



**Australian Government**

**Department of Health and Aged Care**

Office of Drug Control

# Office of Drug Control

## Compliance and Enforcement Framework

2023 - 2025

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Version 1.0, March 2023



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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.

Date	Version	Amendments
March 2023	1.0	First publication

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# Compliance and enforcement framework

## 1. Introduction

The Office of Drug Control (ODC), as part of the Department of Health and Aged Care, regulates the import, export, cultivation, production and manufacture of controlled drugs as part of Australia's obligations under the International Drug Conventions:

- [Single Convention of Narcotic Drugs 1961, as amended by the 1972 protocol \(the Single Convention\)](#);
- [Convention on Psychotropic Substances 1971](#); and
- [United Nations Convention against illicit traffic in Narcotic Drugs and Psychotropic Substances of 1988](#).

The purpose of the drug conventions is to provide an international framework that recognises the medicinal and scientific value of narcotic and psychotropic drugs and ensure that these drugs are available for legitimate purposes.

The ODC consists of three sections:

- **Medicinal Cannabis Section** - responsible for the assessment of applications for licences and permits relating to the cultivation, production and/or manufacture of medicinal cannabis made under the *Narcotic Drugs Act 1967* (the Act), and for a range of administrative functions to support ODC's regulatory activities.
- **Narcotics Control Section** - responsible for the assessment of applications relating to the manufacture of certain narcotic drugs and the import/export of certain narcotic drugs, psychotropic substances, precursor chemicals, antibiotics and anabolic/androgenic substances. The section is also responsible for the collection of data to meet Australia's reporting obligations to the International Narcotics Control Board (INCB).
- **Monitoring and Compliance Section** – responsible for ensuring the effective compliance of licence and permit holders in meeting their obligations under the Act. We use a range of legislative tools and engagement practices to ensure regulated persons<sup>1</sup> are complying with their legislative obligations and take appropriate and proportionate actions where required. We engage with other areas of government at the state, territory and federal level to exchange information and ensure that regulatory compliance risks are effectively managed.

The ODC works in partnership with international partners, Commonwealth, State and Territory government agencies and law enforcement at all levels. These relationships aim to maintain the integrity of the regulation of controlled drugs nationally, while increasing consistency, minimising complexity, and resolving cross-jurisdictional issues to the extent possible.

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<sup>1</sup> In this document any expressions used to denote persons generally (such as "person", "party", "someone" etc), includes a body politic or corporation as well as an individual.

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We exercise powers conferred through the following legislation:

- [Narcotic Drugs Act 1967](#);
- [Narcotic Drugs Regulation 2016](#);
- [Customs \(Prohibited Imports\) Regulations 1956](#); and
- [Customs \(Prohibited Exports\) Regulations 1958](#).

This Framework, the first to be published by the ODC, is intended to assist persons to understand their obligations, and the regulatory and administrative tools the ODC uses to ensure their compliance under the Act, including to mitigate the risk of diversion to illicit supply and use. It illustrates how we apply a risk-based approach to compliance and enforcement options for activities undertaken by narcotic drug industries in Australia.

In particular, the Framework outlines how the ODC will engage the following integrated compliance strategies:

- encourage compliance by educating and informing persons about their responsibilities;
- analyse emerging risks to identify any need to adjust our compliance and enforcement focus and resources;
- manage identified non-compliance, using administrative action or formal enforcement proceedings where necessary and appropriate; and
- work with other agencies to coordinate compliance approaches and refer potential offences that are outside the ODC's remit.

The Framework is consistent with, and provides further detail on key aspects of, the ODC publication [Risk management approach to the cultivation, production, and manufacture of medicinal cannabis](#), available at [www.odc.gov.au](http://www.odc.gov.au).

## 2. Legislative requirements

Regulated persons are responsible for understanding their obligations for import, export, cultivation, production and the manufacture of narcotic drugs. The [Narcotic Drugs Act 1967](#) (the Act) gives effect to Australia's obligations under the [Single Convention on Narcotic Drugs of 1961](#) (the Single Convention) (as amended by the 1972 Protocol) and provides a regulatory framework for:

- the cultivation of cannabis plants, the production of cannabis and cannabis resin, the manufacture of cannabis drugs, and related activities; and
- the manufacture of other narcotic drugs as covered by the Single Convention;
- the import, export and supply of narcotic drugs.

The [Customs Act 1901](#) (Customs Act) is the legislative authority that sets out the customs requirements for the importation and exportation of goods to and from Australia. The [Customs \(Prohibited Imports\) Regulations 1956](#) and [Customs \(Prohibited Exports\) Regulations 1958](#) further outline requirements and restrictions.

Additional legislative requirements also apply as set out in:

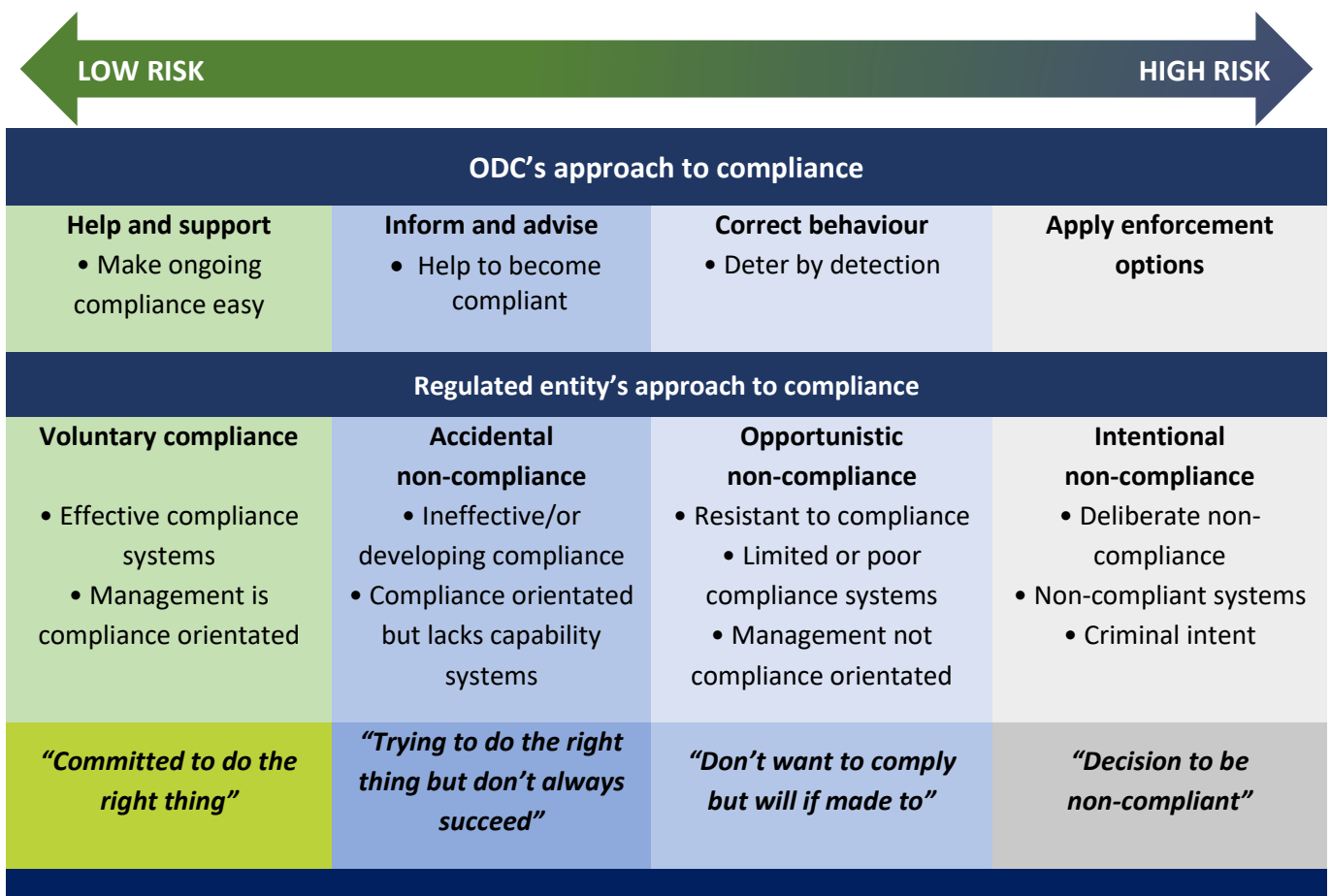
- [Narcotic Drugs Regulation 2016](#)  
The Regulation is an instrument made under the Act and supports the regulatory framework therein.
- [Narcotic Drugs \(Licence Charges\) Act 2016](#)  
Imposes charges on licences granted under the Act.
- [Regulatory Powers \(Standard Provisions\) Act 2014](#) (Regulatory Powers Act)  
The Regulatory Powers Act provides a standard suite of provisions for government agencies in relation to monitoring and investigation powers, and enforcement measures, whilst providing safeguards and protecting important common law privileges for regulated entities.
- [Criminal Code Act 1995](#) (Criminal Code)  
The Criminal Code legislates the general principles of criminal responsibility under laws of the Commonwealth, irrespective of how the offence is created.
- [Crimes Act 1914](#) (Crimes Act)  
The Crimes Act is an act relating to offences against the Commonwealth.

### 3. Risk-based approach to compliance

The ODC adopts a risk-based approach to appropriately respond to the nature and seriousness of non-compliant behaviour by regulated persons. In determining how to manage a risk associated with a particular business, the ODC will consider several factors, including:

- probity of the applicant (fit and proper person requirements)
- type of narcotic
- quantities of narcotic required for cultivation, production and/or manufacture
- site security and storage
- location of the facility
- supply arrangements
- compliance history.

Persons have a responsibility to ensure the risks associated with their proposed activities are clearly identified and that appropriate measures are implemented to mitigate those risks. The graphic below outlines the ODC’s approach to addressing compliance matters based on the level of risk identified.



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The ODC will apply the below compliance principles when undertaking its monitoring and compliance activities:

- Proportionality** The action we take is proportional to the seriousness of the non-compliance.
- Consistency** We ensure our decisions and actions are consistent.
- Transparency** We publish general information on how to comply with the legislation.
- Confidentiality** We keep your information confidential while investigating complaints, however, may publish enforcement outcomes and significant decisions where in the public interest to do so.
- Timeliness** We investigate efficiently and do not unnecessarily impede operations.
- Fairness** We undertake our activities with integrity, professionalism, and due regard to procedural fairness.



## 4. Compliance Monitoring

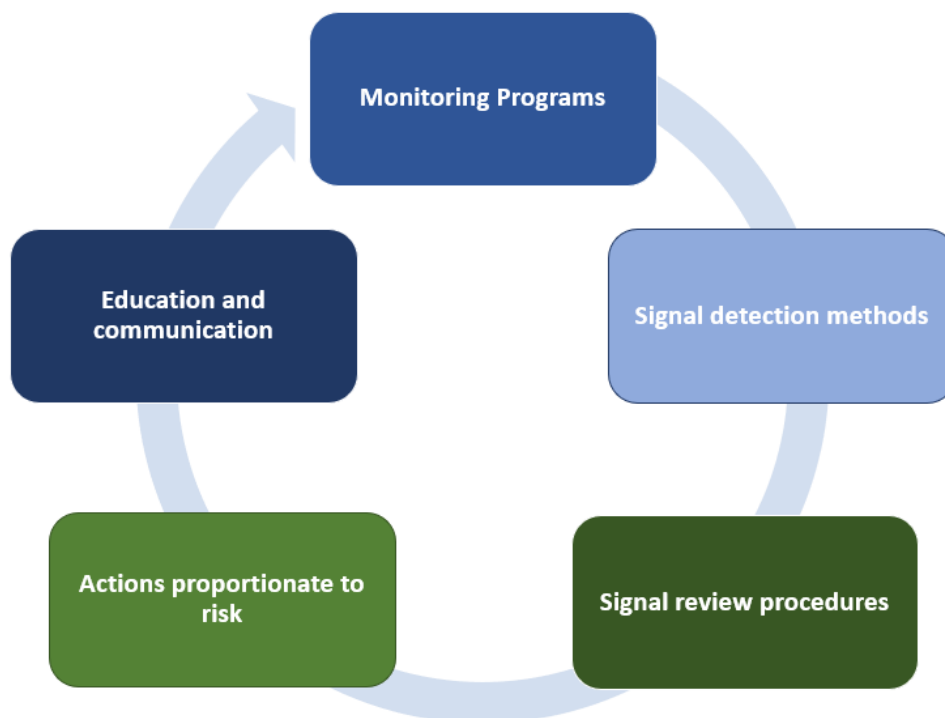
A systematic, risk-based program of activities provides the ODC with a cost-effective approach to monitoring compliance, enables available resources to be targeted to higher priority regulatory risks, and allows for a proactive response to changing and emerging threats.

There are several ways that ODC can detect or receive information relating to non-compliance including through:

- self-reporting and notifying the ODC;
- inspections or assessment activities;
- tip-offs via anonymous sources;
- referrals from industry bodies or other third parties;
- maintaining close relationships with law enforcement and other government agencies;
- sampling of narcotics to ensure they comply with licence and permit requirements; and
- regular requests for information from various sources including regulated persons.

Monitoring compliance through regularly reviewing information received, assists the ODC to identify trends or behaviours that can indicate non-compliance. Examining these trends provides insights into the level of regulatory compliance within industry allowing us to address:

- systemic issues across the industry requiring further education or support to help meet regulatory obligations; and
- areas of non-compliant behaviour so that future compliance activities can target these risk areas.



## 5. Intelligence collection and analysis

The ODC may collect intelligence from other relevant Commonwealth, State or Territory agencies in accordance with the Act and other applicable legislation. This allows us to ensure that we have sufficient information to exercise our regulatory functions and may include cross matching the information received from the other agencies.

### Public media alerts

The ODC regularly reviews publicly available information including media articles, particularly where risks are identified. We also undertake checks to verify allegations where there is an indication of a breach of relevant legislation.

### Notifications

It is a condition under the Act that licence holders are required to notify certain matters to the Secretary of the Department of Health and Aged Care; failure to do so is a breach of the relevant licence. Upon receipt of the notification, the ODC will triage the incident and assess the regulatory response which may include, but is not limited to:

- requiring an application to vary a licence (e.g. change of directors).
- working with persons to correct and prevent reoccurrence.
- compliance or enforcement actions.

### Inspection trends

The ODC will assess the outcomes of compliance activities to determine whether there are issues or themes relating to non-compliance. This information will be used to better inform compliance risk assessments and the targeting of compliance and monitoring effort. The ODC may monitor regulated persons and identify common risk areas to build a profile on trends. This analysis will guide the ODC in determining risk profiles to assist the ODC's regulatory approach for compliance monitoring activities and campaigns.

### Complaints and Tip-Offs

The ODC receives and considers complaints and tip-offs from the public and referrals from other agencies relating to suspected non-compliance. The complaint or referral may include preliminary information to support any allegations. These can be provided to the ODC via the following channels:

- Email: [odc.compliance@health.gov.au](mailto:odc.compliance@health.gov.au)
- Telephone: 02 6289 4550.

When making a tip-off, the more information you give us about the entity, the better we can work to protect honest businesses and the community.

If you are submitting a complaint or referral, useful information includes:

- the name of the individual or business you are complaining about
- the address of the individual or business
- ABN
- phone number
- website

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- social media details (for example, page name and profile addresses)
- details of the behaviour you have identified
- any additional supporting material or evidence you consider relevant.

Due to privacy laws, we will not be able to inform you of the outcome of our consideration of the information you provide, nor updates on the progress of the matter. Rest assured we take all information seriously and consider all information received.

## 6. Stakeholder Engagement and Education

We recognise education and guidance are key to encouraging and assisting with compliance with Australian regulation. We will regularly publish information, conduct education campaigns, and answer enquiries to assist industry in understanding and meeting the regulatory requirements under the Act.

### Monitoring and education campaigns

The ODC carries out targeted campaigns to detect non-compliance and educate regulated persons about compliance requirements. These campaigns may be informed by trends and issues raised during any stage of the regulatory cycle. The campaigns will be designed to inform and educate on regulatory compliance matters with the aim of encouraging best practice procedures.

Monitoring and education campaigns may include onsite or virtual inspections, presentations, publishing material on the ODC's website, conducting meetings with stakeholders, and distribution of educational material, and where appropriate, provide direct feedback to regulated persons to improve best practice.

## 7. Prioritisation

Our regulatory actions and responses are both proactive and responsive, including acting upon information and reports of non-compliance from several external sources.

While all instances of alleged non-compliance are recorded and considered, the ODC cannot pursue every matter that comes to our attention. We use a risk-based approach in deciding priorities, taking into consideration:

- the seriousness of any alleged or detected non-compliance;
- the risk to the community of harm or injury;
- the compliance history and behaviour of the regulated person;
- required action prescribed under the Act;
- trends indicating non-compliance across multiple licence holders or the industry generally.

## 8. Compliance Inspections

The ODC will undertake regular and random property inspections either on-site, or virtually, to assess compliance. All regulated persons are required to notify the ODC of material changes that are relevant to ongoing compliance with the Act and the conditions of their licence. We expect industry to have systems in place to undertake internal auditing and ensure compliance with their licence conditions and the legislation.

### Virtual Inspections

Virtual inspections form an important part of the ODC compliance program and assist us to deliver a flexible way of conducting our compliance program. Notices may be issued to obtain information and documents from the regulated person being inspected. The ODC may also seek information from other sources to verify claims and detect non-compliance. Penalties may apply where a person fails to provide the requested information.

### On-site Announced Inspections

The ODC will undertake announced compliance inspections where the regulated person will be notified in writing prior to the on-site visit being undertaken. These inspections are generally undertaken with the consent of the occupier of the site.

### On-site Unannounced Inspections

The ODC may conduct unannounced monitoring inspections where authorised inspectors will attend a premises without notice. While inspections may be conducted with consent of the occupier, the Act gives authorised inspectors the power to enter premises without consent. As with announced inspections, occupants have the right to observe unannounced compliance inspections; but must not obstruct or hinder an authorised inspector – which is an offence under the Act.

## 9. Investigations

The ODC will conduct investigations in accordance with the [Australian Government Investigations Standards](#) (AGIS), which sets out the minimum standards by which government agencies are to conduct their investigations. The ODC investigates matters by utilising a range of evidence gathering powers and methods, such as:

- using monitoring or investigation powers under the Regulatory Powers Act;
- requiring production of information or documents by way of a notice under the Act, or
- referring matters to law enforcement.

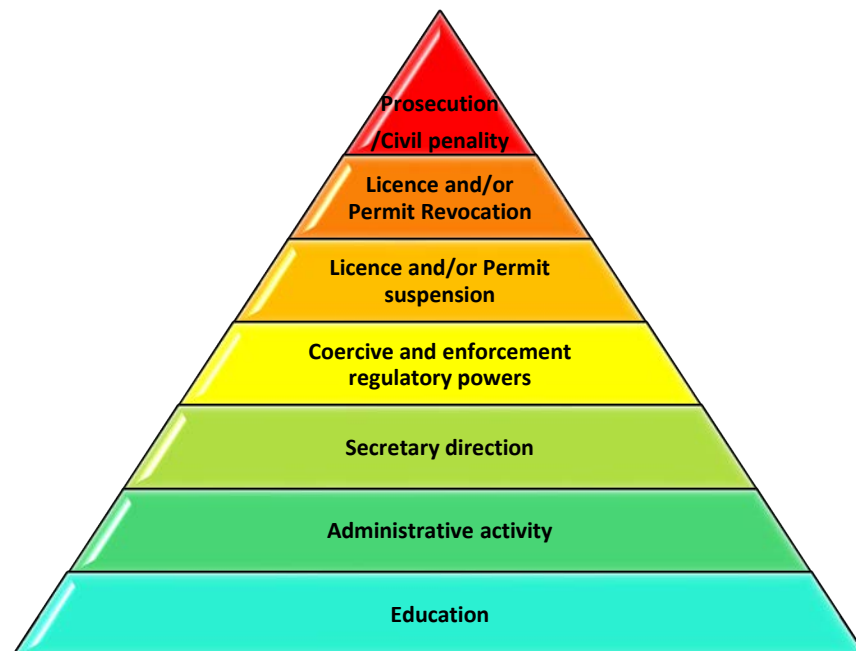
## 10. Enforcement

Hierarchy of regulatory responses

In the first instance, the ODC will often work with the regulated person to provide education and information to assist them to achieve compliance. However, escalation of regulatory action will be considered if:

- the regulated person has repeat breaches or is not willing to comply, and/or
- the alleged breach is likely to result in diversion of narcotics for illicit purposes.

A range of compliance and enforcement tools are employed to address alleged non-compliance, either individually or in combination, and to encourage compliance with the Act. These are depicted in the diagram below.



## 11. Administrative Law Principles

The ODC undertakes its compliance activities with integrity, professionalism and with due regard to procedural fairness and provides information of the persons' rights so they can meet their obligations.

The Act provides a framework for merits review of a range of administrative decisions, this includes a process for review by the Minister or, if delegated, an internal reviewer. The Act provides for internal review decisions to be subject to review by the Administrative Appeals Tribunal in accordance with the [Administrative Appeals Tribunal Act 1975](#).

The [Administrative Decisions \(Judicial Review\) Act 2017](#) also provides for decisions to be subject to judicial review unless prescribed as exempt.