Australian Government

Department of Health

Cost Recovery Implementation Statement: Regulation of Medicinal Cannabis

March 2020

2019-20

Cost recovery involves government entities charging individuals or non-government organisations some or all of 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.*

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

About the Office of Drug Control

- The Office of Drug Control (ODC) is part of the Health Products Regulation Group of the Department of Health.
- The ODC is responsible for administering the *Narcotic Drugs Act 1967* and parts of the *Customs (Prohibited Imports) Regulations 1956* and *Customs (Prohibited Exports) Regulations 1958* relating to drugs.
- As such, the ODC is responsible for issuing and regulating licences and permits for the cultivation, production and manufacture of medicinal cannabis products.
- The ODC is also responsible for regulating and providing advice on the import, export and manufacture of controlled drugs as well as guidance for travellers who are entering or leaving Australia.
- Further information about the ODC is available at https://www.odc.gov.au/.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication.	ODC	13/12/2016
V1.1	Updated to include reference of Narcotic Drugs (Licence Charges) Regulation 2016 and to align fees and licence charge to regulation.	ODC	25/01/2017
V1.2	Updated to include 2016-17 and 2017-18 actual financial results and non-financial information and reflect amendments in the Narcotic Drugs Regulation 2016 and Narcotic Drugs (Licence Charges) Regulation 2016.	ODC	01/07/2018
V1.3	Updated to reflect revised volume updates for future years and actual financial results for 2017-18	ODC	07/02/2019
V1.4	Updated to reflect actual financial results for 2018-19	ODC	26/03/2020

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1. Introduction

1.1 Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) provides information on how the Office of Drug Control (ODC) in the Department of Health implements cost recovery for regulatory activities associated with the direct costs of processing licence and permit applications for the cultivation of medicinal cannabis and the ongoing monitoring and compliance of the regulatory scheme. It also reports financial and non-financial performance information for regulation of medicinal cannabis and contains financial forecasts for 2019-20 and three forward years. The Department of Health will maintain the CRIS until the activity or cost recovery for the activity is discontinued.

The charging premise for regulatory activities is that where an identifiable group creates extra or specific demand for a specific regulatory activity, they should be charged for the activity, where appropriate.[2] It does not include costs associated with licences for manufacture of cannabis products such as oils under Therapeutic Goods Administration (TGA) Good Manufacturing Practice, as the authority for these licences and their fees are already in place.

Further, cost recovery does not apply to all activities associated with administration of the scheme. For example, expenses associated with *Narcotic Drugs Act 1967* (the ND Act) manufacturing licences are not cost-recovered, nor are activities such as public and professional education and communication about the scheme, costs associated with the work of the Australian Advisory Council for Medicinal Cannabis or administrative activities associated with Australia's commitments in meeting the *International Convention on Narcotic Drugs 1961*. Costs of patient access through the TGA Authorised Prescriber and Special Access Schemes are also not currently cost-covered. Partial cost recovery arrangements are in place for non-commercial cannabis research licences. The balance of these costs are met through appropriation from Government.

Based on internal and external reviews of ODC's regulatory practices, the ODC has identified significantly more time is spent on assessing applications than is accounted for in the current charging arrangements. The ODC has conducted a comprehensive review of the cost recovery arrangements and this is likely to result in amendments to some of its fees and charges. These changes, once approved by Government, will be reflected in the 2020-21 CRIS.

1.2 Description of the activity

The ODC is a part of the Department of Health (the Department) and contributes to Outcome 5 as outlined in the 2016-17 Portfolio Budget Statements:

> **Outcome 5: Regulation, Safety and Protection**
>
> Protection of the health and safety of the Australian community and preparedness to respond to national health emergencies and risks, including through immunisation, initiatives, and regulation of therapeutic goods, chemicals, gene technology, and blood and organ products.

[2] Australian Government Charging Framework, p. 13.

5.1: Protect the Health and Safety of the Community through Regulation

Through the ODC the Department advises on and regulates the import, export and manufacture of controlled drugs to support Australia's obligations under the International Narcotic Drugs Conventions. In addition, the ODC implements and administers the regulatory framework for the cultivation, production and manufacture of medicinal cannabis in Australia. As part of this outcome, the ODC administers the licensing and permit regime for the cultivation and manufacture of medicinal cannabis in line with Australian legislation and international conventions to ensure access to essential medications while supporting Government policy on harm minimisation.

The medicinal cannabis regulatory scheme supports the process of supplying medicinal cannabis products consistent with international obligations and state and territory legislation.

The scheme involves facilitating state and territory regulatory decisions to develop safe, legal and sustainable local supply of cannabis for medicinal or scientific purposes. In turn, this supports greater local opportunities to research, develop, manufacture and supply medicinal cannabis products. Through this program, Australians have increased access to high quality medicinal cannabis products and researchers can undertake scientific research into the benefits (or otherwise) of medicinal cannabis products.

The scheme may not necessarily bring a medicinal cannabis product to registration on the Australian Register of Therapeutic Goods (ARTG), in the short or medium term, but facilitates clinical trials that may support such a registration in the future. Cannabis material cultivated and manufactured in Australia can be used to conduct clinical trials and develop therapeutic products to be used in accordance with the *Therapeutic Goods Act 1989* (the TG Act).

The demand for licences is dependent on market forces and their continuation is dependent on compliance with licensing conditions as described in the ND Act and associated regulations. In addition, facilitating cultivation in Australia of legal cannabis crops for medicinal use under strict local controls strikes the right balance between patient access, community protection and our international obligations.

Amendments to the *Narcotic Drugs Regulation 2016* also allow for the export of medicinal cannabis in order to allow the Australian industry to expand and improve supply of medicinal cannabis within Australia. These amendments allow for the export of:

- medicinal cannabis products manufactured in Australia under a Goods Manufacturing Practices (GMP) Licence
- medicinal cannabis products listed as export-only or registered in the ARTG, or
- extracts of cannabis (or cannabis resin) manufactured under a ND Act licence that are not in the final dosage form.

From a law enforcement perspective, state and territory jurisdictions must consider a number of issues regarding access to cannabis for medicinal purposes, including:

- ensuring secure possession and use among identified patients and carers
- preventing crime groups or individuals influencing the production, supply, transportation and administration of cannabis for its approved use
- child safety and welfare requirements
- road safety enforcement relating to driving under the influence of cannabis, and
- crime associated with diversion of controlled drugs to unauthorised use or misuse.

Further information about the medicinal cannabis regulatory scheme can be found in the Regulation Impact Statement for access to cannabis for medical and scientific purpose published on the Department of the Prime Minister and Cabinet website.

The key features of the cannabis cultivation and/or production licence schemes are:

- Issue of a cannabis licence that authorises the cultivation of cannabis plants and/or production[3] of cannabis or cannabis resins for medicinal purposes or research relating to medicinal cannabis.
- A strict 'fit and proper person' test is applied to the applicant and relevant business associates and 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 licence scheme as cover for illegal activities.
- A demonstrated supply arrangement between the applicant for a medicinal cannabis licence with an authorised producer or manufacturer.
- A permit system for controlling how many cannabis plants can be cultivated and/or cannabis or cannabis resins can be produced. This assists in meeting a key obligation of the *International Convention on Narcotic Drugs 1961* (to which Australia is a signatory) to prevent over-production and diversion to illicit uses. Permits are only granted for production where there is a contract between the licence holder and an authorised producer or licensed manufacturer.
- Conditions applying to the licence to promote security of the crop, cannabis and cannabis resins, so that it is not diverted to illicit uses.
- Substantial penalties for offences and contravention of provisions that involve breaches of conditions and the undertaking of activities that are not authorised by or under the cultivation or production licence.
- A comprehensive suite of regulatory controls to assist in ensuring the integrity of the system, including powers to:
  - give directions to licence holders
  - inspect, monitor and investigate the licenced premises for appropriate use
  - issue infringement notices and seek civil penalties
  - accept enforceable undertakings
  - seek injunctions, or
  - order the destruction of cannabis.

The pharmaceutical industry is an identified key stakeholder for the medicinal cannabis activity.

A partial cost-recovery approach is implemented for the administration of non-commercial cannabis research licence, whereby licensees are licensed for the term of the research project to a maximum of three years, and pay only one set of application fees and levy during that period. Full recovery of direct costs for administering non-commercial cannabis research licences risks the stifling of research.

[3] Production refers to the harvest of cannabis flowers/resin from the cannabis plant.

2. Policy and statutory authority to cost recover

2.1 Government Policy approval to cost recovery

The 2015-16 Mid-Year Economic and Fiscal Outlook: Expense Measures states that the Government will establish a Commonwealth licensing scheme to regulate the cultivation of cannabis for medicinal and scientific use. This is administered by the Department of Health, and will include amending complementary legislation to facilitate access to cannabis products for use in clinical trials and in the development of therapeutic products.

The 2016-17 Budget, Budget Paper No.2, Part II: Expense Measures states that the Government will introduce legislation to allow charges to be imposed on licences granted under the *Narcotic Drugs Act 1976*. Any revenue collected will support the licensing scheme for the regulation of cannabis for medicinal and scientific use.

Government further agreed to implement immediate direct cost recovery for medicinal cannabis and partial cost recovery for non-commercial research licences.

2.2 Statutory authority to charge

The primary legislation in relation to this activity is the ND Act, which provides authority to impose a charge. Medicinal cannabis licence fees and permit application fees commenced from 30 October 2016 and are referenced in the *Narcotic Drugs Regulations 2016* (F2016L01613).

The *Narcotic Drugs (Licence Charges) Act 2016* provides authority to impose an annual levy on licence holders. Medicinal cannabis annual levies commenced from 10 December 2016 and are referenced in the *Narcotic Drugs (Licence Charges) Regulation 2016* (F2016L01893).

3. Cost recovery model

3.1 Outputs and business processes of the regulatory activity

The medicinal cannabis program has the following key outputs for which cost recovery is required:

1. Medicinal cannabis licence/cannabis research licence
2. Medicinal cannabis permit/cannabis research permit
3. Variation to licences
4. Variations to permits
5. Compliance activities, including routine and non-routine inspections with plant sampling and site mediation.

The following sections describe the cost recovery model used in the setting of fees and annual charges for the 2019-20 financial year.

Medicinal cannabis licence/cannabis research licence

The licence application for a site seeking an initial licence to cultivate/produce medicinal cannabis (either for medicinal or research final use) has two associated activities:

1. a desktop assessment of the licence application, and
2. a 'fit and proper person' check for all key personnel involved with the application.

The granting of a licence is not dependent on the applicant having an existing facility for the production of cannabis. This reduces the risk of an applicant spending significant money on infrastructure and then having an application refused. However, if the applicant has an existing facility at the time of making a licence application both application and inspection fees will be required.

Once an initial licence expires, the holder will need to re-apply. Continued operations involving cannabis at the site without a current licence and permit is unlawful. The fee for granting a new licence to a previous licence holder is the same as the new licence application as the ODC is required to undertake the same steps.

Key business processes involved in considering a medicinal cannabis licence application include a) receipt of an application and financial processing; b) application assessment including peer review; and c) decision making. A licence application takes approximately 25 hours of staff time. The estimated expense shows the total expense for 31 licence applications.

	Estimated volume	Estimated expense	Output	Cost component
Licence application fee	31	$156,240	Licence application	Staff cost · Application submission finance processing · Application lodgement filter (post payment) · Application assessment · Peer Review · Delegate decision · Decision processing · Decision appeal

**NOTE Medicinal cannabis research licence applications may come from university and government research organisations and from industrial researchers (e.g. of different cannabis strains).

The regulatory effort for assessing applications for research licences is different to non-research licences, due to the smaller scale of cultivation activities and the different nature of certain applicants. A non-commercial research licence is issued for the term of the research, subject to a maximum period of 3 years, rather than the 12-month period.

Medicinal cannabis permit/cannabis research permit

A holder of a medicinal cannabis licence or cannabis research licence requires a permit before that site can undertake cultivation and/or production of medicinal cannabis. A permit application cannot be made (and cannot be lodged in the system) in the absence of a current licence.

Permits are granted for production where there is a contract between the licence holder and an authorised producer or licensed manufacturer under the ND Act. It is necessary for the ODC to have a 'line of sight' from licence holders to the point of final use to ensure the cannabis is used for medicinal treatment. A permit will be given for the production of a specified quantity of cannabis, of a defined composition (i.e. particular tetrahydrocannabinol and cannabidiol content) and the time period the permit will operate.

For the holder of a cannabis research licence, the permit entitles cultivation restricted to amounts needed to meet the requirements of the research program.

All permits automatically expire (regardless of unused quantity) on the licence end date. This prevents a permit being held where the licence for the facility is not current.

An application for an initial permit requires a desktop assessment. Following issue of the permit, there are two onsite inspections, unless an inspection is conducted before the issue of the licence, in which case only one additional inspection is required.

Note that if a physical site is complete and available at the time of licence application, the first inspection is conducted at that time.

If an applicant passes the first inspection and the ODC agrees to issue a permit, the applicant will be required to pay for the second inspection. This inspection is carried out approximately one month following the issue of the initial permit.

Permit applications subsequent to the initial permit application will cost the same but the applicant is not required to pay for any further inspections as they are paid for prior to issuing the initial permit. These secondary permit applications only involve administrative work as the permit holders have already undergone assessments.

Key business processes involved in considering a medicinal cannabis permit application include a) receipt of an application, financial processing and inspection event alignment; b) application assessment including peer review; and c) decision making. On average, a permit application takes around nine (9) hours of staff time and includes sampling costs.

The estimated expense shows the total expense from 75 permit application fees.

	Estimated volume	Estimated expense	Output	Cost component
Permit application fee	75	$137,250	Permit application	Staff cost · Inspection event alignment · Application lodgement filter (post payment) · Application review · Peer Review · Application decision · Decision processing · Sampling cost

Variations to licences

The ODC allows certain aspects of a licence to be changed by the holder through lodgement of a variation application. Variations can relate to matters such as scope and site operations. Licence holders may seek to vary their licence as the business alters over time. These alterations are to be provided to the ODC, including changes to non-managerial personnel.

While business processes for licence variation are similar to the initial licence application, average staff time for a variation application is approximately 19 hours. The estimated expense shows the total application fees for variation of 40 licences.

	Estimated volume	Estimated expense	Output	Cost component
Application fee for variation to a licence	40	$156,000	Licence variation	Staff cost · Application submission finance processing · Application lodgement filter (post payment) · Application assessment · Peer Review · Delegate decision · Decision processing

Variations to permits

Permit applications must be submitted ahead of the actual cannabis activities taking place, however circumstances may change before and during the cannabis cultivation, harvest and production. It is likely that a number of factors covered by the permit may need to be legitimately varied to reflect reality. The ODC will work with permit holders to manage the risk through ongoing negotiation to prevent such an occurrence. For example, the delayed planting of a crop may lead to the potential that flowering (at which point the cannabis can be harvested or produced) would occur after the original expiry date of the permit. To avoid acting unlawfully, the licence holder will need to vary a permit; perhaps more than once. Variations are considered on a case-by-case basis. The ODC will work with permit holders to maintain the viability of any given permit and will develop a library of acceptable permit criteria over time.

A permit variation application will require the same business process as an initial permit application but does not include sampling costs. The estimated expense shows the total expense for 75 variations to vary permits.

	Estimated volume	Estimated expense	Output	Cost component
Application fee for variation to a permit	75	$129,750	Permit variation	Staff cost · Inspection event alignment · Application lodgement filter (post payment) · Application review · Peer Review · Application decision · Decision Processing · Decision appeal

Compliance activities

All licence holders undergo inspections by the ODC to ensure initial and on-going compliance under a compliance program, through planned and unannounced inspections. The frequency is based on a compliance rating determined for the licence holder, based on previous inspections and compliance history. Planned inspections costs are recovered through fees, with the costs of unannounced inspections included in broader compliance charges. Licence holders will be subject to at least one unannounced inspection in any 12-month period.

A compliance team undertakes office-based compliance activities and regular and unplanned inspections. Regulatory compliance activities include, but are not limited to, ensuring that the licence holders comply with licence conditions, monitoring crops and arranging samples and complaints handling. Approximately half the effort of this team is on inspections, the cost of which is recovered through inspection charges. The other half of the team's effort is office-based compliance activities.

If required, sampling of cannabis at each licenced premises is also included in compliance costs. Samples are taken to confirm that the profile matches the specifications outlined in the permit granted to the licence holder.

It is envisaged that a small number of licenced sites will annually require remediation by the ODC. Remediation occurs if a permit holder ceases operations (such as if the business fails) and any cannabis on their premises is removed and destroyed (either off site or in situ). An inspector from the ODC, as a minimum, must attend the site to ensure remediation is effective.

Regular/planned inspections are charged on an hourly rate of $470 per inspector hour with costs of unplanned inspections are included in broader compliance costs. The hourly rate includes staff time for on-site inspection, pre and post inspection work and average travel costs. The ODC does not charge travel costs separately for efficiency reasons. The hourly rate is revised as part of the annual review of fees and levies.

Relevant compliance activities undertaken by the team include:

- give directions to licence holders
- inspect, monitor and investigate the licenced premises for appropriate use
- issue infringement notices and seek civil penalties
- accept enforceable undertakings
- seek injunctions, or
- order the destruction of cannabis.

	Estimated volume	Estimated expense	Output	Cost component
Planned inspection for issue of a licence or a permit	360	$169,200	Inspection	Staff cost · Inspection preparation and arrangements · Conduct of inspection · Inspection close out · Inspection review group · Decision appeal Travel cost

	Estimated volume	Estimated expense	Output	Cost component
Annual charge	65	$1,779,700	Annual charge	Staff cost · regulatory compliance · compliance monitoring Site remediation Sampling cost Unannounced inspection

The estimated volume relates to 360 hours of inspection, not 360 inspections. The estimated expense for annual charges relates to 120 compliance inspections.

3.2 Costs of the regulatory charging activity

In line with the Australian Government Charging Framework, total costs are categorised into the following groups for cost allocation.

Direct costs: are traced to a cost object with a high degree of accuracy. The allocation of direct costs to a cost object is relatively straightforward. The most common direct costs are staff salaries (including on-costs, such as training, superannuation and leave) and supplier costs (e.g. office supplies).

Indirect costs: are the costs that are not easily linked to a cost object or for which the costs of tracking this outweigh the benefits. Indirect costs are apportioned to a cost object using the internal costing methodology. Common indirect costs include overhead costs such as salaries of staff in corporate areas (e.g. finance, human resources, IT), or accommodation costs (e.g. rent, maintenance, utilities).

The activity based costing (ABC) methodology is used to apportion the direct and indirect costs to regulatory activity.

3.3 Design of regulatory charges

The characteristics of a government activity determine the type of cost recovery charge used. There are two types of cost recovery charges:

Cost recovery fees: fees charged when a good, service or regulation (in certain circumstances) is provided directly to a specific individual or organisation.

Fees are used to recover the cost of the pre-market services performed, such as processing of new and variation applications for issue of licences and permits under the scheme. Fees are designed to reflect as closely as possible the underlying cost of the service.

Cost recovery levies: levies are imposed when a good, service or regulation is provided to a group of individuals or organisations rather than to a specific individual or organisation. A cost recovery levy is a tax and is imposed via a separate taxation Act. It differs from general taxation as it is 'earmarked' to fund activities provided to the group that pays the levy.

A holder of the medicinal cannabis licence is required to pay a levy prescribed in legislation. Levies are used to recover the costs of unannounced inspections, site remediation, sampling and ongoing monitoring and compliance activities where:

- they cannot reasonably be assigned to individual participants
- they maintain the integrity of the regulated industry to the benefit of all participants, or
- assigning costs to individual licence holders would deter them from disclosing matters that are relevant to the security, or other matters, of the crop that might trigger an inspection.

Costs of unannounced inspections, site remediation and sampling along with other compliance costs, if any, are recovered through annual charges levied on each licence. To recover the cost of the ongoing compliance program, a levy is charged once a licence is issued.

For non-commercial research licences, full cost recovery may stifle scientific innovation and the development of the medicinal cannabis industry in Australia. To provide relief of regulatory costs, a non-commercial research licence is issued for the term of the research, to a maximum period of three years, rather than the 12-month period. This means a non-commercial research licence are charged around one-third of fees payable for a (commercial) cultivation licence on a yearly basis. The shortfall in revenue will be up to approximately $14,000 for each non-commercial research licence subject to the length of research, which is met by appropriation funding from Government.

The following table provides the fees and charges for 2019-20 together with an overview of estimated cost recovery revenue.

	Type	Rate	Estimated volume	Estimated total revenue	Output
Licence application fee	Fee	$5,040	31	$156,240	Licence application
Permit application fee	Fee	$1,830	75	$137,250	Permit application
Application fee for variation to a licence	Fee	$3,900	40	$156,000	Licence Variation
Application fee for variation to a permit	Fee	$1,730	75	$129,750	Permit variation
Planned inspection for issue of a licence or a permit	Fee	$470/hour/inspector	360	$169,200	Inspection

	Type	Rate	Estimated volume	Estimated total revenue	Output
Annual charge	Levy	$27,380	65	$1,779,700	Annual charge
TOTAL ESTIMATED REVENUE				**$2,528,140**	

4. Risk assessment

A Charging Risk Assessment for the scheme has been undertaken resulting in a 'medium risk' rating. The key to medium risks for cost recovery are the maintenance and review of charging arrangements for the scheme. The source of recovery is through fees and levies under the *Narcotic Drugs (Licence Charges) Act 2016.*

A part of this risk is mitigated by introducing a partial cost recovery for non-commercial cannabis research licences. In order to mitigate these risks further, the current cost recovery arrangements were reviewed in 2019. Further information about the Regulatory Charging Risk Assessment process is available on the Department of Finance website.

5. Stakeholder engagement

The ODC has undertaken an extensive review of its cost recovery arrangements. This involved a review of the staffing effort involved in the assessment of applications and compliance activities performed. It also involved re-examining the structure of the fees, charges and levies.

The ODC has engaged with stakeholders throughout the review. This included a number of consultation forums conducted in November 2019 and January and February 2020. The ODC also published a public consultation paper inviting written feedback on the cost recovery arrangements proposed for implementation on 1 July 2020.

The 2020-21 CRIS documenting the revised cost recovery arrangements, once approved by Government, will be published on the ODC website in the coming months for public comment.

The ODC website will be utilised to keep stakeholders abreast of the latest developments relating to the regulation of medicinal cannabis. The facility to accept industry or participant feedback is available through email.

6. Performance

6.1 Financial estimates

Revenue[4] and expenses	2019–20 Estimate $'m
Cost recovery revenue	2.528
Total Revenue	**2.528**
Staff expenses	2.182
Supplier expenses	0.413
Total Expense	**2.595**
Surplus (deficit)	**-0.067**

Balance Management Strategy

The ODC has undertaken a complete revision of the cost recovery arrangements, including a review of the time spent on application assessment and licence holder compliance and assumptions, with a view to aligning cost recovery more closely with resource expenditure. The revised cost recovery arrangements will be published in the 2020-21 CRIS. As a result, the financial estimates for 2020-21 and the forward estimate years will be included in the 2020-21 CRIS.

Additionally, the ODC is implementing the recommendations from an independent review of the ND Act conducted in 2019, as required under s 26A of the Act (the Review of the *Narcotic Drugs Act 1967*).

[4] Administered revenue is returned to the Consolidated Revenue Fund.

6.2 Financial performance

Volumes	2017-18 Estimate	2017–18 Actual	2017-18 Variance	2018-19 Estimate	2018-19 Actual	2018-19 Variance
Licence applications	18	49	+31	15	95	+80
Permit applications	36	11	-25	75	30	-45
Application for a variation to a licence	12	5	-7	40	30	-10
Application for a variation to a permit	30	2	-28	75	21	-54
Planned inspection hours	540	86	-454	180	19.75	-160.25
Annual charges	15	25	10	65	25	-40

Financial performance

Revenue[5] and expenses	2016-17 Actual $'m	2017-18 Actual $'m	2018-19 Estimate $'m	2018-19 Actual $'m	Variance
Cost recovery revenue	0.471	0.818	2.363	1.046	-1.317
Total Revenue	**0.471**	**0.818**	**2.363**	**1.046**	-1.317
Staff expenses	0.601	0.837	1.996	1.099	-0.897
Supplier expenses	0.435	0.158	0.378	1.013	0.635
Total Expense	**1.036**	**0.995**	**2.374**	**2.112**	**-0.262**
Surplus (deficit)	**(0.565)**	**(0.177)**	**(0.011)**	**(1.066)**	**(1.055)**
Cumulative Balance	**(0.565)**	**(0.742)**	**(0.753)**	**(1.808)**	**(1.066)**

Notes on material difference

In 2018-19 there was a significant variance between the estimated and actual financial results. The 2018-19 estimates were based on an influx in applications received during the previous year. This influx was realised, however due to the increase in resourcing (largely contractor resourcing) and subsequent training requirements, the time taken for assessments increased resulting in fewer than expected licences being granted. As a result of fewer licences being granted, fewer annual charges were issued than estimated. The increase in assessment time reduced the staff available to conduct inspections, resulting in fewer inspections than estimated.

[5] Administered revenue is returned to the Consolidated Revenue Fund.

6.3 Non-financial performance

The *Narcotic Drugs Act 1967* does not include statutory timeframes for decision-making or application processing. The ODC provides an indicative timeline for processing licence applications of approximately 210 days from receipt (this includes time spent receipting and invoicing applications), available on the ODC website.

Where possible, the ODC will keep records against timeframes for all application processes and regulatory decision processes. This will allow the development of processing guidelines and expectations and will be used to update guidance available to applicants on the ODC website, from time to time.

Should ongoing assessment identify any particular points in the process where delays are occurring, the Department will work on strategies to address those delays. For example, in 2018 the ODC implemented the screening taskforce. This taskforce reviews each application to ensure that information and documentation provided meet legislative requirements. It is intended that this will save time in the assessment process. Further reviews and improvements to processes were implemented in 2019.

Evaluation and audit

The design and implementation of the medicinal cannabis regulatory scheme was included in the Department's internal audit schedule in 2017-18. The ODC finalised the implementation of the recommendations on 30 June 2019.

Additionally, the *Narcotic Drugs Amendment Act 2016* requires the Minister of Health to commence a review of the scheme as soon as possible after the second anniversary of the commencement of Schedule 1 of the ND Act, that is, on or soon after 30 October 2018. This review was conducted and a report was tabled in Parliament in October 2019. The ODC are currently implementing the recommendations of this review.

In addition to this, the ODC has concluded a more comprehensive review of the cost recovery arrangements with a view to implementing revised arrangements from 1 July 2020.

International evaluation

The progress of the medicinal cannabis regulatory scheme will be the subject of scrutiny from the International Narcotics Control Board (INCB), which will make comment on that scrutiny through the publication of its annual reports.

Should the INCB make negative comment, this would be cause for significant concern and there would be a need to revisit the scheme.

It is anticipated that the lack of negative comment would be a trigger for political discussions around opening the scheme for export. If this occurs, then the performance measures for the scheme will require amendment.

7. Key forward dates and events

- Implementation of the recommendations of the Review of the *Narcotic Drugs Act 1967*.
- Review of cost recovery arrangements and implementation of revised fees, charges and levies from 1 July 2020.

8. CRIS approval and change register

Date of CRIS change	CRIS change	Approver	Basis of change
21/10/2016	Certification of the CRIS	Secretary Department of Health	New regulatory charging activity
02/11/2016	Agreement of the CRIS	Minister for Health	New regulatory charging activity
10/11/2016	Approval for the CRIS release	Finance Minister	High risk rating for the new regulatory charging activity
16/04/2019	Update of financial results and estimates.	Secretary Department of Health	2016-17 and 2017-18 financial results reported. 2018-19 and forward estimates updated.
20/03/2020	Update of 2018/19 financial results	First Assistant Secretary – Regulatory Practice and Support Division	2018/19 financial results reported.

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