Medicinal Cannabis Industry Australia

Medicinal Cannabis Industry Australia (MCIA)

Submission to the Office of Drug Control
Medicinal Cannabis Program Regulatory Fees and Charges Review - Consultation

February 2023

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 in relation to the Medicinal Cannabis Program Regulatory Fees and Charges Review.

MCIA is the peak industry organisation for Australia's 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 (ODC) is undertaking consultation following a review of the Medicinal Cannabis Program Regulatory Fees and Charges.

The consultation is limited to cost recovery for regulatory activities relating to medicinal cannabis undertaken under the Act. It does not have any implications for regulatory activities relating to imports, exports, licences or permits granted for other narcotics.

This is in response to changes to the Narcotic Drugs Act (Dec 21) including the single licence model, reforms to permits and administrative reforms to reduce regulatory burden. As part of these reforms, the existing cost model was also reviewed.

Through this review, ODC found that some regulatory effort was not included in the existing fees and charges for the Medicinal Cannabis Program (the Program) and undertook a more comprehensive review which has determined the minimum efficient costs of regulation. These costs have been reflected in the proposed new fees and charges outlined in the ODC consultation paper.

It is proposed that the new schedule of fees and charges will commence on 1 July 2023.

The ODC is now seeking feedback on these proposed changes to the structure and quantum of fees and charges for the medicinal cannabis industry.

3.0 Background

MCIA is supportive of a regulatory framework that enables the development of a medicinal cannabis industry in Australia, however, MCIA has also consistently highlighted that the current system requires streamlining 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 Review as a positive step in improving the previous 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).

However, there remains an urgent need to ensure that licence holders have an efficient and timely pathway through ODC which is not hindered by unnecessary regulatory process or restrictions, including in the context of this review, excessive and/or inequitable financial burdens. This 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.

4.0 Response to the consultation paper

MCIA welcomes the review of fees and charges by ODC and is supportive of some of the proposed changes to the structure of fees and charges. In particular, the proposed approach to split variations into parts is attractive to the sector.

However, there remains a number of elements of the proposed fees and charges that MCIA has concerns about. These are discussed following.

4.1 Lack of accountability and inconsistency with Government's Cost Recovery Guidelines

While acknowledging the need for ODC to recover costs, MCIA is concerned around the accountability to industry given the open-ended budget approach outlined. We note that ODC has published its annual business plan which has some high level statements regarding performance, and the more detailed Cost Recovery Implementation Statement (CRIS), however, there remains little clear guidance to industry around the incentives and activities that ODC will undertake to reduce costs, and increase efficiency and service to the sector.

It was industry's expectation that a single licence, less applications, more experienced staff, better streamlined processes, etc would contribute to a reduction of costs. However this is not reflected in the forward projections outlined in the CRIS.

The lack of clear and measurable efficiency and performance improvements could be seen as inconsistent with the Government's Cost Recovery Guidelines e.g.:

- Section 15 it indicates:

  Government entities should aim to minimise cost recovery charges through the efficient implementation of cost recovered activities, in the context of the specific policy outcomes and legislation. The cost recovery framework is underpinned by three principles that must be applied across all stages of the cost recovery process:
  i. *efficiency and effectiveness*: these two are further explained in section 24 and 25 and further in section 50 and 53 re: "cost padding"
  ii. *transparency and accountability*
  iii. *stakeholder engagement.*

- And section 74, clearly says that

  A well-developed cost recovery model enables entities to:
  i. ***measure and improve efficiency:***
  ii. *minimise over- and under-recovery of costs*
  iii. *manage costs and* ***monitor performance***
  iv. *justify how cost recovery charges have been calculated and how they relate to the costs of the activity* ***(stakeholders who pay cost recovery charges expect to receive value for money****).*

  MCIA does not believe that clear and measurable targets have been articulated by ODC.

4.2 Baseline for costs driven by poor historic performance by ODC

In a somewhat related point, MCIA is concerned that the fees and charges are based on an inefficient/ low level of performance which is not necessarily fair to industry as the cost baseline.

The CRIS notes that in determining the cost drivers, a number of assumptions were made based on historical data and experience from undertaking such activities. MCIA would argue that historical performance is not an appropriate basis for setting future charges as the level of service is below what industry believes is appropriate and consistent with other regulatory activities such as those undertaken by TGA.

The CRIS talks about *Continuous improvement* and says **"**To ensure that the Department remains an agile and responsive regulator, the costs of undertaking continuous improvement of the Scheme by the Department has been incorporated into the cost recovery arrangements."

However, the industry has not observed any substantiative improvement in performance and timelines, nor any commitment to improved efficiency/timelines. If historical performance is to be used as a baseline for costs rather than undertaking modelling of target performance, then it is not unreasonable that the imposition of costs based on inefficiencies be aligned to a commitment to measurable/quantifiable improvement.

The ODC Business Plan's strategic objective 4 is focused on "Reform ODC's Business Processes and Systems". This states that "*We will aim to continuously improve our processors and performance and make regulatory decisions in the context of our international obligations, applicable legislation and impacts on the regulated community. This will include building staff capability and a culture that identifies and implements improved business practices."*

One of the performance indicators included is "*Continuously improve business services, processes and systems to ensure they are fit for purpose."* MCIA supports the following elements that were noted as ODC focus for 2022-23, however, the organisation has an expectation that the ODC would be implementing more specific and quantifiable targets to support the transparency and accountability that underpins and validates the cost recovery model. The 2022-23 areas of focus are:

1. Meeting timeframes published on the ODC website.
2. Revising the medicinal cannabis cost recovery model to ensure compliance with the Australian Government Charging Framework.
3. Progressing ODC digital transformation and significant business process and administrative improvements.
4. Redeveloping ODC website to provide a more user centric and modern design to ensure information is useful for industry and other stakeholders.
5. Building capability through training and cross-skills development and promoting an impartial, flexible and innovative workforce.

4.3 Uncertainty around total costs and implications for industry i.e. potential for further cost increases

MCIA is concerned that there is considerable uncertainty for the industry around the future quantum of ODC costs and therefore the potential for further cost increases. Further if the number of licence holders reduce, but ODC total costs remain the same or increase, this will result in a higher annual charge for remaining licence holders. In addition, ODC's total costs are being borne by a relatively small number of licence holders, but the benefits flow to non-licence holders and the Australian community more broadly as access to quality Australian medicinal cannabis increases. This has not been recognised in the proposed fees and charges structure.

MCIA believes there are a number of approaches that, if adopted, would assist ODC to reduce costs and improve performance. These include:

- *Transparency on status of applications* – the current lack of transparency on applications results in licence/ permit holders having to continually contact ODC re the status of their applications. If there was a way for this to be regularly updated (preferably as live updates) for applicants, this would reduce ODC staff time answering administrative queries. It is important from a corporate governance and planning perspective as well as reporting to shareholders for companies to be aware of the status of applications.

- *Legislated evaluation timelines* – A key way to deliver improved outcomes to applicants and licence/ permit holders would be to provide statutory timelines for ODC activities, and where possible, shorten timelines compared to current practice. Such certainty around the processing time for different matters being reviewed and assessed by ODC would provide substantial operational efficiency for companies which would flow through to improved interactions with ODC.

  We note that the while Act does not include statutory timeframes for decision-making or application processing, indicative timeline for processing applications are provided on the ODC website. However, industry experience is that these can be very different to actual timelines incurred.

The CRIS states that prior to the commencement of the single licence and related permit reforms on 24 December 2021, the published timeframes were:

- cannabis licence application - approximately 210 days
- application to vary a cannabis licence: Simple – approximately 70 days
- application to vary cannabis licence: Complex – approximately 210 days

Further the CRIS says that "The Department anticipates the implementation of the medicinal cannabis licence and permit reforms in late 2021, including the related legislative amendments, will result in a reduction in the assessment periods for medicinal cannabis licences and permits from these previous timeframes. "

MCIA welcomes this comment, but would encourage ODC to adopt formal evaluation timelines with an appropriate 'stop clock' guidelines to accommodate the need for additional information.

MCIA recognises that ODC lacks the IT capability to support some of these improvements and encourages the Government to make funding available for ODC to implement an IT based system to support activities.

MCIA notes that ODC is requesting companies to meet certain timelines e.g. in relation to permit renewals ODC requests companies to apply a minimum of 3 months prior to the expiry of current permit. MCIA believes that a "fair approach" would be for ODC to commit to an evaluation process/timeline including a 'stop clock' provision.

4.4 Quantum of charges

MCIA does not have any comments on the specific fees and charges, but notes that MCIA members may have specific comment on this in their individual submissions.

However, MCIA believes that fees and charges should be in line with other similar regulatory services and subject to acceptable/improved levels of service and implementation of response timelines by ODC. MCIA also believes that ODC should provide some level of certainty to industry around the total quantum of costs, recognising the challenges with accurately forecasting demands on ODC.

The CRIS notes that "Each year the Department has underestimated the volume of applications submitted, which has had an impact on the number of cannabis licences and permits granted and broader workload of the Department. This can be attributed to the fact that the Scheme is regulating an emerging sector and it has been difficult to predict trends. Additionally, the sector has been financially impacted throughout 2020-21 by the COVID-19 pandemic which has resulted in a lower than anticipated number of new licence and permit applications."

However, as the sector matures and ODC has better historical data, it should be possible to more accurately estimate demand. MCIA would be happy to provide industry insights to assist ODC in their forecasting.

4.5 Clarifications

A clarification that has been raised by members is:

- Charges for variations relating to adding (Licence Variation Type 3) and (separately) removing (Licence Variation Type 1) an authorised person, with different fees applying for each of these tasks. However, often these actions would be undertaken together i.e. replacing an authorised person. Thus, the query is if these actions are concurrent, can they be done in one application for one fee or do licence holders need to lodge two applications incurring two sets of fees? This is a single example alone, however we foresee a number of occasions where a variation to achieve a single business change would require multiple variations and thus multiple fees even though each would share a common set of considerations that the reviewer would need to consider.

- The justification for the significant increase (from $12,000 to $34,000) for dormant licenses

5.0 Summary/recommendations

MCIA welcomes the opportunity to make this submission to the Office of Drug Control in relation to the Medicinal Cannabis Program Regulatory Fees and Charges Review.

MCIA is supportive of some of the proposed changes to the structure of fees and charges. In particular, the proposed approach to split variations into parts is attractive to the sector.

MCIA believes that there a number of actions that would assist to improve ODC performance and outcomes for industry and the regulator.

Thus, MCIA:

- Supports the cost recovery framework subject to this being matched by improved levels of service and efficiency by ODC, noting that individual companies may raise specific issues with charges based on operational experience
- Requests that ODC publish and agree to meet defined timelines for licence/permits applications and variations (this could include a stop clock to accommodate additional information requirements)
- Notes the need for better transparency in regard to how ODC is measuring and improving efficiency, including measurable performance targets
- Requests the Government to provide funding for ODC to invest in an IT based system/portal that:
  - provides a single source of truth
  - is focused on critical information to enable ODC staff to quickly understand company's history and risk/compliance rating
  - supports a risk based approach, and audit schedule aligned to the risk rating
  - automates actions and communications for both ODC and licence/permit holders.