Australian Government

Department of Health

Cost Recovery Implementation Statement: Regulation of Medicinal Cannabis

Version 1.1, January 2017

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.

[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.
- ODC is responsible for administering the *Narcotic Drugs Act 1967* (the ND Act) and parts of the *Customs (Prohibited Imports) Regulations 1956* and *Customs (Prohibited Exports) Regulations 1958* relating to drugs.
- As such, ODC is 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.
- For further information about ODC, please visit its website http://www.odc.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	ODC	13/12/2016
V1.1	Update to include reference of Narcotic Drugs (Licence Charges) Regulation 2016 and to align fees and licence charge to regulation	ODC	25/01/2017

Contents

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 of licence and permit applications for the cultivation of medicinal cannabis and the ongoing monitoring and compliance of the regulatory scheme. The CRIS also discusses a partial cost recovery arrangement for non-commercial cannabis research licences. It also reports financial and non-financial performance information for regulation of medicinal cannabis and contains financial forecasts for 2016-17 and three forward years. The Department of Health will maintain the CRIS until the activity or cost recovery for the activity has been 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 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 proposed Australian Advisory Council for Medicinal Cannabis or administrative activities associated with Australia's commitments in meeting the International Convention on Narcotic Drugs. Costs of patient access through the TGA Authorised Prescriber and Special Access Schemes are also not currently cost-covered. The cost of partial cost recovery for non-commercial cannabis research licences is met through appropriation from Government.

1.2 Description of the activity

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.

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

Through the Office of Drug Control (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

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

regulatory framework for the cultivation and manufacture of medicinal cannabis in Australia. As part of this outcome, 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 the continuation of licence 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.

From a law enforcement perspective, state and territory jurisdictions must consider a number of issues in regard to 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
- 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 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 involve 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 expected to remain 'fit and proper'. This

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

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 United Nations Single 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
  - 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 3 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 is considered to risk stifling research.

2. Policy and statutory authority to cost recover

2.1 Government policy approval to cost recovery

In the 2015-16 Mid-Year Economic and Fiscal Outlook: Expense Measures it was stated that the Government will establish a Commonwealth licensing scheme to regulate the cultivation of cannabis for medicinal and scientific use to be administered by the Department of Health and will also amend complementary legislation to facilitate access to cannabis products for use in clinical trials and in the development of therapeutic products.

In the 2016-17 Budget, Budget Paper No.2, Part II: Expense Measures it was stated 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 Narcotic Drugs Act 1967 (the ND Act) and the Narcotic Drugs Amendment Act 2016 which provides authority to impose a charge. Medicinal cannabis licence fees and permit application fees are to commence 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 are to commence 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 would have the following key outputs for which cost recovery would be required. These are:

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.

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. These activities are:

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, in case 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, it will require the holder to re-apply for a licence. Continued operations involving cannabis at the site without a current licence and permit would be 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.

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.

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 approximately25 hours of staff time. The estimated expense shows the total expense for 18 licence applications.

	Estimated volume	Estimated expense	Output	Cost component
Licence application fee	18	$90,720	Licence application	Staff cost - Application submission finance processing - Application lodgement filter (post payment) - Application assessment - Peer Review - Delegate decision - Decision processing - Decision appeal

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. For modelling purposes there are 2 permits issued for each licence.

Permits are only 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 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 contents) and the time period the permit will operate (that is, the plant lifecycle).

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

A single permit is required for each supply chain arrangement the licence holder is entering into. For example, a licence holder that seeks to supply two manufacturers with cannabis, or cannabis resin, requires two permits, to cover each arrangement

All permits automatically expire (regardless of unused quantity) on the licence end date (12-month period) unless a new licence has been granted. This prevents a permit being held where the licence for the facility is not current and may not be renewed.

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 ODC agrees to issue a permit, the applicant will be required to pay for the second inspection. This inspection will be carried out one month following the issue of the initial permit.

Permit applications subsequent to the initial permit applications will cost the same amount but the applicant is not required to pay for any further inspections as inspections are already paid for before issue of the initial permit. These involve only administrative work as the permit holders are already known to the ODC.

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

The estimated expense shows the total expense from 36 permit application fees.

	Estimated volume	Estimated expense	Output	Cost component
Permit application fee	36	$65,880	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

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

While business processes for a licences 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 12 licences.

	Estimated volume	Estimated expense	Output	Cost component
Application fee for variation to a licence	12	$46,800	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. ODC will work with permit holders to manage the risk though 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 will be considered on a case by case basis. 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.

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 30 variations to vary permits.

	Estimated volume	Estimated expense	Output	Cost component
Application fee for variation to a permit	30	$51,900	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 are inspected by 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 inspection and compliance history. Planned inspections are recovered through fees and the costs of unannounced inspections are included in broader compliance costs. Licence holders will be subject to at least one unannounced inspection over the 12-month period.

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

Sampling of plants at each licenced premises is also included in compliance costs. Samples are taken to confirm that the plant profile matches the level outlined in the permit granted to the licence holder.

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

While regular/planned inspections are charged on an hourly rate of $470 per inspector hour, 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 will be reviewed 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
- order the destruction of cannabis.

	Estimated volume	Estimated expense	Output	Cost component
Planned inspection for issue of a licence or a permit	540	$253,800	Inspection	Staff cost - Inspection preparation and arrangements - Conduct of inspection - Inspection close out - Inspection review group - Decision appeal Travel cost
Proposed annual charge	15	$410,700	Annual charge	Staff cost - regulatory compliance - compliance monitoring Site remediation Sampling cost Unannounced inspection

The Estimated volume relates to 540 hours of inspection, not 540 inspections. The estimated expense for annual charges relates total annual charges for 15 licence holders.

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: can be easily 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 cannot be 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 has been 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
- assigning costs to individual licence holders would deter them from disclosing matters that 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 to be recovered through annual charges levied on each licence. To recover the cost of the ongoing compliance program, a levy of would be charged once a licence is issued. The charging of a levy is subject to the passage of the Medicinal Cannabis Charging Bill later this year.

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 3 years, rather than the 12-month period. This means a non-commercial research licence may have to pay around one-third of charges 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 fees and charges schedule is in Appendix 1.

	Type	Rate	Estimated volume	Estimated total revenue	Output
Licence application fee	Fee	$5,040	18	$90,720	Licence application
Application fee for variation to a licence	Fee	$3,900	12	$46,800	Licence Variation
Permit application fee	Fee	$1,830	36	$65,880	Permit application
Application fee for variation to a permit	Fee	$1,730	30	$51,900	Permit variation
Planned inspection for issue of a licence or a permit	Fee	$470/hour/inspector	540	$253,800	Inspection
Proposed annual charge	Levy	$27,380	15	$410,700	Annual charge

4. Risk assessment

A charging risk assessment for the Scheme has been undertaken resulting in a 'High' risk rating. The key medium to high risks for cost recovery are the introduction of new charging arrangements for a new activity, the source of recovery is through fees and levies and they involve an Act of Parliament (the Narcotic Drugs (Licence Charges) Bill 2016) and many stakeholders will be affected.

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, it is proposed to undertake a review of cost recovery arrangement in 3-5 years. This period will allow for the medicinal industry to mature and a trend will be known. Further information about the Regulatory Charging Risk Assessment process is available on the Department of Finance website at http://www.finance.gov.au/resource-management/charging-framework/risk-assessment-template/.

5. Stakeholder engagement

Targeted consultation with States and Territories, researchers, manufacturers and relevant Commonwealth departments occurred throughout the development of the scheme.

A number of information and consultation sessions regarding the domestic cultivation and manufacture of medicinal cannabis products have been held in most capital cities for those interested in becoming a licensed cultivator or manufacturer of medicinal cannabis products. Attendees were advised that a cost recovery model would likely be applied and that fees and charges and the CRIS will be released on our website after they have received necessary approvals.

In October 2016, further information sessions were held in Sydney, Melbourne. These sessions provided more detailed information into the requirements of licence applicants and the costs associated with submitting an application for research, cultivation or manufacture under the ND Act. Attendees did not raise any concerns with the charging model presented, although it was noted that the proposed license charge was significantly lower than is charged by state/territory jurisdictions in regards to other comparable controlled crops.

The ODC will review its fees and levies on an annual basis and stakeholders will be asked to provide their feedback on the cost recovery arrangement through the ODC website.

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 performance

Volumes	2016–17 Estimate	2017–18 Estimate	2018–19 Estimate	2019–20 Estimate	2020–21 Estimate
Licence	15	20	23	19	16
Permit application	24	36	36	36	36

Revenue and expenses	2016–17 Estimate $'m	2017–18 Estimate $'m	2018–19 Estimate $'m	2019–20 Estimate $'m	2020–21 Estimate $'m
A: Revenue					
Cost recovery revenue	0.613	0.912	0.908	0.910	0.916
Departmental appropriation[4]	-	0.014	0.028	0.020	0.007
Total A	**0.613**	**0.926**	**0.936**	**0.930**	**0.923**
B: Expenses					
Staff expenses	0.541	0.815	0.822	0.818	0.813
Supplier expenses	0.072	0.111	0.114	0.112	0.110
Total Expense B	**0.613**	**0.926**	**0.936**	**0.930**	**0.923**
Surplus (deficit)	**-**	**-**	**-**	**-**	**-**

6.2 Non-financial performance

The *Narcotic Drugs Act 1967* does not include statutory timeframes for decision making or application processing. ODC maintains a policy of processing all applications within 20 days of receipt (this does not include time consulting with either the applicant or state and territory

[4] To provide relief of regulatory costs, a non-commercial research licence will be issued for the term of the licence, subject to a maximum period of 3 years, rather than the 12-month period. The cost of additional annual inspections for non-commercial research licences will be met through existing departmental resources/ appropriation.

agencies) and making regulatory decisions (such as variations, suspensions and revocations) within a similar timeframe.

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 reported through the Medicinal Cannabis Program Board after the end of each financial year.

ODC will also put in place the following metrics:

- Complaints actioned within 20 days
- Referrals relating to possible criminal activity actioned within 1 business day
- Regulatory interventions (remediation or destruction activity) actioned within 20 days.

Should ongoing assessment identify any particular points in the process where delays are occurring, the Department will work on strategies to address those delays.

Evaluation and audit

The Department will put in place an evaluation program in line with the Department of Health's *Evaluation Strategy 2016-19*. This Strategy will allow for consideration of the medicinal cannabis regulatory scheme governance and associated effectiveness of processes and protocols. The focus of such evaluation will be on benefits realisation and quality improvement.

It is anticipated that the design and implementation of the medicinal cannabis regulatory scheme will also be included on the Department's internal audit schedule in either 2017-18, or for the following year.

Additionally, the *Narcotic Drugs Amendment Act 2016* requires the Minister of Health to cause a review of the scheme to commence 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.

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

- Update after the commencement of the scheme on 30 October 2016
- Update for introduction of levies after passage of necessary legislation (first quarter 2017)
- Update for actual financial performance for 2016-17 (third quarter 2017)
- Undertake a review of cost recovery arrangement in 3 years once the medicinal industry matures or a trend is established.

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

Appendix 1 - Schedule of fees and charges

	Fee/Charge
Licence Application	
Licence application fee[5]	$5,290
Application fee for variation to a licence	$4,150
Permit Application	
Permit application fee	$1,830
Application fee for variation to a permit	$1,730
Inspections	
Inspection for issue of a licence or a permit	$470/hour/inspector
Levy	
Annual charge	$27,360

[5] If an applicant has an existing facility, both application and inspection fees will be required at the time of making a licence application.

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