Medicinal Cannabis Industry Australia (MCIA)

Submission to the Office of Drug Control
Medicinal Cannabis Cost Recovery Framework

March 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 Cost Recovery Framework.

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 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 has undertaken an engagement program over the past few months in relation to the McMillan Report recommendations and proposed changes to the fees and charges under the *Narcotic Drugs Act 1967* **(the Act).**

The ODC is now seeking formal feedback on the cost recovery framework, including specifically:

- the minor permit modification fee
- a licence charge
- a site charge
- follow up charges for audit, inspection and sampling
- investigation charges
- enforcement charges

While the consultation paper is focussed on the existing legislative arrangements, respondents are invited to provide feedback on the recommendation from the McMillan Review in regard to the transition for existing licences to the single licence model. Further consultation on the operational elements of the transition arrangements are to be conducted at a later stage.

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 is meeting the objectives of the Act and is operating 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.

Some of the unnecessary regulatory process or restrictions include regulatory authorisations involved at multiple steps; drawn out and variable turnaround times, even for repeat activity by the same applicant; and challenging pipeline management.

4.0 Key matters raised in the consultation paper

4.1 Cost recovery model

The industry is concerned that in contrast to other TGA activities, fees and charges collected in accordance with the Act go into consolidated revenue, with no guarantee that the industry will receive equivalent resources back through funding of the ODC. The ability of the ODC to implement the McMillan Report and other business improvements depends on the case put forward by ODC and the discretion of the Department of Finance. It is critical that ODC has sufficiently increased resources for the 2020/21 year and ongoing.

The ODC review found that the existing fees/charges do not adequately recover its costs for undertaking its activities as required under the Act. For most activities, the time required to complete the relevant tasks associated with the fees and charges is significantly higher than what was forecast before the medicinal cannabis scheme came into effect.

MCIA recognises that ODC has been under resourced since the scheme's introduction in late 2016, based on estimates at that time which did not reflect the true demand for licences. Thus, in principle, MCIA supports the need for ODC to increase fees and charges, however, higher fees and charges must be accompanied by an improved level of service and efficiency that enables companies to not only obtain licences and permits, but also to be able to operate effectively where variations to licences and/or permits are required.

A key way to deliver improved outcomes to applicants and licence/permit holders would be to provide statutory timelines for activities, and where possible shorten timelines compared to those currently being incurred. Such certainty and consistency around the different matters being reviewed and assessed by ODC would provide substantial efficiency and assist in operational planning for companies.

4.2 Fees and charges

MCIA does not have comment on the specific fees and charges, but is generally comfortable that they are in line with other similar regulatory services subject to improved levels of service and implementation of response timelines by ODC.

In particular, MCIA is interested to understand service levels and delivery as applied to new applications, migration of existing licence holders to the new single licence, and requests from existing licence/permit holders. MCIA would like clarification on how the ODC will manage and prioritise across these groups. MCIA believes that it is critical existing licence/permit holders are dealt with effectively in the transition to the single licence approach in order to maintain continuity of supply to patients.

MCIA would also like additional feedback/clarification on:

- How the new permit system will operate under a single licence model and clarification of when ODC plans to release information on how this will work
- Definition of and/or review of categories for each fee/charge (i.e. clarification of the boxes on p12 of the consultation document) and how ODC plans to determine what falls into each category. For example, will ODC:
  - Publish new definitions in fees and charges documents
  - Publish a guidance document
  - Review and allocate internally

MCIA agrees with the suggested approach of a single licence fee for multiple sites noting that additional compliance activities may be as a separate charge for 'follow-up' activities.

4.3 Single licence

MCIA is, in principle, supportive of the single licence approach, however, the focus/resourcing should be targeted at ensuring that existing licence holders are, and remain, operational (hence prioritise permit and licence variations).

It is also important that through simplifying the licence process, the complexity of permits is not increased, but instead that the new permit(s) support the activities actually undertaken by licence holders, including areas which under the current system have been difficult to manage (such as breeding and research). Moreover, it is the view of the MCIA that careful consideration and industry consultation in respect of the redrafting of permits specifically, and consolidation of the current multi-licence/permit model more generally, is required to ensure this leads to efficiencies for both the ODC and licence holders, and as a result, that the estimated fees and charges being proposed are sufficient and appropriate.

MCIA is concerned that the consultation document does not provide any assurance that timeframes will be improved with a single licence – this is more critical than the single licence per se.

MCIA recommends that the approach where existing licence holders, whether one or multiple licences, are deemed to hold a single licence from the commencement day for the new legislative arrangement is adopted.

MCIA is also concerned about how pure research fits into the single licence as there will be an unnecessary burden if companies have to meet commercial manufacturing standards/requirements when only operating in research. The set of different activities under the research umbrella is key to the sustainability of the Australian medical cannabis industry and should be enabled across the value chain.

4.4 Perpetual licence

The ODC had previously sought stakeholder feedback on the five year term as recommended by the McMillan report, or whether a perpetual licence would be preferable for medicinal cannabis licences, subject to a sufficiently robust compliance and enforcement framework. The ODC noted that licences or authorisations have effect perpetually in other Commonwealth regulatory contexts, including under the *Therapeutic Goods Act 1989*.

MCIA would welcome clarification as to whether the perpetual license option is still being considered.

5.0 Summary/recommendations

MCIA supports:

i. The cost recovery framework including increased fees and charges subject to:
   - these being matched by improved levels of service and efficiency by ODC and greater pathway transparency
   - ODC publishing and agreeing to meet defined timelines for licence/permits applications and variations

ii. In principle, the single licence approach, however,
   - implementation of defined (and shortened) timelines are critical
   - the focus/resourcing should be targeted at ensuring existing licence holders are operational

iii. The approach where existing licence holders, whether one or multiple licences, are deemed to hold a single licence from the commencement day for the new legislative arrangement is adopted.

MCIA would like clarification in relation to:

i. How ODC will manage and prioritise new applications, migration of existing licence holders to the new single licence, and requests from existing licence/permit holders in order to maintain continuity of supply to patients

ii. Further definition of permits by category is required

iii. Whether the perpetual license option is still being considered