



MCIA

Medicinal Cannabis Industry Australia

Medicinal Cannabis Industry Australia (MCIA)

Submission to the Office of Drug Control

Medicinal Cannabis Permit Reform

December 2020

1.0 About Medicinal Cannabis Industry Australia (MCIA)

Medicinal Cannabis Industry Australia (MCIA) welcomes the opportunity to make this submission to the Office of Drug Control (ODC) in relation to the Medicinal Cannabis Permit Reform.

MCIA is the peak industry body and voice 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 provides 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 Office of Drug Control is undertaking a consultation activity in relation to the McMillan Report recommendations and proposed changes to the permit process under the Narcotic Drugs Act 1967 (the Act).

The ODC is now seeking formal feedback on proposed changes to the permit process, including specifically:

- the scope and contents of permits relating to medicinal cannabis
- the permit application process and information requirements
- the approach to specifying supply pathways, and
- information recording and reporting obligations (including frequency of reporting), with increased compliance monitoring.

The ODC is also seeking observations on issues relating to transitioning existing permit holders to the new permit and single licence arrangements.

The ODC is seeking to deliver the following with the proposed reforms:

- simplify the level of detail in the permits, particularly for cultivation and production
- allow for greater flexibility in business decision-making
- improve the ODC's efficiency, and
- improve industry understanding of regulatory obligations and compliance requirements.

3.0 Background

MCIA is supportive of a regulatory framework that enables the development of a medicinal cannabis industry in Australia, however, it has also consistently highlighted that the current system requires streamlining and appropriate governmental resourcing to ensure it meets the objectives of the Act and operates efficiently and effectively.

MCIA has welcomed the support of the Government in adopting all recommendations from the McMillan Report as a positive step in improving the current arrangements. However, MCIA also recognises, and has promoted, the need for further improvements to enable licence holders to operate and to facilitate patient access to timely, cost effective and quality Australian product. MCIA believes a strength of the Australian approach is 'Australian quality' product underpinned by GMP standards and relevant Therapeutic Goods Orders (TGO).

MCIA strongly believes that, there is an urgent need to ensure that licence holders have an efficient and timely pathway through the ODC which is not hindered by unnecessary regulatory process or restrictions.

Underpinning this is the need for statutory timelines for progression of activities, and transparent reporting of performance under these measures. An efficient and timely pathway is critical to enable licence holders to obtain the relevant permits and other regulatory approvals required to support operations and facilitate the supply of Australian product to the market.

Streamlining and improving the current permit arrangements, particularly for cultivation and production related permits, is critically important to achieving an efficient and timely pathway.

Permit arrangements were initially designed to authorise relevant activities and assist the ODC in managing compliance and reporting functions in the infancy of the Scheme. However, due to the way the Scheme has evolved, the permit process and permits themselves have increased in complexity and have evolved to create potential inequities across licence holders. This evolution has also resulted in a very prescriptive approach, requiring holders to seek variations to change what are operational matters. This places a high, and unnecessary, regulatory burden on industry.

ODC is proposing to:

- simplify the information required in an application for a permit
- simplify the contents of permits for cultivation
- clarify and simplify supply pathways
- clarify obligations in permits by adding maximum quantities for starting materials and waste held onsite to manufacture permits
- implement a reporting scheme for permit holders to routinely report on actual and forecasted activities over the permit period

These changes are expected to benefit the medicinal cannabis sector by making permit requirements easier to understand and comply with, and reducing the need for permit variations. This is expected to reduce the regulatory burden and provide cost savings for industry, and allow industry to respond more quickly to market demands. It will also allow ODC to more effectively monitor cultivation and manufacture activities to ensure compliance with Australia's obligations under the Single Convention.

4.0 Key matters raised in the consultation paper

4.1 Consistent permit format

Permit arrangements are designed to enable ODC to manage compliance and reporting functions to ensure compliance with Australia's obligations under the Single Convention. However, there is no published framework regarding permits and the permit process and permits themselves have evolved in an inconsistent manner. This has seen permits and the permit process increase in complexity and has resulted in differences in permits across license holders. This potentially leads to inequality across license holders, causing the regulatory burden to fall unevenly.

It also causes inefficiencies for ODC where permits are detailed, and unique in structure and layout, thus making interpretation of requirements difficult, particularly given the complexity of cannabis research and cannabis material. This can result in substantial time delays, particularly where there is a change in staff, as ODC staff familiarise themselves with each permit.

The way that the permit system has evolved has also resulted in a very prescriptive approach, requiring holders to seek variations to change what are operational matters. This places a high and unnecessary regulatory burden on industry, without demonstrably impacting risk.

MCIA **recommends** that there is a common permit format, that is aligned with the ODC approach for simplifying elements of the permit. This common permit framework should be published.

This would make the permit process easier and more efficient and more commercially focused.

4.2 Information requirements for an application

Related to the common framework above, MCIA recommends that there is a published list of information that forms part of the permit application, and that this is agreed with industry as required.

The current information requirements are extensive and highly prescriptive, which leads to impractical outcomes that have significant operational constraints for licence holders and impedes industry development. Further, some information requirements are not possible to provide prior to cultivation or manufacture, or if they are provided, adversely impact on research and product development activities.

The information requirements that MCIA believe are appropriate and reasonable are outlined below, and reflects for the most part the proposed permit application information requirement put forward by the ODC. We recognise that ODC will need to assess this against their obligations and risks. We would be happy to discuss further once ODC has undertaken this assessment.

MCIA supports the proposed application information requirements put forward in the ODC consultation paper, with the exception of:

- When delineating between low THC and high THC strains, we recommend that the concept of 'expected' THC limits are used, thus taking into account the variability of a crop which is generally a <1% THC but which may, across the harvest lot, contain some material which slightly exceeds this limit.
- With respect to supply contracts (described on page 13 of the paper) we note that the words 'commercial contract' have been used when describing the type of contract to be submitted. In practice these contracts may be highly detailed (containing information which goes beyond regulatory requirements) and commercially sensitive in nature. We recommend that the words 'contractual arrangement' be used instead, which will allow companies to formalise their regulatory supply obligations in a document that is related to, but separate from, the overarching commercial arrangement.
- On Reporting (page 14) we note that a Licence holder is required to report (amongst other matters) the 'strain' being supplied, however in previous sections the delineation has been restricted to 'low THC' and 'high THC' strains. Although we do not believe that reporting against strain will be overly onerous, we question the value of the information given no official strain identity and nomenclature, and, given the designation of 'low THC' and 'high THC' in other parts of the permit, whether this should be reflected in all aspects of the permit system including reporting.
- On waste, we acknowledge the description of 'un-processed waste material' (page 16) as constituting the Licence holders' record keeping requirement. We do not oppose entirely this requirement, but we seek further clarification of exactly what needs to be recorded given that there can be significant differences in weights from day-to-day (both increases and decreases) due to moisture content. We suggest that an estimate based on cultivation activity would be a more appropriate measure.

4.3 Proposed matters to be specified in the permit

Following from above in respect to information required at the application stage, the MCIA agrees with the overall approach suggested by the ODC in reducing the matters that are to be specified in an issued permit. However, the MCIA notes that the list of information is described in the paper as information that would be specified 'in general'. The MCIA recommends that for the sake of consistency and equity amongst licence holders that this list is reflected identically for all permit holders based on a single pro-forma permit template, and preferably electronic in nature to assist in reporting by permit holders to the ODC.

Additionally, the MCIA recommends that guidance documents as issued, and where appropriate new or revised definitions are written into legislation, to assist permit holders to accurately report values.

Also, as per our views above at 4.2 in respect of information to be submitted in respect to manufacturing, we recommend that greater clarity is required around how to appropriately report manufacturing activity, which may include starting material from sources outside of the ND Act.

4.4 Regulation – monitoring and reporting

The adoption of a common framework and streamlined set of information requirements, will allow ODC to undertake regulation by reporting, monitoring and inspection, rather than prescriptive up-front controls.

The maximum quantities of material would be managed through reporting and inspection, with reporting processes and inspection/audits frequency aligned with a risk-based approach.

The proposed model reflects this shift in the approach to managing risks. It notes that the application assessment functions will not seek to manage every potential risk and will use monitoring and compliance activities where appropriate and/or effective. The proposed revised approach:

- Will allow permit holders the flexibility to undertake a pre-approved scope of activities without requiring direct authorising action from the ODC for every matter or event undertaken by the permit holder;
- Will give permit holders greater flexibility to manage operations, but must do so within the limits specified in their permits;
- Will no longer require ODC to approve individual proposed supply pathways prior to supply activities being undertaken;
- Require permit holder to conduct their own due diligence and, if found to be non-compliant, may be subject to compliance action.

MCIA **supports** the proposed move to a risk-based reporting and monitoring system. This will assist licence holders as timing/compliance requirements will be more aligned with commercial practice.

The ability to provide notifications and reports via an online portal would also significantly improve timeliness and provide transparency.

4.5 Timelines

MCIA also recommends that ODC adopt standard and published timelines for responding to permit applications and variations (both complex and simple). This could include the ability to 'stop the clock' if additional information is required but it would provide greater certainty for license holders.

4.6 Transition

The consultation paper provides little guidance on the process and implications for companies under the transition to a single licence, although it does propose that existing permits will move across in the transition.

Combining licences into a single model should deliver advantages to the processing and maintenance of licences, however, in comparison combining many authorised activities under a single permit structure could lead to more complexity unless there is streamlining of information required in the permit.

Thus, MCIA would propose that if there is a single licence, then there should be a single permit aligned to this. However, MCIA **recommends** that the ODC collect only the mandatory data required to meet the requirements under the obligations to the International convention (as outlined in 4.3) and that regulation is implemented as outlined in 4.4.

4.7 Clarifications sought

MCIA is supportive of the reform of the permit system subject to the qualifications and issues above. However, there are a number of questions and clarifications that MCIA would seek input from ODC. These include:

1. What is the scope and contents of permits relating to medicinal cannabis – we note that the discussion paper lists the data types, but without exact definitions or particulars about the expectations of data points? For example, how is waste to be recorded, how are cuttings counted, including cuttings that do not progress successfully to vegetative growth, how is research cultivation (which may be repetitive in nature, particularly breeding and/or tissue culture work) to be recorded?

2. What is the approach in respect of recognising new supply pathways? Will a permit holder (the “supplier”) be able to rely on the granting of a licence/permit to its intended recipient as evidence that the pathway is legitimate?
3. Following from point 2 above, will the ODC issue guidance on the request for alternative requirements for recipients who are not holders of an ND Act licence/permit under those other relevant supply pathway ‘categories’, for example supply to testing labs, supply to TGA-Licence holders, supply to waste management facilities?
3. In respect of starting material, generally ‘mother plants’ and the taking of cuttings from mother plants, we seek clarification on whether it is appropriate to forego counting the number of cuttings take, (given that losses are expected in this early stage of growth) and instead record and report the successful vegetative plants only in monthly reports.
4. We note that the ODC has requested both **forecasted** and **actual** activity to be reported. We also note that the ODC will implement cultivation, production and manufacturing **maximums** based on permitted activity. Accordingly, we question the value of requiring the reporting of forecasting at all, given that forecasts are inaccurate by their very nature, and that the site capacities provide an accurate and thus more appropriate measure of potential activity under the permit.

5.0 Summary/recommendations

MCIA is supportive of the ODC’s proposals to streamline and improve the current permit arrangements as this will support a more efficient and timely pathway. ODC acknowledges that due to the way the Scheme has evolved, that the permit process and permits themselves have increased in complexity resulting in potential inequity across licence holders, and a very prescriptive approach that requires licence holders to seek variations to change what are operational matters. This places a high, and unnecessary, regulatory burden on industry.

MCIA welcomes the move to improve the format and implementation of permits. MCIA recommends that:

- there is a common permit format, that is aligned with the ODC approach for simplifying elements of the permit. This common permit framework should be published. This would make the permit process easier and more efficient and more commercially focused
- there is a published list of information that forms part of the permit application, and that this is agreed with industry as required. We have provided feedback on informational requirements as proposed by ODC and would suggest that ODC hold a workshop with industry representatives to further discuss the permit format and information requirements
- for the sake of consistency and equity amongst licence holders that this list is reflected identically for all permit holders based on a single pro-forma permit template, and preferably electronic in nature to assist in reporting by permit holders to the ODC
- guidance documents are issued, and where appropriate new or revised definitions are written into processes, to assist permit holders to accurately report values
- ODC adopt standard and published timelines for responding to permit applications and variations (both complex and simple). This could include the ability to ‘stop the clock’ if additional information is required but it would provide greater certainty for license holders.

The consultation paper provides little guidance on the process and implications for companies under the transition to a single licence, although it does propose that existing permits will move across in the transition. MCIA proposes that if there is a single licence, then there should be a single permit aligned to this, but ODC should collect only the mandatory data required to meet the requirements under the obligations to the International convention.