



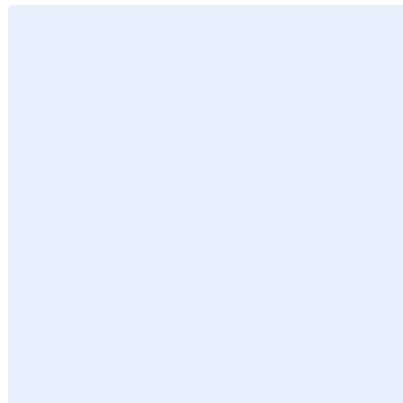
Australian Government

Department of Health

Office of Drug Control

Risk management approach to the cultivation, production and manufacture of medicinal cannabis

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Version control

Updates to this document will occur automatically on the Office of Drug Control website and the revision table below will list the amendments as they are approved.

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About the Office of Drug Control

The Office of Drug Control (the ODC) within the Health Products Regulation Group in the Department of Health (the Department), regulates and provides advice on the import, export and manufacture of controlled drugs, as well as the cultivation of cannabis for medicinal purposes to support Australia's obligations under International Drug Conventions.

The ODC is responsible for:

- the regulation of the medicinal cannabis scheme
- providing in-depth travel advice regarding travelling with controlled drugs
- the regulation of the import and export of controlled drugs and precursor chemicals
- the regulation of the manufacture of controlled drugs
- reporting on activities to the International Narcotic Control Board
- applying amendments to international drug controls in Australia
- ensuring Australians have access to essential medications.

The ODC exercises powers conferred through a number of international treaties and domestic legislation and regulations.

1. Introduction

This document outlines the broad approach adopted by the ODC to identify and manage risks associated with the medicinal cannabis scheme in the *Narcotic Drugs Act 1967* (the Scheme).

The risk management approach for the Scheme has been developed in line with the Commonwealth Risk Management Policy¹, the Australian Standard, Risk Management – Principles and Guidelines² and the Department's Risk Management Policy. It also implements recommendation 24 of the 2019 Review of the *Narcotic Drugs Act 1967*³ (the Act) that:

The Office of Drug Control develop a risk management framework dealing with the exercise of its regulatory functions, drawing from the Commonwealth Risk Management Policy and the Australian Standard, Risk Management - Guidelines.

The document will be further refined as the industry matures and the regulatory systems change through any future legislative amendments.

¹ Department of Finance, Commonwealth Risk Management Policy, available at <https://www.finance.gov.au/government/comcover/commonwealth-risk-management-policy>

² AS/NZS ISO 31000 Risk management – Principles and Guidelines

³ See recommendation 24 of the Final Report in the Review of the Narcotic Drugs Act 1967, by Prof John McMillan AO, tabled in Parliament 5 September 2019. The Final Report is also available on the ODC's website at <https://www.odc.gov.au/news-media/news/tabling-report-review-2016-medicinal-cannabis-amendments-narcotic-drugs-act-1967>

What is risk?

The Commonwealth Risk Management Policy defines risk as the 'effect of uncertainty on objectives'⁴. Commonwealth risk management guidance further clarifies that risk is the possibility of an event or activity preventing an outcome or objective from being realised⁵.

Effective risk management requires several steps:

- establishing the context
- risk identification
- risk analysis
- risk evaluation
- risk treatment
- monitoring and review
- communication and consultation.

Risk management is about defining what can go wrong, why and what can be done.

2. Establishing the Context

Medicinal cannabis regulation

Prior to the commencement of the Scheme in 2016, the cultivation of cannabis for medical or scientific purposes was an unlawful activity in Australia. When the Scheme commenced, the ODC necessarily took a low tolerance to risk and applied a detailed and prescriptive process through the licence assessment process and permit process.

The Scheme has been in operation for four years and the ODC is now applying a more nuanced approach to risk management with regard to the full scope of its regulatory functions. The ODC recognises there are opportunities to manage risk through education and compliance measures such as monitoring and inspections, rather than over-reliance on detailed licence and permit assessments.

This shift is in line with Departmental policy to engage with higher levels of risk and look for innovation where the potential rewards may provide improvements to the health and well-being of the Australian public through increased access to domestically produced medicinal cannabis and related products. As such, it provides a balance between public benefits and the risks to the public through diversion of supply of cannabis or cannabis products for illicit purposes.

External context

The external context to the ODC's medicinal cannabis functions is a complex integration of legal, social and commercial factors. Each of these may have implications for the way the ODC considers and addresses risks over time.

⁴ AS/NZS ISO 31000 Risk management – Principles and Guidelines, p1-2

⁵ Department of Finance, Implementing the Commonwealth Risk Management Policy—Guidance; Resource Management Guide 211, 2016, p 5

Australia's international obligations

Australia is a party to the *Single Convention on Narcotic Drugs 1961*, as amended by the *1972 Protocol* (the Single Convention). At a high level, the Single Convention's aim is to ensure medical use of narcotic drugs is accessible while minimising the risk to public health. The Single Convention covers all parts of the use of narcotics including cultivation, manufacture, trade, distribution and access.

In accordance with the Single Convention, Australia has two key responsibilities to administer in relation to cannabis cultivation. The first is an obligation to carefully control, supervise and report on cultivation, production and manufacture of cannabis. The second is to take measures to prevent the stockpiling or diversion of cannabis to illicit activities.

The ODC was instituted in line with Australia's obligation under the Single Convention to establish a single entity to exercise functions of granting licences for cannabis cultivation and production, designating where cultivation is permitted, purchasing and taking physical possession of licensed crops and controlling import, export and wholesale trading of cannabis stocks⁶. As such, the ODC's medicinal cannabis functions directly relate to Australia's commitments under the Single Convention with its functions and related powers set out under the Act.

Legislative factors

The Act includes a legislative framework enabling the cultivation of cannabis plants, the production of cannabis and cannabis resins in Australia and the manufacture of cannabis drugs for the purpose of providing Australian patients with access to medicinal cannabis for therapeutic purposes. The legislation is consistent with obligations under the Single Convention.

Cannabis is further regulated under a range of other Commonwealth and state and territory legislation relating to the regulation of supply or access to cannabis as a therapeutic medicine, the regulation of industrial hemp and penalties for illicit cultivation and use of cannabis. The various legislative frameworks across Australia mean risks associated with medicinal cannabis are managed through different bodies. The risk management approach described in this document only relates to the Scheme administered by the ODC.

Operational factors

The operating environments where cultivation, production and manufacture of medicinal cannabis activities are undertaken vary significantly. These can range from outdoor grow areas, greenhouses and indoor grow rooms, in both rural and metropolitan locations.

An important variable in the operating environment of the Scheme is the cannabinoid profile of medicinal cannabis. The level of the psychoactive component, delta-9-tetrahydrocannabinol (THC), in the cannabis crop increases the diversion risk and as such risks must be managed accordingly (e.g. low THC crops may be cultivated to lower security requirements).

Social factors

There has been increasing interest over the past decade in the use of cannabis for medical purposes in Australia. Legislative and policy change has been driven partly by community and

⁶ Single Convention on Narcotic Drugs 1961, opened for signature 30 March 1961, 520 UNTS 204 (entered into force 13 December 1964), as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs 1961, Art. 23 and 28

advocacy groups and the media, as well as being informed by the development of medicinal cannabis programs in other countries.

Despite various views on efficacy, the demand for medicinal cannabis is increasing.

Commercial factors

There is a strong commercial interest in the Australian medicinal cannabis industry as evidenced by the larger than anticipated number of licence applications received since the Scheme commenced. Licence holders under the Scheme and other interested stakeholders, have mobilised into several peak bodies including a focus on licenced entities and patient access interests, amongst other things⁷.

Medicinal cannabis must be recognised as an internationally controlled drug under the Single Convention as it is not a normal tradable commodity as compared to other commercial products. Quantities of cannabis cultivated and manufactured nationally must be justified and approved by the United Nations International Narcotic Control Board. International supply must be strictly in line with obligations under the Single Convention. Overproduction could result in limits placed on licensees as required under the Single Convention to reduce stockpiling. As such, any discussion relating to the development of the Australian medicinal cannabis sector should be mindful of Australia's obligations under the Single Convention.

Another objective of the Scheme is to comply with the Australian Government Guide to Effective Regulation with an emphasis on minimising unnecessary 'red tape' and that the Scheme (although mandatory under the Single Convention) provides a net benefit.

Internal context

Risk management is an inherent part of the ODC's functions. This includes the management of internal risks and risks associated with the Scheme and the activities authorised under the Scheme.

3. Identifying and managing risk

Identification and analysis are used to determine various measures to manage risks. Managing risk must be proportionate to the risk posed by an activity.

Identifying risks

There are three key strategic risks that arise from the administration of the Scheme and the ODC's activities.

1. Diversion of supply of cannabis and protecting public health

Recognising that cannabis is an internationally controlled narcotic drug with psychoactive properties, a risk to public health could arise from the unlawful diversion and illicit use of medicinal cannabis cultivated under the Scheme. This could occur, for example, through the theft of cannabis from licence holders and its illegal sale or supply to members of the public, potentially negatively impacting the health and wellbeing of individuals that consume it.

This risk might also arise through the ODC's inadequate application of mitigation measures aimed at managing the risk of diversion, such as through the inadequate application of the

⁷ McMillan, J. Prof., Review of the Narcotic Drugs Act 1967; Final Report, July 2019, p 7

eligibility/suitability criteria during licencing (fit and proper person test) or through inadequate compliance monitoring and investigation of licence holders.

2. Efficient, effective and fair management of the Scheme.

The social and commercial drive for the establishment of a domestic medicinal cannabis industry could be negatively impacted by the ODC's inability to administer the Scheme in an efficient, effective and fair manner.

Matters such as insufficient cost recovery arrangements or poor accountability of work effort and the costs of regulating industry can limit available resources.

Inadequate ODC internal business processes and governance, such as delays in making regulatory decisions or consistency in applying risk mitigation measures and undertaking regulatory action can result in a lack of confidence in the regulator and an increase of licensees becoming non-compliant.

3. The integrity of the Scheme and Australia's reputation and international standing

The inability to protect the Scheme's integrity could lead to a lack of confidence in the ODC's regulation of the Scheme and negatively impact Australia's international standing in narcotic drugs control.

This risk could arise for example through inappropriate or inadequate fraud control and anti-corruption strategies in the ODC's administration of the Scheme or in relation to industry participants.

The risk may also arise if the ODC's ability to monitor, manage and report on national drug stocks, in accordance with the Single Convention, is negatively impacted. For example, if the ODC does not have access to sufficient, appropriate and up to date information relating to the quantity of medicinal cannabis material within Australia.

The internal administration of the ODC could therefore also impact this risk. The Single Convention covers a broad range of obligations, not just a focus on cultivation.

Risks based on activities

There are a number of risks identified under the Scheme that are inherent to the activities of a licenced business, including in relation to the suitability of staff, type and size of crop, the security of the site and facilities within the supply chain and to realising Australia's obligations under the Single Convention.

Crop Type & Size

The type and size of a medicinal cannabis crop are factors which influence risk of diversion and the approach to regulatory scrutiny. THC is the psychoactive component of cannabis which can be present at low levels in the cannabis plant (such as what is commonly referred to as hemp) or in high levels that might be attractive for illicit drug use.

The risk management the ODC applies to the cultivation of high or low THC cannabis is dependent on the concentration of THC in the flowers and the volume of cannabis that may be cultivated or used by manufacturers. The size of the crop is another consideration as it may affect security, storage and transport arrangements.

Suitability of licence holders, business and activities

The licence holder, the business structure and/ or personnel may have implications for the level of risk associated with an activity. As medicinal cannabis containing THC is a narcotic drug, it makes it potentially attractive for criminal elements including organised crime, to infiltrate the licence scheme and use it as a cover for illegal activities. In addition, there is scope for individuals and businesses to be vulnerable to pressures to divert supply for unlawful purposes.

These risks can apply at all or some levels from the licence holder, persons authorised to perform activities and staff, through to the business, business structures, business plans, shareholders and profit participants. There is a clear need to ensure all parties are fit and proper to participate in the Scheme and are not vulnerable due to associations, history, financial need or dependence in a way that maintains the integrity of the Scheme.

Security of land, premises or facilities

As noted above, medicinal cannabis containing THC is a drug that may be attractive for diversion for illicit use, resulting in the need for appropriate and robust security measures to prevent unauthorised access to the locations where activities occur. The nature of the risks will depend on the type of activity, the specific site or facilities and knowledge about the type of activities performed, materials stored on the site and the THC content.

These risks may be identifiable at the licence and permit application stage, but also may change over the course of a licence due to the nature of the activity, time of year or other environmental factors. Inadequate or breaches of security arrangements may result in cannabis illicitly entering the Australian market for recreational use. Poor security can make a particular facility more attractive to organised crime, as well as a target for opportunistic crime. Security arrangements are one of the key risks under the Scheme.

Physical security of cannabis plants, cannabis, cannabis resin, extracts and drugs derived from cannabis

The physical security of cannabis and cannabis products grown, produced, manufactured, obtained or supplied under a licence and permit issued under the Act presents a major risk. There is a need for appropriate security measures to prevent unauthorised access to the locations where cannabis or the extracts are present. The nature of the risks will depend on the THC content, volume, storage, site facilities and public knowledge about the materials stored on the site.

These risks may be identifiable at the licence application stage but also may change over the course of a licence due to the changes in volumes and crop types, time of year or other factors. Inadequate security arrangements may result in diversion of cannabis for illicit purposes, whether onsite or during transport. Managing the risk of diversion of cannabis for illicit purposes is a key priority in protecting the public and meeting international drug treaty obligations.

Supply chain security

Supply security risks relate to cannabis plants, cannabis, cannabis resin, extracts and/ or drugs derived from cannabis being obtained, produced, or supplied for purposes outside the Scheme under the Act. Supply chain risks may include the potential for theft or diversion during transportation or through the supply of cannabis to someone not authorised to receive it.

The level of risk may vary depending on the level of THC in cannabis material or product and the volumes required, for a licence holder, over the course of a licence.

Managing risks

Once risks have been identified, risk management can be applied.

ODC process for managing risk and risk tolerance

In considering how to manage a risk associated with a particular business, the ODC will consider a number of factors, including:

- probity of the applicant (fit and proper person requirements)
- level of THC in the crop
- quantities of cannabis required for cultivation, production and manufacture
- site security and storage
- location of the facility
- supply arrangements
- compliance history of licence holder.

By considering the factors relating to risk the management of risk is tailored to the individual licence applicant or licence holder's circumstances.

If a licence is granted, management of risk can consist of a few or all of the following measures:

- Conditions on licences and permits
- Directions
- Limits on crop size, type and use
- Reporting obligations
- Inspections
- Audits
- Enforcement

The measures applied to manage a risk will be dependent on the activity and the compliance history of the licence holder.

Licence holders with poor compliance history will be subject to greater scrutiny and oversight even if the crop is a low risk crop.

Risk management through licence and permits

Licence holders have a responsibility to ensure the risks associated with their proposed activities are clearly identified and that appropriate measures will be in place to mitigate those risks.

It is up to the licence holder to demonstrate its ongoing and routine commitment to managing risks under the Scheme, in accordance with notification and reporting obligations and under the *Narcotic Drugs Regulation 2016* (the Regulation) and licence conditions. Specifically, the licence holder must, as needed, provide quality and appropriate information about its activities and management of risks, in order for the ODC to meet its own obligations for managing the licence holder under the Act and Regulation.

Non-compliance may result in additional conditions placed on a licence, restrictions on permits, increased inspections and audits.

Education

Education activities and guidance are key to encouraging and assisting with compliance with Australian regulation. This includes publishing guidance, undertaking education activities and answering enquiries to assist industry in understanding and meeting the regulatory requirements under the Act and Regulation.

Enforcement

When ensuring risks are managed effectively through compliance and enforcement activities, the ODC will give consideration to whether an individual, business or activity has complied with the licence and permit plans, protocols or procedures. This will establish the effectiveness of risk migration measures and the appropriateness of the risk assessment.

Monitoring and compliance activities ensure licence holders establish a viable medicinal cannabis industry over time and assist in protecting public health. However, changing business activities could potentially result in a changed risk assessment, either up or down, based on emerging risks or the track record of the licence holder over time.

The Act provides for several enforcement measures:

- Criminal penalties
 - There are a range of offences attracting a criminal penalty in the Act, including both strict liability and fault-based offences. Serious non-compliance may warrant criminal proceedings where these may apply.
- Civil penalties
 - The Act has certain civil penalty provisions. Where appropriate the ODC may apply to the Federal Court for an order against an entity to pay a penalty for breaching the Act.
- Injunctions
 - The ODC can seek injunctions from the Federal Court or the Federal Circuit Court to restrain an entity from contravening the Act or the Regulation or compel compliance with the Act, or regulations if an entity refuses or fails to comply.
- Enforceable undertakings
 - Instead of pursuing court action, the ODC may negotiate an enforceable undertaking with an entity. This is where an entity which has breached an offence or civil penalty provision in the Act enters into a written agreement with the ODC, subject to approval by the Secretary.
 - Where an entity breaches the terms of the enforceable undertaking, the Secretary may apply to the Federal Court for certain orders to be made under the Act.
- Revocation of licence or permit
 - A licence or permit may be revoked on various grounds set out in the Act. The Secretary includes where the licence holder (or its directors) has engaged in conduct that constitutes a serious offence since the licence was granted, where the licence holder is no longer a fit and proper person to hold the licence, or where a business associate of

the licence holder is not a fit and proper person to be associated with the holder of a cannabis licence. There are also various discretionary grounds on which the Secretary may revoke a licence or a permit.

- Suspension of licence or permit
 - A licence or permit may be suspended on various grounds set out in the Regulation, meaning activities under the licence or permit can no longer be undertaken during the period of suspension. The ODC can revoke or extend a suspension and can also take actions against the licence holder.
- Infringement notices
 - There are various criminal offences and civil penalty provisions in the Act. Where the ODC believes the Act has been breached, the ODC may issue an infringement notice as an alternative to undertaking formal court action. If the entity does not pay the infringement notice, further action may be taken.
- Exercise of directions powers
 - The Secretary has various powers under the Act to issue directions with respect to: security of premises and handling of things; the destruction of cannabis plants, cannabis or cannabis resin or narcotic preparations; and the manufacturing and labelling of drugs. The failure to comply with a direction is both a criminal offence, an offence of strict liability and a civil penalty provision.
 - The imposition of an infringement notice assists in mitigating further risk of non-compliance of the same or similar kind by that entity.
- Investigation activities
 - The ODC has a range of investigation functions and powers available to assist in managing the risk of non-compliance with the requirements of a licence, or permit, or the Act. This includes inspections; issuing search warrants; exercising entry and inspection powers; obtaining information and documents.
- Monitoring activities
 - The ODC has a range of monitoring functions and powers available to it to assist in managing the risk of non-compliance with the requirements of a licence, or a permit, or the Act. This includes inspections; monitoring voluntary and mandatory reporting; sample testing; random and targeted desktop monitoring for compliance with licence, permit and requirements of the Act; obtaining information and documents; review and response to intelligence and tip-offs.
- Administrative activity
 - This includes corresponding with the applicant including issuing warning letters. Warning letters may be issued for low compliance risks.

In general, the above risk management should be deployed based on the level of risk(s) and/ or the nature of the consequence(s) relevant in the circumstances with the treatments applied being appropriate and proportionate to the level of risk involved.

The specific mechanism(s) employed in a particular case will depend on the significance of the risk. Compliance performance of the licence holder over time will be taken into consideration.

It is also possible that more than one mechanism may be utilised to assist in managing the identified risk. In particular, education activities may be undertaken in conjunction with other treatments.