matter is that clearly and obviously far from it- as vast and growing data from across the globe increasingly illustrate.

We would further add the SAS pathways were specifically devised for use on a one-off, patient-by-patient, case-by-case basis - each unique (or 'exceptional') and each requiring its own, unusual, distinct and sparingly used type of medicine, usually those registered for use overseas. Cannabis and cannabis patients clearly do not fall into this category, yet (as we discuss below) their treatment *does* require a high degree of personalisation to determine the most effective protocol. [45] This is extremely difficult, time-consuming and inefficient using the SAS since every product being appraised for its suitability requires a separate, long-winded application, to say nothing of repeat applications for obtaining more of the same medication.

It thus remains our contention that accessing cannabis and cannabis products via the SAS pathways offers a makeshift solution at best. It seeks to stuff the 'square peg' of MC into the 'round hole' of whatever existing regulatory apparatus happened to be to hand at the time. Such a regulatory 'stop-gap' not only flies in the face of the Quality Use of Medicines (QUM) requirements [46] but suggests little in the way of compassion and nothing in the way of wanting a truly useful or innovative solution on the part of policy-writers and lawmakers alike. The number of 'illicit' users compared to those doing so legally is testimony enough to this fact.

In addition to the use of this inappropriate 'access pathway' contorted to perform functions for which it was never designed is the fact that the 'Framework' as it currently stands requires ***two*** levels of approval or sanction, one Federal - the Special Access Scheme just discussed - the other from State or Territory Departments of Health. This, again, is due to the medicine's Scheduling in the SUSMP, since Schedule 8 substances are controlled by State Governments. And while UIC acknowledges and has seen evidence of efforts by the Federal Health Minister to 'streamline' this two-tiered procedure and - via the introduction of an online 'single application' portal – harmonise the process across all S&Ts, such an initiative, we believe, *has failed in conspicuous fashion.*

Notwithstanding the TGA's withholding a breakdown of the number of SAS approvals on a State-by-State basis this assertion is based on the fact that at least two - Tasmania and Western Australia - have refused to participate in the 'portal' project altogether [47]

and in the Northern Territory UIC understands not a single medical practitioner has been prepared to write a prescription for cannabis. [48]

Problems are aggravated further by a general insistence on the part of most State Health Departments and often by the TGA that 'specialist' doctors are required to endorse or authorise a GP's prescription for MC or undertake such prescribing themselves. It is therefore assumed a knowledge of cannabis and cannabis medicine is presumed- which is (somehow) greater than that of their counterparts in General Practice - and we know from direct experience this categorically is not the case.

The result, in any event, has been the creation of a 'postcode lottery' in Australia in which the comparatively small number of patients that can afford it are relatively likely to be able to access some cannabis product or another in certain States (we believe mainly Victoria and NSW) whilst being almost completely unable to do so in others (such as Tasmania). This creates what have been termed (in the US) 'cannabis refugees' involving patients having to move from States where MC is unavailable to those where it is not.

3.9.2.1 Minimal approval levels compared to overseas jurisdictions

Moreover, the approvals figures in Australia are unimpressive when compared to other jurisdictions in which MC is legally available. Hence, we find Canada with c. 300,000[49] patients, The Netherlands with c. 40,000 patients, [50] Germany (which legalised the drug for medical use a year later than Australia) also with c. 40,000 patients [51] and Israel with a similar number. [52] *What all of these jurisdictions have in common however are regulatory models established to deal with cannabis* **outside** *of those used for conventional medicines.*

3.9.3 'Pathway' Three: Authorised Prescribers (APs)

The 'Authorised Prescribers' (AP) scheme meanwhile – a further purported 'pathway' granting a medical practitioner the authority to prescribe a specified, unapproved medicine to multiple patients (in this instance cannabis products) – was ostensibly (and according to the Explanatory Memorandum of the Narcotic Drugs Act Amendments) implemented in order to overcome what the TGA itself admits is the '*cumbersome and costly exercise*' [53] of using the SAS pathway, discussed above and neither do these figures reflect well om Australia when adjustments for population sizes are factored.

Becoming an 'Authorised Prescriber' however requires medical practitioners to have their applications approved by a Human Research Ethics Committee (HREC) or endorsed by a specialist college, and none of these Colleges are prepared to do so in Australia. [54] Thus to the best of our knowledge and to date, almost all Ethics Committee approvals have been granted to those undertaking or involved in clinical trials, with just a single HREC alone (that of NIIM – the National Institute of Integrative Medicine) approving GPs or doctors outside of these trial settings. We understand only around ten

GPs have thus far been approved by the NIIM HREC [55] and in any case as of December 2018 the TGA's own figures confirm only 54 APs have been created in total out of a population of around 100,000 doctors, [56] 38,000 of them GPs. [57] This method of access too then, we would argue, has been wholly and glaringly ineffectual.

3.9.4 'Pathway' Four: Clinical Trials

The final 'pathway' to accessing MC and cannabis products available as a result of the 'Framework' ushered in by the Narcotic Drugs Act Amendments are the clinical trials themselves, which, we suggest, do not and should not merit the descriptor of 'access pathway' at all.

UIC naturally welcomes research into the cannabis plant and its derivatives and recognises that a number of trials are currently underway in Australia with more to follow in 2019. Common sense however dictates that exercises such as these are open to a limited number of individuals only and are absolutely *not* designed to facilitate general access to medicines among the wider population. Additionally, we are particularly critical of the attitude expressed by at least one researcher who is quoted as saying she opposed cannabis being made readily available to patients because of the adverse effects this might have on research funding. [58]

3.10 Consequences of the 2016 Legislation

We have, we hope, made the case that the 2016 Amendments to the Narcotic Drugs Act serve to place medicinal cannabis into a permanent state of what we have termed ‘regulatory limbo'. Additionally illustrated has been that this predicament has forced upon it so-called ‘access pathways’ that are – to understate matters appreciably-sub-optimal if not completely inadequate. There are however several more serious consequences the legislation (intentionally or otherwise) has precipitated.

3.10.1 Stifling of Domestic Cannabis Industry

Of these, we believe one of the most serious is the fact that it (the legislation) and its attendant regulatory apparatus has severely retarded the growth (or even, in practice, any real commencement) of a (legal) cannabis industry in Australia, and hence an affordable supply.

Whilst it is true several companies have obtained Government Cultivation, Research and Manufacturing Licences and some are now publicly listed on the Australian Stock Exchange just three have managed – to the best of our knowledge – to put 'seeds in the ground' and only one to create any locally produced medicine for sale (Little Green Pharma Co as previously mentioned).

Ample evidence exists to suggest this is partly due to poor management practices and under-resourcing within the ODC but we would also argue, it is also because the current regulatory and legislative model has – for reasons already explained - kept the market

for (licit) MC and cannabis products artificially and unrealistically minuscule (while the unregulated market continues to blossom).

3.10.2 Distortion of market/unaffordable prices

Concurrently, demand for these products is huge. Thus, by creating a scenario in which such demand is not matched by the ability to access the medicine more readily the market has become badly distorted. Development of a local cannabis industry - which would have the effect of decreasing prices - is hamstrung because of a seemingly modest demand while the growth of 'specialist clinics' (their 'expertise' not in cannabis medicine itself but negotiating the bureaucracy involved in accessing it) is ensured.

These establishments in turn prescribe imported products sold at grossly inflated prices, [59] placing them well out of reach of most patients so that, three years after the NDA Amendments were enacted, almost the only products currently available (in so far as they are available at all) are those obtained from overseas, mainly Canada. 'Licensed Producers' in the meantime are presumably adapting their business models accordingly and seeking the bulk of their custom from abroad – indeed a number are known to be doing so. [60] It is not within UIC's remit or this document's to speculate as to their likely success, nor is it of particular interest. But it does illustrate nevertheless how *millions of dollars in domestic business is being gifted to illegal operators despite cultivation and production of cannabis being perfectly permissible by Australian law under licence*.

The cost of these imported medicines – in all but one State (Tasmania, which we have discussed) is borne by the patient – which we find equally untenable. And we categorically refute the 2018 claim by a business operating one of the above-mentioned 'clinics' (happy to prescribe cannabis and cannabis products for a $300 consultation fee to individuals it believes 'qualify') that prices for such items are plummeting. [61]

In fact, we know the exact opposite to be true; on an almost daily basis UIC hears directly from sick Australians or their carers or read in the press about the preclusively high cost of such products *if* they can be accessed at all (hundreds of dollars per month – much more for medicines for epilepsy - is not an uncommonly cited figure.) [62]

3.10.3 Causes black market to flourish

The net effect has been that for most people – despite very substantial risk – the black market remains by far the most economical and realistic option for obtaining their medicines. In fact, we are aware of many dozens of illicit 'dispensaries' every one of which individually services more 'clients' than there are patients accessing legally prescribed cannabis products in the whole of Australia. This is an absurd and dangerous state of affairs in a country professing to have made MC available, placing people in harm's way from what might be poorly manufactured and / or contaminated products which are by definition used outside of the care of a doctor.

3.10.4 Prevents medical professionals accessing critical information

A further effect of the legislation – by ensuring that MC and cannabis products remain 'approved yet unapproved' medicines (i.e. meeting the high production and other standards stipulated by the TGA yet not listed on the ARTG) - has been to prevent lawful suppliers from 'marketing' (in other words providing information about) their goods to the public and doctors alike.

Subject to legislation and the Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG), the TGA makes the position explicitly clear on its website:

> *'The advertising of prescription only medicines (including medicinal cannabis preparations) to the public is prohibited.*
>
> *Prescription medicines not included on the ARTG are considered unapproved therapeutic goods and cannot be advertised in Australia to consumers or health professionals.*
>
> *Medicines accessed through the approved therapeutic goods pathways generally are, or are likely to meet the requirements for scheduling as, prescription medicines. In any case, such goods cannot be advertised to consumers.'* [63]

Since doing so is unlawful under both civil and criminal law, instead, healthcare practitioners interested in prescribing MC and cannabis products must first find a supplier's identity (provided on the ODC website) then contact the business directly before particulars may be finally provided.

This obstacle to knowledge flowing between doctors and MC suppliers, at a time when medical education is desperately needed in this sphere is unacceptable. UIC is contacted on a regular basis by medicos seeking product details where the sharing and dissemination of such information should clearly be permissible for the cannabis Industry itself. The current position therefore represents a highly inadequate and haphazard means for clinicians to acquire what is often critically important data and information enabling practitioners to assess whether MC or cannabis products may be suitable (or otherwise) for their patients.

3.10.5 Cannabis & cannabis products impossible to subsidise for the less well off

Inclusion of cannabis in this country's Pharmaceutical Benefits Scheme (PBS) is also currently out of the question since a prerequisite is that all products to be considered must be ARTG-registered. Such a subsidy therefore will never be possible for medicinal cannabis without comprehensive regulatory or legislative change.

Only an abundant and varied source of domestically cultivated product grown to the high standards already specified, readily accessible in straightforward fashion to all those who need it can possibly address these and other concerns raised within the Submission. In practice this means a decision must be taken at the political level as to whether sick Australians deserve a *genuine* programme for *actual* medical cannabis since we believe unequivocally this currently does not exist.

3.10.6 Policy-writers and legislators misled?: A misunderstanding of 'medicinal cannabis' - why the Therapeutic Goods Act is an inappropriate mechanism for its regulation

When amending the Narcotic Drugs Act in 2016 only two perceptions of the medicine and access to it were practically possible, meaning at the time legislators must have been of the belief either that:

> a) It was somehow possible for whole-of-plant cannabis itself (per the Ware/Britannica definition) to be regulated like 'conventional' medicines OR
>
> b) 'Cannabis' when used as a medicine is best (hence should only be) administered – at some unidentified future point – as a suite of proprietary single-agents derived (or not) from the cannabis plant and delivered in pharmaceutical form.

UIC's position is that neither of these propositions is currently true yet innumerable hours spent discussing the matter with politicians indicates to us that many (not all) simply fail to grasp fully the issues at stake.

Further, for reasons this Submission attempts to set out, if the two statements (a & b above) were presented to lawmakers as fact then we feel they (the politicians) were badly misled.

Section 4 Review of the arguments, notes on evidence selection and privilege, further obstacles to availability of MC

Almost all of the discussions and disagreements around this subject were, as we have said, aired fairly exhaustively, in the six Public Inquiries into MC held in Australia to date, most especially the Federal Inquiry into the cross-bench 'Regulator of Medicinal Cannabis Bill 2014'.

We strongly recommend therefore, as context and for background purposes, re-visiting (or visiting for the first time) the Public Submissions and Oral Evidence given to the Inquiry as well as the Final Report of the Senate's Legal and Constitutional Affairs Legislation Committee all of which are available at the below link:

https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Legal_and_Constitutional_Affairs/Medicinal_Cannabis_Bill

4.1 Argument for separate Regulator made, won, then rejected

From these documents, it is clear, sufficient evidence was provided to satisfy the Senate Committee that 'medicinal cannabis' should indeed be made available to patients and furthermore, for this to occur, a stand-alone Regulator would be required necessarily operating outside of the Therapeutic Goods Act 1989.

4.2 Minority against separate Regulator win policy battle

Conversely, and just as importantly, opponents of the idea (essentially, conservative elements within the medical profession together with the pharmaceutical companies with which they are frequently allied [64] were not so convincing in their objections as to persuade the Committee to think otherwise. Yet, as the below (Australian Medical Association) position cited in the Regulation Impact Statement for MC demonstrates, such views were the *only* ones seriously taken into account by the Department of Health when framing the Narcotic Drugs Act Amendments: [65]

> *'While the AMA acknowledges that cannabis has constituents that have potential therapeutic uses, it argues that:*
>
> *1. Appropriate clinical trials of potentially therapeutic cannabinoid formulations should be conducted to determine their safety and efficacy compared to existing medicines, and whether their long-term use for medical purposes has adverse effects;*

2. *Therapeutic cannabinoids that are deemed safe and effective should be made available to patients for whom existing medications are not as effective;*
3. *Smoking or ingesting a crude plant product is a risky way to deliver cannabinoids for medical purposes and other appropriate ways of delivering cannabinoids for medical purposes should be developed; and that*
4. *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'*. [66]

4.3 'Medicinal cannabis' *not* to be made readily available

Thus, regardless of the Public Inquiries' findings and the Senate Committee's Recommendations to the contrary, the Amendments did indeed ensure that 'medicinal cannabis' itself would *not* be made readily available and would instead be subjected to the (demonstrably inappropriate) regulatory processes undergone by conventional, pharmaceutical medicines.

4.4 Results of the legislation

The result, as we have argued, is that Australia has been left with a chaotic and profoundly unsatisfactory situation that - to review some of the points already raised and highlight a number of others - comprises:

- Tens if not hundreds of thousands of sick Australians continuing to be forced to use illicit products and being criminalised as a result;
- A medicinal cannabis 'programme' based on an assessment of regulatory change that did not meet the Government's Best Practice requirements at the time and leading to legislation that was hopelessly flawed from the outset;
- 'Medicinal cannabis' itself forever consigned to the void of 'regulatory limbo' (i.e. an 'approved unapproved medicine');
- 'Access pathways' which are wholly inadequate;
- Untenable and obscenely high prices of the limited choice of imported cannabis products available (if and when they can be accessed at all);
- An Australian 'Postcode Lottery' where such access is concerned;
- No (legal) Australian cannabis Industry to speak of thus almost no domestic product grown or available;
- Patients having move to States to source their medicines or even doing so by going overseas, sometimes relocating there;
- Patient deaths, including those of children.

4.5 'Cherry-picking' of 'experts' to assist & support Government position

To help defend and justify these otherwise unconscionable circumstances, the TGA enlisted the services of a carefully selected group of academics, clinicians and public health 'experts' almost all with known prohibitionist stances on cannabis and antagonistic toward its use as a medicine. Many of the same individuals have either built their careers demonising the plant or have received drug company funding or both. [67] They were set to work producing documentation ('Systematic Reviews' and 'Clinical Guidance Documents' [68, 69] which - as predicted by advocates a full twelve months earlier [70] – supported the position taken by opponents of MC that 'not enough evidence' exists as to its safety and efficacy. Their publication prompted one eminent medico (Associate Professor David Caldicott of the Australian National University - who created the most thoroughgoing of the three RACGP-accredited 'Medical Cannabis Courses' available in Australia) to criticise this work publicly. The week the 'Guidance Documents' mentioned above were released Dr Caldicott noted:

> *'In just a decade's time, they (the Guidances) will be mocked as an example of the abuse of science. (They are) political, designed to arrive at conclusions that suit parties other than patients. The sad reality is these documents ...will do next to nothing to change the status quo – an illicit market of uncertain provenance, accessed by desperate people. They don't tally with the experience of tens of thousands in Australia – millions worldwide - and so will simply be ignored, even by doctors who choose to educate themselves, overseas and online, about the 'actual' pros & cons of medicinal cannabis.'* [71]

In addition to this, UIC has gathered evidence and examples of how these opponents of cannabis medicine rather than cannabinologists and clinicians expert in its use have been positioned to lead Journal debate and regulatory review and routinely disseminate misinformation in evidence synthesis. [72] This includes failure to consider the synergistic action of cannabis for therapeutic benefits and the massively reduced side effects when MC is compared to other drugs - a matter that rarely crops up in the literature. Such efforts also ensure the lower costs of MC against other drugs when used as a whole plant-based therapy are also omitted from consideration. Meanwhile reviews that take a public health perspective and allow for practice and epidemiological evidence or calls for public health and health economic evidence synthesis are excluded from the discussion or suppressed altogether. [73] Factually inaccurate 'danger messages' about cannabis are at the same time unrelentingly forced home to non-experts and the general public. [74]

Passage of the Amendments to the Narcotic Drugs Act therefore, along with a clear collaboration of forces antithetic to MC, have together served to create a plethora of obstacles – many of them believed dealt with and overcome by the Federal Public Inquiry into the 'Regulator' Bill. These, in our view, if left unaddressed, will effectively prevent any form of genuine or meaningful medical cannabis programme ever from existing in Australia yet, practically and as a matter of policy, they help underpin the

current, highly unacceptable position in which the country finds itself in respect of this issue.

4.6 Summary of current obstacles to a functioning MC Programme for Australia

A number of these obstacles are as follows; some already addressed by this Submission:

- A refusal by the Government and 'medical establishment' to consider any evidence as to the efficacy of MC other than that of Randomised Controlled Trials (RCTs) – often expressed in shorthand as 'not enough evidence';
- An apparently unshakeable ambition to treat and regulate cannabis like other conventional medicines;
- The belief (more a policy position) that 'a crude plant product' is 'a risky way' (i.e. impermissible way) to 'deliver cannabinoids for medical purposes' and that 'other appropriate ways of delivering cannabinoids for medical purposes must be sought' – e.g. the creation of pharmaceutical products made from them, and this despite permitting overseas products that themselves are based on or comprise 'crude plant';
- Generally a regulatory framework that was neither designed for nor is able to cope with a medicine like cannabis;
- A patchwork of State and Federal regulation which has the net effect of interfering with the doctor/patient relationship while creating a 'postcode lottery';
- An assumption that medical 'specialists' are better qualified and have a greater understanding of medicinal cannabis than do GPs;
- No concessions made for patients subjected to Roadside Drug Testing while using even legally prescribed cannabis products. The RDTs do not test for impairment but for the presence of THC, which is fat soluable and thus may remain in the body for days – sometimes weeks – after use. Meanwhile no such testing is done or required for the use of equally intoxicating drugs such as benzodiazipines and other products even when these are likely to cause impairment, creating a wholly discriminatory situation where MC is concerned. [75]

4.7 The matter of 'Acceptable Evidence' & a note on Randomised Controlled Trials (RCTs)

Of these, one issue in particular is of considerable importance – and which we have not thus far examined in detail. Its absence from the discussion however would render any such exercise incomplete and is the first of the above-listed points: the matter of what constitutes 'acceptable evidence'.

For policy-writers, drug companies and the medical 'establishment' the only acceptable form this may take is that of the Randomised Controlled Trial (RCT) – the 'Gold Standard' of 'Evidence Based Medicine'.

On this matter, UIC accepts the relative paucity of RCT data where MC is concerned – the result of decades of complete prohibition – although the UK's Centre for Medical Cannabis reports over 700 RCTs investigating the medical benefits of various cannabis products have been published in the last 10 years. [76] Nor do we consider this Submission an appropriate platform from which to engage in debate (which exists) [77] over whether RCTs are indeed the most effective means of assessing the medicine. Still a though a significant issue arises.

When the Department of Health experts conducted their 'Literature Review' and concluded only that 'insufficient' or 'low quality' evidence could be found for the drug's safety and efficacy they failed to include any material outside of RCT data. Such an approach we consider to be a significant oversight given increasingly large volumes of information that are becoming available from around the world, particularly from those jurisdictions where MC is accessible legally. [78]

4.7.1 All other evidence disregarded

Any thoroughgoing and truly disinterested exercise of this nature we therefore suggest should and must consider a range of evidence, not just RCTs - though we acknowledge the summarising of evidence is where most of the skill is required and that the potential for bias is a threat.

Disregarding huge demographic data however (involving millions of people using the medicine with remarkable degrees of success) along with countless clinically conducted observational studies and prescribing know-how and scholarship on the part of innumerable clinicians worldwide is certain to be partial at best and unscientific and dishonest at worst. It is also detrimental to the interests of patients and insulting to those thousands of sick Australians currently making use of MC illegally, many to maintain a basic quality of life that would otherwise be unavailable. In some of these instances its use is a life or death matter. [79] Discounting this extensive 'lived experience' among patients furthermore in effect brands them as liars.

4.7.2 UIC's Position on the above

UIC finds such a stance unacceptable, particularly since, at time of writing, our organisation is in the process of producing a fourth 'Medicinal Cannabis Symposium (in March 2019). [80] This world-class, international event will feature - as have its predecessors [81] - some of the best and most celebrated scientists and medical practitioners working with cannabis globally. We continue to be dismayed and perplexed therefore that the individuals and work being showcased – not to mention the events themselves - are all but ignored by those whose opposition to MC has been of most hindrance to its re-introduction. In particular we refer here to those Governmental advisors and organisations such as the AMA and other medical bodies which persist - in the face of such expertise - with the argument that 'not enough evidence' exists in

relation to the drug's safety and efficacy.

Here it is worth returning once more to Professor L. Mather cited earlier, who argued in his Submission to the Federal Inquiry into the Regulator of Medicinal Cannabis Bill that:

> '*the present complications of cannabis as a medicine are not due to a lack of evidence, as some would claim'* since *'hard-backed' peer-reviewed published evidence supports the use of cannabis.'* This had, he said, *'been reported and analysed in various places, including Australian parliaments, the British House of Lords and the US Institute of Medicine.'*

And crucially, Prof. Mather went on to add:

> '...*there are many drugs in current use, including some supported by PBS listing, for which the evidence of therapeutic efficacy is not as strong as that for cannabis, and this is reinforced when anecdotal evidence is admitted into the argument.'*

This somewhat disturbing fact too we believe needs to be taken into account when considering the availability cannabis and cannabis products and the effects of the 2016 legislative change.

And whilst UIC is certainly not arguing RCTs are faulty by design, or that other forms of evidence are equally valid, we do challenge what we consider to be the difficult-to-understand rationale behind a 'Framework' that is denying patients legal access to MC essentially because of a lack of the supposedly highest levels of evidence. This has directly left thousands of people with the only option of tackling complex health problems alone and without appropriate clinical oversight by a licensed medical practitioner. Such policy, we argue, is contradictory at best and risks the health and safety of patients by subjecting them to illicit, unregulated products. We suggest it is safer and in fact within the scope of duty of care to clinically monitor patient use of an easily accessible, affordable and better regulated medicinal cannabis product - *even if with sub-optimal scientific evidence* - than it is to subject them by default to using unregulated products, unsupervised by a healthcare professional, via illicit use.

4.7.3 Hierarchy of Evidence: A possible solution

Moreover, according to the National Health and Medical Research Council (NHMRC) [82] evidence comes in the form of systematic reviews (Level I), randomised controlled trials (Level II), pseudo-randomised controlled trials (Level III-1), comparative studies with concurrent controls (Level III-2), comparative studies without concurrent controls (Level III-3) and case series with either post-test or pre-test/post-test outcome measures (Level IV). This 'hierarchy of evidence' underpins the clinical decision-making process of government departments, research institutes and universities as well as individual medical practitioners making informed clinical judgements for the health and well-being of their patients on a day-to-day basis.

Of particular relevance to this discussion therefore is the N of 1 clinical trial, which fits within the hierarchy of evidence framework. This level of evidence considers an individual patient as the sole unit of observation in a study investigating efficacy or side-effect profiles of different interventions, with the goal of determining the optimal intervention for an individual patient using objective data driven criteria and outcome measures. Results of such studies can be collected and collated to ascertain proof of concept and establish a scientific rationale for treatment of a particular condition, which can then lead to more rigorous forms of evidence as required. This approach, we suggest, should be made genuinely available to all patients currently using unregulated (i.e. illicit) products.

Finally, before turning to our conclusions in this Submission's final Section – which provides a number of recommendations for better policy and regulation around MC in Australia – we note alongside the obstacles listed above, a disturbing lack of knowledge about cannabis and cannabis medicine among healthcare professionals.

As Professor Mather has additionally pointed out, despite widespread use, and possibly because of it, there lies a marked gap in medical expertise – partly, he says:

> '*a consequence of the bias in research support (and consequent publication bias) arising from the intentional promotion of research into the harms of 'recreational' cannabis and the dearth of research into the benefits of 'medicinal' cannabis*.'
> '*Evidence in support of this viewpoint*,' Prof. Mather continues, *'lies in the volumes of publications in the 'drug abuse' literature compared to those in the 'applied therapeutics' literature*.

4.8 Poor/limited knowledge of cannabis & cannabis products & medicine among healthcare professionals

As if proof of these assertions were needed, last year the Lambert Initiative at Sydney University produced a 'cross sectional survey' of Australian GPs in relation to MC published in the British Medical Journal. [83] It showed only 28.8% felt comfortable discussing the matter with patients and the paper concluded there was a '*need for improved training of GPs around medicinal cannabis, and the discrepancy between GP-preferred models of access and the current specialist-led models*.'

Yet only three RACGP-accredited training courses exist for healthcare professionals across the whole of Australia (one of them UIC's) even as the Federal Government repeatedly lays the slow take-up of this medicine at the feet of medicos [84] – while failing to assist with or fund these or any other learning or knowledge-sharing initiative.

These, and many more issues, we hope give an indication of some of what currently troubles Australia's MC 'Framework' and why it remains our view that, in its current form,

it is irredeemably unfit for purpose.

Section Five: Further Comments & Recommendations

This Submission has set out to argue and demonstrate that, for numerous reasons explained, the 2016 Amendments to the Narcotic Drugs Act have resulted in a messy, ill-considered and ultimately unworkable Framework for medicinal cannabis in Australia.

Though its architects may (and likely will) attempt to argue that the current 'system' was designed to - and indeed does - meet patient need and ensure best outcomes for them by restricting access to untested cannabis products by individuals who could be harmed from their use, UIC refutes this position entirely.

5.1 In Summary

To summarise once again why this is our view:

- Australia still has a significantly sized black market for medicinal cannabis and cannabis products which are supplied without provenance or quality assurance, dwarfing the licit market by orders of magnitude. Results of the legislation have obliged sick Australians to rely on this source with no clinical supervision available to them, necessarily placing themselves in harm's way;
- No real objectives in terms of what of the 2016 legislation set out to achieve (other than compliance with the UN Single Convention on Drugs) were ever identified making it impossible to determine whether it (the legislation) has 'succeeded' or 'failed';
- The NDA Amendments have caused medicinal cannabis and other cannabis products to fall into a state of permanent 'regulatory limbo' – quite literally '*approved unapproved medicines*' - a situation we find highly illogical if not completely nonsensical;
- The above regulatory position has resulted in an access pathway to cannabis and cannabis products that ensures they are treated and viewed only as medicines of last resort, for use in 'exceptional clinical circumstances'. This is notwithstanding the ineliminable fact that in excess of 100,000 individuals are already using such products illegally.

5.1.1 Moving forward – remedy needed at political level

Faced with this reality, UIC believes the only genuine solution available is a root and branch overhaul of this country's entire MC Framework, beginning with and requiring the political will to make medicinal cannabis and cannabis products genuinely available to patients and far more coherently regulated.

5.1.2 Judiciary might solve the problem

Without such resolve at the political level, we anticipate little progress will be made outside of (possibly) the Judiciary - which we predict will continue to take an increasingly lenient view of individuals caught in possession of cannabis and cannabis products purely for medical purposes. [85] Pleas of 'not guilty on grounds of medical necessity' could well become more frequent and acquittals from these charges not uncommon, setting increasingly firm legal precedent (as in the November 2018 instance of *R v Katelaris* in Sydney). [86] It is thus possible such cases, over time, will bring into effect a *de facto* decriminalisation of cannabis possession but outside of political or regulatory control. In any event, we believe a 'do nothing' approach will, in the immediate and longer terms, be entirely counter-productive.

5.2 Five Policy Objectives for the Future

In our consideration therefore, UIC is here suggesting **five** *minimum required policy objectives* we feel should be placed at the heart of any revised scheme or Framework for MC in the future. These could and should then serve as benchmarks for further Review processes against which the success or otherwise of policy can be evaluated. These five 'objectives' are as follows:

Australian MC regulation should, going forward:

- Assess and meet patient need as well as ensure best outcomes for patients based on the reality of the situation across the country;
- Create an MC programme that optimises net clinical and health system benefits;
- Provide a serious and better alternative to the black market as well incentivisation of patient migration from black market products;
- Deliver legal, accessible, and affordable products domestically;
- Optimise the financial and economic benefits offered by a regulated and vibrant local cannabis industry.

With these aims placed at its centre UIC believes a far better solution for regulating and delivering MC should be possible.

5.3 Immediate Actions Required

In the meantime however, and as a matter of urgency and absolute priority, we call on all Governments in Australia **immediately** to:

1. Recognise demonstrably medicinal use of cannabis and cannabis products (per a note of confirmation from a practising doctor) to be an *absolute defence* against arrest and charges for cannabis possession;
2. Ensure every MC user has the opportunity to transition from unregulated to regulated products;

3. Provide resource and support in the sphere of training for healthcare practitioners in the use of medicinal cannabis.

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