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.