Australian Government
Department of Health
Office of Drug Control

# Cost Recovery Implementation Statement (CRIS)

## Regulation of Medicinal Cannabis 2022-23

Effective from April 2023

Office of Drug Control

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# 1. Introduction

Cost recovery involves government entities charging individuals or non-government organisations some or all the efficient costs of a regulatory activity. This may include goods, services or regulation, or a combination of them. The Australian Government Charging Framework, which incorporates the Cost Recovery Guidelines (the CRGs)[1], sets out the framework under which government entities design, implement and review regulatory charging activities, consistent with the *Public Governance, Performance and Accountability Act 2013*.

### Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) provides information on how the Australian Government Department of Health (the Department) implements cost recovery for activities associated with the Medicinal Cannabis Scheme (the Scheme) under the *Narcotic Drugs Act 1967* (the Act).

It is a requirement that the CRIS is regularly updated with the financial results of the current financial year. However, publishing of the updated CRIS was delayed due to the review of the cost recovery model and resulting consultation. This CRIS reports financial and non-financial performance information for the regulation of medicinal cannabis and contains financial forecasts for the 2022-23 to 2024-25 financial years.

A further updated CRIS will be published in line with the introduction of the revised cost recovery model and amended fees and charges, if approved, in June 2023 for the 2023-24 financial year.

The Department will maintain the CRIS until the activity or cost recovery for the activity is discontinued.

## Single Convention on Narcotic Drugs

Australia is a party to the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol (the Single Convention). This convention aims to limit harm from illicit use or abuse of narcotic drugs while setting out the scope of permitted activities, such as for medical and/or scientific use. The Single Convention imposes two key responsibilities on the Australian Government, as a party to the Single Convention. The first is an obligation to carefully control, supervise and report on cultivation, production, and manufacture of narcotic drugs, including medicinal cannabis. The second is to take measures to prevent the stockpiling or diversion of narcotic drugs, including medicinal cannabis, for illicit purposes.

The Act was enacted in 1967 to give effect to certain of Australia's obligations under the Single Convention. Significant amendments were made to the Act in 2016 to allow for the establishment of the Scheme and provide a pathway for lawful supply of medicinal cannabis to Australian patients. The amended Act was designed to ensure that Australia will remain compliant with its international treaty obligations in the Single Convention. In accordance with the Single Convention, the Office of Drug Control (ODC) within the Department is the agency that has sole responsibility for the regulation of the cultivation and production of medicinal cannabis for medicinal and research purposes. No other Government agencies are involved in this partial cost recovery arrangement. The Department implemented and continues to administer the Scheme, which includes a licence and permit framework that allows for the cultivation, production, and manufacture of medicinal cannabis in Australia. The Scheme helps ensure Australian patients have

[1] The Australian Government Charging Framework and the CRGs are available on the Department of Finance website (www.finance.gov.au).

access to essential medicine while supporting the Australian Government's policy of harm minimisation.

**Description of the regulatory charging activities**

On 24 December 2021, amendments to the Act, made by the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* (the 2021 Amendments), came into effect to implement certain recommendations from the 'Review of the Narcotic Drugs Act 1967' undertaken by Professor John McMillan AO in 2019. The 2021 Amendments implemented a single, perpetual licence model for medicinal cannabis regulation, replacing the previous structure of requiring separate medicinal cannabis licences for different activities. These broader reforms also resulted in the need for changes to the Scheme's fees, charges, and cost recovery arrangements.

During 2022, a review of the existing medicinal cannabis cost recovery model, including the level at which fees and charges were set, was conducted in accordance with the Australian Government Charging Framework and in consultation with stakeholders. In doing so it became evident that some regulatory effort was not included in the existing fees and charges for the Scheme. This comprehensive review determined the minimum efficient costs of regulation.

Resulting changes to fees and charges are proposed to commence on 1 July 2023, subject to approval by the Australian Government. If approved, a new CRIS reflecting both the new licence structure and associated cost recovery arrangements will be published at that time.

Cost recovery for the regulation of the Scheme aligns with the Government's overarching cost recovery policy which is, where appropriate, non-government recipients of specific government activities should be charged some or all of the costs of such activities. The cost recovery policy promotes consistent, transparent, and accountable charging for Government activities and supports the proper use of public resources. Fees and charges are imposed on applicants and licence holders who engage with the Scheme.

For the purposes of this document, the Scheme's cost recovery arrangements apply to:

- medicinal cannabis licences, for any one or more of cultivation, production and manufacture activities
- medicinal cannabis permits relating to cultivation and production activities
- medicinal cannabis permits relating to manufacture activities, and
- compliance activities related to such licence and permit holders.

### Transitional period from 24 December 2021 to 30 June 2022

From 24 December 2021, where multiple licences were converted into a single licence, transitional provisions operated to clarify the licence year anniversary date for the purposes of imposing annual charges. This equated to the earliest anniversary date out of the previously held licences that occurred following the single licence transition on 24 December 2021. Licence charges will be invoiced annually by reference to this date going forward.

However, to prevent the possibility of a licence holder paying a site charge twice in the 2021-22 financial year due to these changes, an exemption from payment was made in the following circumstances:

- if the licence holder has a payable amount of site charge under a licence in force under the old framework between 1 July and 23 December 2021

and

- the new licence year date for the converted single licence falls within the period 24 December 2021 and 30 June 2022 inclusive (the transitional period),

then

- that licence holder did not have to pay any amount of site charge that would (but for this exception) have been due to be charged on the first new licence year date in the transitional period.

For further clarity, the following activities are not included in the cost recovery arrangements as they are conducted under separate legislation:

- costs for activities related to the import and export of medicinal cannabis under the Customs (Prohibited Imports) Regulations 1956 and the Customs (Prohibited Exports) Regulations 1958.
- costs for activities authorised under the *Therapeutic Goods Act 1989*, such as licences to manufacture therapeutic goods (Part 3-3) and costs for patient access to medicinal cannabis drugs through the Therapeutic Goods Administration's (TGA's) Authorised Prescriber process and Special Access Scheme.

## Outline of the regulatory activities

### Medicinal Cannabis Licences

An applicant may make an application for a licence to undertake one or more of medicinal cannabis cultivation, production or manufacture activities. The Secretary of the Department of Health and Aged Care (the Secretary) or a Delegate of the Secretary (a Delegate) must make a decision on that application. In making a decision, the Delegate must be reasonably satisfied with the following factors.

- The applicant, and the applicant's relevant business associates, must be considered fit and proper persons to either hold a licence or be associated with a licence. This involves consideration of a range of matters including criminal history, connections, associates and family, financial status, business history and capacity to comply with licensing requirements. Licence holders are to remain 'fit and proper' for the duration of the licence. This test is explicitly designed to ensure the exclusion of persons who may be tempted to use the Scheme as cover for illegal activities.
- For a medicinal cannabis licence, it must be established that a legitimate supply arrangement exists between the applicant and the holder of a licence to produce or manufacture medicinal cannabis. This is to prevent the diversion of cannabis and to ensure that the activities are related to the medicinal use of cannabis.
- It must be established that the applicant can maintain the physical security of the cannabis plants, cannabis, or cannabis resin and/or medicinal cannabis drug.

### Medicinal Cannabis Permits

Once a licence is granted, a licence holder must undertake the activities authorised under the licence in accordance with one or more permits. A licence holder must submit a permit application and a Delegate must make a decision on that application. In deciding to grant a permit, the Delegate will set limits on the scope of the activities that can be undertaken, such as:

- the quantity of cannabis plants that can be cultivated
- the quantity of cannabis and/or cannabis resins that can be produced
- the maximum quantity of the drug that may be manufactured.

Cannabis permits are only granted for production where there is a contract between the licence holder and an authorised producer or licensed manufacturer. Permits are granted for a 12-month period and require subsequent applications to be submitted and approved to continue permitted activities. This assists in meeting a key obligation of the Single Convention to prevent over-production and diversion to illicit uses.

### Monitoring and Inspections

Cannabis licences are subject to statutory conditions and a Delegate can impose conditions on the licence to promote security of the crop, cannabis, and cannabis resins, so that it is not diverted to illicit uses. Substantial penalties exist for contravention of these conditions and offences relating to activities that are not authorised by the cultivation or production licence.

## 2. Policy and statutory authority to cost recover

### Government policy authority

In the 2015-16 Mid-Year Economic and Fiscal Outlook, the Government announced its intention to establish a Commonwealth licensing scheme, to be administered by the Department[2], to regulate the cultivation of cannabis for medicinal and scientific use.

Additionally, in the 2016-17 Budget, the Government announced that it would introduce legislation to allow charges to be imposed on cannabis-related licences granted under the Act. Any revenue collected will support the Scheme for the regulation of cannabis for medicinal and scientific use.

Given the greater than anticipated interest in the Scheme, in the 2018-19 Mid-Year Economic and Fiscal Outlook, the Government increased resourcing to administer the Scheme and required the Department to review the cost recovery arrangements[3]. As a result of the review, the Department developed a proposal for amendments to fees and charges for the Scheme and undertook a detailed program of stakeholder engagement.

In the 2020-21 Budget, the Government announced the extension of cost recovery arrangements to medicinal cannabis-related manufacture licences and increased resourcing to meet the ongoing demands of administering the Scheme. Changes to fees and charges were outlined that commenced on 1 November 2020.

There are no changes to the partial cost recovery arrangements that relate to non-commercial medicinal cannabis licences. It was determined that full recovery may reduce investment in research. The shortfall in costs will continue to be met through appropriation from the Australian Government.

[2] Mid-Year Economic and Fiscal Outlook 2015-16, https://archive.budget.gov.au/2015-16/myefo/MYEFO_2015-16_Final.pdf, p.180.
[3] Mid-Year Economic and Fiscal Outlook2018-19, https://archive.budget.gov.au/2018-19/myefo/myefo_2018-19.pdf, p.189.

## Statutory authority to charge

The Act[4] allows for regulations that provide for the imposition of fees for any matters within it, including matters relating to the payment of fees and charges. The Narcotic Drugs Regulation 2016 (Narcotic Drugs Regulation) is the instrument that specifies the fees related to applications and inspections.

The *Narcotic Drugs (Licence Charges) Act 2016* (Licence Charges Act) provides authority to impose a charge on a licence granted under the Act and that is in force within a specified period. These charges assist the Commonwealth in recovering the costs of the administration, monitoring and assessment of compliance with the requirements under the Act. Section 8 of the Licence Charges Act allows regulations to prescribe the amount of charges.

The *Narcotic Drugs (Licence Charges) Regulation 2016* (Licence Charges Regulation) specifies the period the charge is imposed, the amount and how the charge is calculated. It also provides for non-commercial medicinal cannabis licence holders to pay one licence charge for the period for which the licence is in force, instead of for each 12-month period that the licence is in force as with perpetual commercial medicinal cannabis licences. A non-commercial medicinal cannabis licence is defined in section 54A of the Narcotic Drugs Regulation. Non-commercial medicinal cannabis licences are generally not perpetual but issued for a relevant period related to the research project timeline to be undertaken.

## Statutory Review of the Narcotic Drugs Act 1967

In 2018, in accordance with section 26A of the Act, the Hon Greg Hunt MP appointed Professor John McMillan AO to conduct a review and provide a report on the operation of the Act. The Report on the Review of the *Narcotic Drugs Act 1967* (the Report) was tabled in Parliament in September 2019.

The Report made 26 recommendations to improve the regulatory framework for the cultivation, production, and manufacture of medicinal cannabis in Australia, which were accepted by Minister Hunt. The recommendations broadly aim to reduce the regulatory burden on the medicinal cannabis sector as well as to promote and allow greater flexibility in the administration of the legislation to support innovation and development.

A two-stage reform process was undertaken to ensure that the recommendations were appropriately implemented. Stage 1 involved making amendments to the Narcotic Drugs Regulation to streamline the application process, which were implemented on 1 January 2020.

Stage 2 involved amending the Act to implement certain recommendations from the Report. The *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* (the Amendment Act) received Royal Assent on 24 June 2021 amending the Act to provide a single licence framework to reduce the burden of regulation in the licence assessment process, provide greater certainty to business and reduce duplicative processes. The amendments and relevant transitional provisions commenced on 24 December 2021, along with consequential regulation amendments.

[4] *Narcotic Drugs Act 1967*, Section 28 (1)(c), (d) and (e).

# 3. Cost recovery model

## 3.1 Outputs and business processes of the regulatory activity

### Outputs

The Scheme has the following key outputs for which costs are recovered:

1. applications for licences and permits
2. inspections
3. activities covered by annual licence charge
4. activities covered by annual site charge
5. non-compliance follow-ups

### Business processes to deliver key outputs

The business processes below allow similar business processes to be categorised together. However, the mechanism for recovering the costs of these processes differs depending on the context in which the business process occurs.

#### 3.1.1 Output 1 - Applications

The Scheme allows for several different applications that have similar processes. However the effort and time required for each process varies depending on the nature of the application.

The process related to an application is as follows:

- receipting - which includes filing all documentation and handling payment of invoices
- qualitative screening of the applications
- assessment of the application
- decision by a delegate to grant or refuse to grant a medicinal cannabis licence, permit, or variation to a medicinal cannabis licence or permit
- notification of decision made.

***Application for a medicinal cannabis licence***

Any person interested in undertaking cultivation, production, or cannabis–related manufacture under the Scheme must apply for a medicinal cannabis licence authorising any or all of these activities and a Delegate must make a decision on the application. While each medicinal cannabis licence application considers different information that reflects the nature of the activity to be authorised, the Department's internal cost recovery review found that, in general, the average efficient time for assessing an application is comparable.

The assessment of a medicinal cannabis licence application includes consideration of the applicant as a fit and proper person to hold a licence, the ability of the applicant to maintain security of the cannabis, cannabis resin or cannabis drugs, and alignment of the proposed activities with Australia's obligations under the Single Convention.

***Application to vary a medicinal cannabis licence***

A licence holder can apply to vary a medicinal cannabis licence. The effort required for the handling of such an application differs significantly, depending on the nature of the variation. As a result, the application fee to vary a medicinal cannabis licence is divided into two categories:

- application to vary a medicinal cannabis licence – minor
- application to vary a medicinal cannabis licence – major.

***Application for a medicinal cannabis permit***

Any activities authorised under a medicinal cannabis licence must be undertaken in compliance with a valid cannabis permit. As such, once a medicinal cannabis licence is granted, a licence holder may apply for one cultivation and production permit and/or one manufacture permit per site.

Medicinal cannabis permits are used to control the quantities of cannabis plants cultivated, cannabis or cannabis resin produced and quantities of cannabis drugs that are manufactured. A medicinal cannabis permit is a critical tool in ensuring Australia complies with its international obligations under the Single Convention. The assessment of a medicinal cannabis permit will verify that the source/s of the cannabis plants, cannabis or cannabis resin are licit and require evidence of contracts between entities that are supplying or receiving cannabis plant, cannabis, or cannabis resin.

***Applications to vary a medicinal cannabis permit***

As with a medicinal cannabis licence, a licence holder can apply to vary a medicinal cannabis permit and the effort associated with handling that application differs significantly on the nature of the variation. Similarly, the application fee to vary a medicinal cannabis permit is divided into two categories:

- application to vary a medicinal cannabis permit – minor
- application to vary a medicinal cannabis permit – major.

### 3.1.2 Output 2 - Inspections

An inspection is undertaken to verify matters relating to medicinal cannabis licences or permits. It is Departmental policy that two Authorised Inspectors attend all inspections given the potential seriousness of the non-compliance and all charges are indicative of this effort. The manner in which the costs of inspections are recovered varies depending on the context of the inspection and effort undertaken.

The following activities are associated with all inspections:

- plan and book
- travel
- conduct inspection
- finalise inspection
- notification and follow up.

### *Planned Inspection*

Upon the granting of a medicinal cannabis licence and prior to the granting of an initial cannabis permit, the Department will conduct a planned inspection of the premises to ensure that the site is compliant with the conditions of the medicinal cannabis licence and is in accordance with the proposed site/facility plans provided with the application.

Historical data has demonstrated that all planned (pre-permit) inspections occur within a similar timeframe and are shorter in duration compared to subsequent compliance monitoring inspections as there are usually no cannabis plants, cannabis, or cannabis resin on site at the time of the pre-permit inspection.

### *Compliance monitoring inspections*

Every licence holder is subject to an annual compliance monitoring inspection whereby Authorised Inspectors undertake an inspection using monitoring powers as outlined under Division 2, Subdivision A of the *Regulatory Powers (Standard Provisions) Act 2014* (the Regulatory Powers Act). Associated costs are included in the 'Annual Site Charge'.

### *Public concern (tip off) inspections*

This is a compliance monitoring inspection as described above. However, it is in response to a tip off or complaint from the public.

### *Follow up inspections*

This is a compliance monitoring inspection as described above. However, it is undertaken in response to suspected non-compliance by a licence holder. The associated costs are categorised as 'non-compliance follow-up charges'.

### *Investigation inspection*

Authorised Inspectors can undertake an inspection using investigation powers as outlined in Part 3, Division 1 of the Regulatory Powers Act as the result of identified non-compliance. The associated costs are categorised as 'non-compliance follow up charges'.

### *Inspection related travel costs*

Inspection related travel costs include accommodation, airfares, train fares, car hire, taxi or other car services, tolls, meals, or other allowances for departmental employees, and whole of government booking fees. The actual travel costs depend on the geographical location, with licensed sites in all states and territories and some within regional and remote areas. In keeping with Cost Recovery Guideline principles, costs for inspection related travel will be recovered in different ways, depending on the type of inspection.

**Planned inspections:** Applicants will not pay any inspection related travel costs for planned inspections. The Department has been provided appropriated funding for this cost, to remove any financial disadvantage for potential licence or permit holders in rural or remote locations who would be subject to higher travel costs based on their location.

**Compliance monitoring and public concern (tip off) inspections:** The travel costs for inspections will be rationalised across the industry and recovered through the annual licence and site charges.

**Follow up and investigation inspections:** The department will seek reimbursement of all reasonable domestic travel costs from licence holders that are subject to inspections. The licence holder will be provided with an invoice for the costs of all reasonable travel expenses. This

ensures that those responsible for non-compliant behaviour pay for the costs incurred by the Department in managing the issues. It removes any cross subsidisation of such costs by compliant licence holders.

***Testing of cannabis samples***

During an inspection, an Authorised Inspector has the power to gather samples of cannabis or cannabis resin and take that sample for testing. Samples are tested at the TGA's laboratories to determine the cannabinoid content of the cannabis and verify if the test results comply with the cannabinoid content listed on the relevant cannabis permit. The cost of undertaking these tests is $1,230 and this is passed directly to the licence holder.

### 3.1.3 Output 3 – Annual licence charge

***Annual licence charge***

An annual licence charge covers the costs of the following activities:

- response to mandatory notification
- public concern (tip off) inspections – refer to section 3.1.2
- continuous improvement.

***Response to mandatory notification***

In accordance with section 10K of the Act and section 20 of the Narcotic Drugs Regulation, it is a condition that all licence holders notify a Delegate of certain matters. As the Department must respond to these notifications, the cost of such responses is included in charges to licence holders. Not all matters relate to non-compliance. However, the Department must review each matter and respond accordingly.

Some of the matters that a licence holder must notify a Delegate of relate to the loss or theft of cannabis plants, cannabis, or cannabis resin. Other matters relate to the licence holder itself, such as notification of new shareholders and business associates. As a result, the recovery of costs associated with a response to mandatory reporting is divided between the annual charge and the site charge, recognising that a certain volume of effort is only required once a cannabis permit is granted.

The following activities are associated with a response to mandatory notification:

- receive and register the notification
- review and analyse the notification
- make a determination on the matter
- refer matter of potential non-compliance to the relevant team for action (where relevant)
- notify licence holder of outcome.

***Continuous improvement***

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.

The following activities are associated with this business process:

- legislative reform and the associated processes
- development and maintenance of publicly available guidance
- stakeholder engagement activities
- activity based costing processes and ongoing management of the cost recovery arrangements.

### 3.1.4 Output 4 – Annual site charge

***Annual site charge***

In addition to the annual licence charge, if one or more permits are granted to a licence holder, an annual site charge will be incurred that covers the costs of the following activities:

- compliance monitoring inspection – refer to section 3.1.2
- cannabis permit reporting
- education and corrective action
- response to mandatory notification – refer to section 3.1.3.

***Review of mandatory cannabis permit reporting***

Once a cannabis permit is granted, permit holders are obliged to provide reports on their activities in accordance with that cannabis permit. The Department will assess these reports on a quarterly basis as follows:

- receive and register reports
- review and analyse the report/s
- make determination on matter
- where relevant, refer matter of potential non-compliance to the relevant team for action
- notify licence holder of outcome.

***Education and corrective action***

As the result of an inspection, desktop audit, cannabis permit report or a follow up audit, the Department may identify actions or behaviours on the part of a licence holder that, while not a matter of non-compliance, raises some concerns. In these instances, the Department may elect to undertake an educative approach with the licence holder or seek that the licence holders take corrective actions.

The following activities are associated with this business process:

- receive and review matter
- liaise with licence holder
- where relevant, provide documentation outlining corrective action to licence holder
- reconcile evidence that corrective action has been undertaken
- refer matter of potential non-compliance to the relevant team for action (where relevant)
- notify licence holder of outcome.

### 3.1.5 Output 5 – Non-compliance follow up

***Follow up desktop auditing***

Where the Department identifies potential non-compliance, either as the result of an inspection, a tip off from the public, or the analysis of a cannabis permit report, they may elect to undertake a desktop audit to gather further information. For example, the Department may request that a licence holder provide all records related to the harvest of a specific crop to audit, in the office. Any findings of concern may be referred for an investigation.

The following activities are associated with this business process:

- receive and review matter
- document facts and assess risk
- develop audit plan
- gather documentary evidence
- analyse data and complete report
- refer matter of potential non-compliance to the relevant team for action (where relevant)
- notify licence holder of outcome.

***Investigations***

While inspections and testing of cannabis samples are related to investigations, a significant amount of this work is undertaken within the office.

The following activities are associated with the in-office component of an inspection:

- receive and review matter
- document facts and assess risk
- develop investigation plan
- gather documentary evidence
- prepare brief of evidence
- finalise report.

***Enforcement action***

In the circumstances where non-compliance with a medicinal cannabis licence or permit or an offence against the Act has been confirmed, a number of enforcement actions are available to the Department. The enforcement action available is outlined in the Act, through reference to the Regulatory Powers Act.

While the specific enforcement action ranges in severity, and the effort required to prepare for such action differs, the activities associated with such business activities are similar, as described below:

- receive and review matter
- assess the non-compliance and information available

- review compliance history
- decision
- notification.

The enforcement actions are separated into minor, moderate and major to reflect the significance of the effort involved in preparing and undertaking the enforcement action. The charges associated with enforcement action are separate to any financial penalties that may result from the enforcement action.

**Minor enforcement action:** This category of charge relates to the preparation of an infringement notice given to a licence holder in accordance with Part 5, Division 2 of the *Regulatory Powers (Standard Provisions) Act 2014* (Regulatory Powers Act). Further, it includes the preparatory effort associated with a Secretary's own variation of a medicinal cannabis licence or permit which may result from a matter of non-compliance or in issuing a direction to a licence holder under Part 3 of the Act.

**Moderate enforcement action:** This category of charge relates to the effort required by the Department to prepare for an enforceable undertaking in accordance with Part 6 of the Regulatory Powers Act or suspending a medicinal cannabis licence or permit as provided for in section 11A of the Act.

**Major enforcement action:** This category of charge relates to the effort required by the Department to prepare for an injunction in accordance with Part 7 of the Regulatory Powers Act or the revocation of a medicinal cannabis licence or permit as provided for in section 10P of the Act.

## 3.2 Costs of the regulatory charging activity

### Activity Based Costing

An activity-based costing exercise was undertaken to determine the average efficient time spent by a departmental employee on each task. This process included accounting for the time spent across tasks such as medicinal cannabis licence and permit application assessments and compliance inspections. This allowed the Department to determine the direct and indirect costs of regulating the Scheme. Some indirect costs, such as the Secretariat function for the Australian Advisory Council on the Medicinal Use of Cannabis, have not been included within the cost recovery arrangements and alternative funding arrangements have been sought for this activity.

Generally, fees and charges are indexed annually to reflect the efficient costs of providing the services and undertaking the activities required to regulate the medicinal cannabis industry. However, the fees and charges were not indexed in 2022-23 due to the review of the cost recovery arrangements being conducted in accordance with the Australian Government Charging Framework, and in light of the revised legislative framework that commenced in December 2021.

Tables 1 and 2 summarise the direct and indirect costs of each fee and charge for the 2022-23 financial year.

### Cost drivers and assumptions

In determining the cost drivers, several assumptions were made based on historical data and experience from undertaking such activities. The Department analysed the trends in volumes of applications received, time taken to undertake specific activities and the behaviours of the medicinal cannabis sector in predicting future volumes. For example, the Department determined

the average time from the point at which a medicinal cannabis licence is granted to the point when a licenced site is completed and a cannabis permit granted is approximately 2 years. This period was factored into the future volumes of cannabis permit applications and planned inspections.

These estimates are highly sensitive to the growth of both the domestic and global medicinal cannabis markets, which are limited by the requirements of the Single Convention and regulated by the International Narcotics Control Board (INCB).

**Table 1: Estimated costs for fees and charges**

| Estimated costs | Direct costs | Indirect costs | Total costs |
|---|---|---|---|
| **Output 1 - Applications** | | | |
| Application for a cannabis licence (Single) | $6,447 | $1,581 | $8,028 |
| Application to vary a cannabis licence – minor | $865 | $234 | $1,099 |
| Application to vary a cannabis licence – major | $4,438 | $1,065 | $5,503 |
| Application for a cannabis permit | $2,788 | $653 | $3,441 |
| Application to vary a cannabis permit – minor | $96 | $27 | $123 |
| Application to vary a cannabis permit – major | $2,349 | $547 | $2,896 |
| **Output 2 – Planned Inspection** | $2,927 | $741 | $3,668 |
| **Output 3 - Annual licence charge** | $9,712 | $2,295 | $12,007 |
| **Output 4 – Annual site charge** | $16,131 | $3,102 | $19,233 |

## 3.3 Design of regulatory charges

Australian Government policy is that it will charge the non-government sector some or all the efficient costs of specific government activities. The characteristics of a government activity determine the type of cost recovery charge used.

### Fees

The Department uses fees to recover costs when services are provided directly to an individual applicant or licence holder. A fee is applicable where the activity is driven by an action of the applicant or licence holder.

All applications are subject to an application fee, to be paid by the applicant. All planned inspections that relate to an application are also subject to a fee. These services are in direct response to a request from an individual or organisation.

## Charges (Levies)

The costs of activities relating to the monitoring or response to potential or actual non-compliance of a licence holder are recovered using charges. Charges, also referred to as levies, legally are taxation charges. However, they differ to general taxation in that the costs recovered are earmarked to fund activities directly related to the Scheme.

The annual charges (levies) are associated with costs which are not driven by the actions of individual persons or entities but pertain to the industry as a whole or to an identifiable sub-set of the industry. The activity is driven by the government as part of its regulation of the industry. A charge is levied to all entities in the particular sector.

There are different activities undertaken by the Department for the regulation of medicinal cannabis licences and for the regulation of sites as outlined above at 3.1.3 and 3.1.4.

Under the Cost Recovery Guidelines there should be no cross-subsidisation of one identifiable group of entities by another. For this reason, the annual levies have been divided into an annual licence charge (charged once annually to each licence holder) and an annual site charge which is charged annually where a licence has an associated permit.

For non-commercial medicinal cannabis licences full cost recovery may stifle scientific innovation and the development of the medicinal cannabis industry in Australia. These non-commercial medicinal cannabis licence holders are subject to both a licence charge incurred following the grant of a licence and a site charge incurred following the grant of a permit. Non-commercial licences are granted for a specific licence period relevant to the related research project timeline.

To provide reduced regulatory costs, non-commercial medicinal cannabis licence holders are only required to pay each of these charges once during the period of the licence, compared with the requirement for commercial licence holders to pay these charges annually (commercial licences being perpetual). The shortfall in revenue for each non-commercial medicinal cannabis licence is met by appropriation funding from government.

Charges which can be identified with individual entities are the recovery of costs associated with non-compliance. These are determined on an hourly basis for associated staff time, plus costs as outlined in Table 2.

**Table 2: Indicative costs for non-compliance follow up (Output 5)**

| Indicative costs | Direct Costs | Indirect costs | Total costs |
|---|---|---|---|
| Follow up desk top auditing | $2,538 | $585 | $3123 |
| Follow up inspection | $5,727 | $899 | $6,626 |
| Investigation | $7,122 | $1,738 | $8,860 |
| Investigation inspection | $6,766 | $1,143 | $7,909 |
| Enforcement action – minor | $3,660 | $782 | $4,442 |
| Enforcement action – moderate | $4,256 | $897 | $5,153 |

| Indicative costs | Direct Costs | Indirect costs | Total costs |
|---|---|---|---|
| Enforcement action - major | $5,796 | $1,218 | $7,014 |

## Fees and charges – effective from 24 December 2021

The 2021-22 fees and charges remain unchanged in the 2022-23 financial year. Following the review of the cost recovery arrangements, any proposed changes to fees and charges are expected to apply from 1 July 2023, subject to approval by the Australian Government.

The fees and charges payable in the 2022-23 financial year and the estimated volume and revenue are listed in Tables 3 and 4. These estimates are based on the existing cost recovery arrangements, which were established for the multiple licence framework applicable prior to the implementation of the single licence/permit reforms. The ODC acknowledges that some of the estimated volumes refer to the multiple licence framework, or to the previous permits' arrangements.

**Table 3: Fees and charges 2022-23**

| Fees and charges for 2022-23 | Type | Charge | Estimated volume | Estimated total revenue |
|---|---|---|---|---|
| Application for a cannabis licence (Single) | Fee | $8,030 | 17 | $136,510 |
| Application to vary a cannabis licence – minor | Fee | $1,100 | 55 | $60,500 |
| Application to vary a cannabis licence – major | Fee | $5,500 | 55 | $302,500 |
| Application for a cannabis permit | Fee | $3,440 | 143 | $491,920 |
| Application to vary a cannabis permit – minor | Fee | $120 | 1242 | $149,040 |
| Application to vary a cannabis permit – major | Fee | $2,900 | 84 | $243,600 |
| Planned Inspection | Fee | $3,670 | 30 | $110,100 |

| Fees and charges for 2022-23 | Type | Charge | Estimated volume | Estimated total revenue |
|---|---|---|---|---|
| Annual licence charge | Levy | $12,010 | 153 | $1,837,530 |
| Annual site charge | Levy | $19,230 | 93 | $1,788,390 |

The charges in Table 4 for non-compliance activities are indicative only. The actual charge will be based on the rate of **$108** per hour, calculated on the actual staff hours undertaken with each activity, charged in arrears. In addition, expenses incurred by the Department such as travel, accommodation, sampling testing and other associated expenses will be included in the charges payable for non-compliance follow up.

**Table 4: Indicative charges for non-compliant activities**

| Indicative charges | Type | Charge | Estimated volume | Estimated total revenue |
|---|---|---|---|---|
| Follow up desk top auditing | Fee (at hourly rate) | $3,120 | 193 | $602,160 |
| Follow up inspection | Fee (at hourly rate + costs) | $6,630 | 97 | $643,110 |
| Follow up cannabis sample test | Fee (at cost) | $1,230 | 49 | $60,270 |
| Investigation | Fee (at hourly rate) | $8,860 | 15 | $132,900 |
| Investigation inspection | Fee (at hourly rate + costs) | $7,910 | 10 | $79,100 |
| Investigation cannabis sample test | Fee (at cost) | $1,230 | 5 | $6,150 |
| Enforcement Action – Minor | Fee (at hourly rate) | $4,440 | 125 | $555,000 |
| Enforcement Action – Moderate | Fee (at hourly rate) | $5,150 | 33 | $169,950 |
| Enforcement Action – Major | Fee (at hourly rate) | $7,010 | 14 | $98,140 |

## 4. Risk assessment

A Charging Risk Assessment for the Scheme has been undertaken resulting in a **LOW RISK** rating.

This is attributed mainly to there being no increase in fees and charges. In addition, no legislative changes have been made in this financial year.

## 5. Stakeholder engagement

On 24 December 2021, various changes to the Act came into effect, including the introduction of a single licence model for cultivation, production and/or manufacture activities. At this time the ODC also implemented simpler permit processes and administrative reforms to reduce regulatory burden. These changes were implemented following the Medicinal cannabis reform – single licence reform (Information session) held on 13 October 2021. ODC contacted all existing licenced entities from October 2021 to confirm their details and ensure the entities were aware of the transition process. The ODC worked closely with each licence holder throughout the licence/permit transition process including to issue them with revised instruments.

Following these reforms, the existing cost recovery arrangements were reviewed, including the level at which fees and charges are set. In doing so it has become evident that some regulatory effort was not included in the existing fees and charges for the medicinal cannabis Scheme. The outcome of the review has informed the Australian Government's consideration of the costs to be recovered for the regulatory effort for the Scheme.

Stakeholder consultation regarding the *Medicinal Cannabis Program Fees and Charges Review* opened 19 December 2022 and closed 10 February 2023. This consultation period included 2 online webinars open to all internal and external stakeholders that registered their interest in attending. A published consultation paper available on the ODC website summarises the findings of the fees and charges review, including the proposed changes, and Interested parties were encouraged to provide feedback.

## 6. Financial Estimates

**Table 5: Financial estimate for 2022-23 and forward years**

| Financial estimate | 2022-23 $'m | 2023-24 $'m | 2024-25 $'m |
|---|---|---|---|
| Expenses = X | 7.506 | 8.136 | 9.427 |
| Revenue = Y | 7.467 | 7.862 | 9.158 |
| Balance = Y- Z | -0.039 | -0.274 | -0.269 |
| Cumulative balance | -1.732 | -2.006 | -2.275 |
| Explain material variance | The forecast revenue for 2021-22 was $4.906 million and the forecast expenses were $5.188 million. Actual revenue was lower than expected at $3.162 million and expenses were higher than expected at $5.397 million. The reason for the variance is explained below in 'Reasons for variance'. | | |
| Explain balance management strategy | The Department has sought appropriation funding from the Australian Government to cover the cumulative balance variance resulting from partial cost recovery arrangements. | | |

# 7. Performance

## 7A. Financial performance

**Table 6: Financial performance in previous years**

| Financial performance in previous years | 2017-18 Actual $'m | 2018-19 Actual $'m | 2019-20 Actual $'m | 2020-21 Actual $'m | 2021-22 Actual $'m |
|---|---|---|---|---|---|
| Expenses = X | 1.446 | 2.112 | 3.702 | 4.548 | 5.397 |
| Revenue = Y | 0.818 | 1.046 | 2.086 | 3.137 | 3.162 |
| Balance = Y – X | -0.628 | -1.066 | -1.616 | -1.411 | -2.235 |
| Cumulative Balance | -1.193 | -2.259 | -3.875 | -1.411 | -3.646 |

| | |
|---|---|
| Notes on balance management strategy | Revised cost recovery arrangements were introduced in the 2020-21 financial year. The cumulative balance was re-set to commence from that year. Appropriation funding has been provided by the Australian Government for the partial cost recovery arrangements in place. |

## 7B. Non-financial performance

**Table 7: Non-Financial performance of regulatory activity over 2021-22 – Volumes**

| Activity | 2021-22 Estimated | 2021-22 Actual | 2021-22 Variance |
|---|---|---|---|
| Cannabis licence applications | 20 | 21 | 1 |
| Cannabis permit applications | 63 | 33 | -30 |
| Application for a variation to a cannabis licence | 78 | 98 | 20 |
| Application for a variation to a cannabis permit | 63 | 48 | -15 |

| Activity | 2021-22 Estimated | 2021-22 Actual | 2021-22 Variance |
|---|---|---|---|
| Planned inspections | 23 | 6 | -17 |
| Annual charges | 125 | 164 | 39 |

## Reasons for variances

Revenue for 2021-22 was forecast to be $4.906 million with forecast expenses of $5.188 million. Actual revenue was lower than expected at $3.162 million and expenses were higher than expected at $5.397 million. This variance in revenue was in part due to the financial impact COVID-19 had on industry throughout 2020-21 and 2021-22. This resulted in a lower than anticipated number of new permit applications and also impacted on the number of onsite inspections that could be performed. Although virtual inspections were conducted throughout 2021-22, this time-consuming process resulted in another reason for the variance in 2021-22.

The reformed single licence framework that commenced on 24 December 2021 transitioned multiple licences existing under the multiple licence framework into single perpetual licences. Overall, the effect of the 2021 reforms is to reduce the total number of licence holders. However, in relation to the annual charge, while 125 annual charges were forecast, 165 were invoiced. This variance was in part, due to the fact that half of the annual licence charges in 2021-22 were invoiced under the multiple licence framework (so multiple licence charges and site charges were applicable) and half were invoiced after the commencement of the single licence framework,

In addition to the above, it should be noted that the Medicinal Cannabis Scheme is regulating an emerging sector making it difficult to predict forward trends. Ultimately the program is demand driven, resulting in fluctuations from year to year compared to forecast volumes.

In addition, there is a link between the variance in cannabis permit applications and the number of hours estimated for planned inspections. Such an inspection only occurs after a medicinal cannabis permit application has been submitted. The existing cost model estimated a lead-time of approximately 18 months between the date on which a medicinal cannabis licence is granted and the date on which a site is ready for inspection. However this has not proven to be the case. This assumption has been revised in the new cost model which should more accurately reflect anticipated permit applications for future years. Similarly, this has an impact on the volume of applications to vary a medicinal cannabis licence or permit variations that are submitted.

## Performance measures

The Act does not include statutory timeframes for decision-making or application processing. The Department provides an indicative timeline for processing applications on the ODC website, from the date of receipt. However, this excludes any time where the application is referred back to the

applicant for further information, or due to delays in receiving information requested from external Commonwealth, State and Territory agencies (including law enforcement agencies).

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 (including receipting and invoicing)
- application to vary a cannabis licence: minor – approximately 70 days
- application to vary cannabis licence: major – approximately 210 days

In 2022 the ODC undertook a business process and systems transformation review to identify both system and process improvements allow the ODC to perform its functions in a more effective and efficient manner. Industry representatives were consulted as part of the review. The review made a number of recommendations on the possible future state of the ODC's processes and systems. Should government approve the proposed ODC digital transformation and process reforms, implementation would allow for, amongst other things, the replacement of manual application submissions with smart forms, a case management system for the tracking of applications and regulatory actions, effective sharing of information across multiple software systems and data transferability, and several other system and process improvements to assist both industry and ODC staff.

### International Scrutiny

The progress of the Scheme will be the subject of scrutiny from the INCB. Australia is required to provide annual datasets to the INCB outlining the quantities of cannabis plants cultivated, cannabis and cannabis resin that has been produced and cannabis drugs that have been manufactured in a calendar year.

The INCB then makes comments in its annual report on the performance of Australia against the requirements of the Single Convention. If the INCB make a negative comment on Australia's performance, for example that production of cannabis resin has exceeded the medical need, then remedial action may need to be considered. Such an event could impact on the data provided in this document.

## 8. Key forward dates and events

- July 2023 – If approved by Government, updated cost model and changes to fees and charges introduced aligned to the revised legislative framework and in accordance with the Australian Government Charging Framework.
- Publishing of the CRIS in June 2023.

## 9. CRIS approval and change register

**Table 8: CRIS Approval and Change Register**

| Date of CRIS change | CRIS change | Approver | Basis of change |
|---|---|---|---|
| 21 October 2016 | Certification of the CRIS | Secretary Department of Health | New regulatory charging activity |

| Date of CRIS change | CRIS change | Approver | Basis of change |
|---|---|---|---|
| 02 November 2016 | Agreement of the CRIS | Minister for Health | New regulatory charging activity |
| 10 November 2016 | Approval for the CRIS release | Finance Minister | High risk rating for the new regulatory charging activity |
| 16 April 2019 | Update of financial results and estimates. | Secretary Department of Health | 2016-17 and 2017-18 financial results reported. 2018-19 and forward estimates updated. |
| 20 March 2020 | Update of 2018/19 financial results | First Assistant Secretary – Regulatory Practice and Support Division | 2018/19 financial results reported. |
| October 2020 | Revision of fees and charges to reflect review of cost recovery arrangements and changes announced in 2020-21 Budget. | Minister for Health | Review of cost recovery cost recovery arrangements. Revised and new fees and charges. |
| July 2021 | Annual update of CRIS and application of indexation to fees and charges for the 2021-22 financial year | Minister of Health and Aged Care | Annual update and review. |
| December 2021 | Update of 2020-21 financial results | First Assistant Secretary – Regulatory Practice and Support Division | 2020/21 financial results reported |
| April 2023 | Annual update of CRIS for the 2022-23 financial year, including actual financial results for the 2021-22 financial year | First Assistant Secretary – Regulatory Practice and Support Division | Annual update and review. |