Australian Government

Department of Health and Aged Care
Office of Drug Control

Office of Drug Control

Business Plan 2024-25

ACKNOWLEDGEMENT OF COUNTRY

The Office of Drug Control proudly acknowledges the Traditional Owners and Custodians of Country throughout Australia and pay respect to those who have preserved and cared for the lands on which we live, work, and benefit from each day.

We recognise the inherent strengths and knowledge Aboriginal and Torres Strait Islander peoples provide to the health and aged care system and thank them for their existing and ongoing contributions to the wider community. We extend this gratitude to all health and aged care workers who contribute to improving health and wellbeing outcomes with, and for, First Nations peoples and communities.

We also recognise and respect Aboriginal and Torres Strait Islander peoples' continuing connections and relationships to the lands, waters, culture, and community; and pay respect to all Elders past and present.

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MESSAGE FROM THE DEPUTY SECRETARY

I am pleased to present the 2024-25 Business Plan for the Office of Drug Control (ODC). This document outlines our strategic direction and priorities for effective regulation preventing the diversion of controlled drugs, including narcotic drugs and psychotropic substances, for illicit supply and use. The ODC is committed to contributing to the safeguards and health of the Australian community through effective regulation of controlled drugs and the medicinal cannabis industry.

The ODC ensures Australia meets its international obligations. The ODC has maintained its strong commitment to international drug treaties and conventions by meeting all reporting timeframes for internationally controlled drugs. The ODC works to ensure the safety and wellbeing of the Australian community by continuing to maintain a strong relationship with the International Narcotics Control Board and overseas National Authorities in the operation of the drug treaties. A further focus has been monitoring and responding to trade issues to ensure no disruption to access to essential medicines.

The ODC is also responsible for supporting licence and permit arrangements for Government initiatives such as the new vaping regulations and the kava pilot program. In 2023-24 the ODC issued 14,325 licenses and permits to import and export, a 19% increase over 2022-23.

We will continuously improve our performance and engage with stakeholders on Australia's regulatory framework for medicinal cannabis. Last year we strengthened stakeholder engagement through consistent and transparent communication. Moving forward, we will build on this by increasing opportunities for stakeholder input and leveraging feedback to refine our processes.

In 2023-24 requests for medicinal cannabis permits continued to grow, with the ODC granting more permits compared to the previous 2 years. This growth required the ODC to invest in improved data reporting mechanisms to better monitor cannabis volumes and avoid stockpiling.

We are committed to improving our stakeholders' experience with us. A transformation of the ODC's systems and related business processes commenced in 2023-24, with the rollout out of the first phase in July 2024. Outdated and inefficient manual processes are being replaced by a digital portal enabling stakeholders to lodge and track applications, pay fees and charges, and manage reporting and regulatory obligations. The transformation continues in 2024-25 and will streamline application processes for our customers.

Compliance with the relevant legislation and conditions of narcotics-related licences and permits remains a priority. We work with partner agencies to ensure an intelligence-led and rigorous approach to compliance activity. The ODC continues to explore ways to support continuous improvement in compliance and support education of the sector. Our commitment to rigorous regulatory standards and stakeholder collaboration underscores our role in protecting public health and supporting broader public health objectives. The ODC will continue to evolve its approach to appropriately manage risk while not unnecessarily impeding the operations of the entities that it regulates.

Professor Anthony Lawler

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OUR PURPOSE

The ODC, as part of the Department of Health and Aged Care, regulates and provides advice on the import, export , and manufacture of controlled drugs as part of Australia's obligations under International Drug Conventions:

- Single Convention of Narcotic Drugs of 1961, as amended by the 1972 protocol (the Single Convention)
- Convention on Psychotropic Substances of 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 value of narcotic and psychotropic drugs and use of chemicals which may be used in clandestine drug manufacture and ensures that these drugs are available for legitimate purposes.

Our responsibilities include:

- the regulation of the import, export, and manufacture of controlled drugs to ensure access to essential medications
- the regulation of the import and export of internationally controlled precursor chemicals
- the regulation of medicinal cannabis cultivation and production
- reporting on activities to the International Narcotics Control Board
- applying amendments to comply with international drug controls in Australia, and
- ensuring Australians have access to essential medications.

We work in partnership with other Commonwealth, state and territory government agencies, including law enforcement agencies 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.

We exercise powers conferred through the following Commonwealth legislation:

- *Narcotic Drugs Act 1967*
- Narcotic Drugs Regulation 2016
- Customs (Prohibited Imports) Regulations 1956
- Customs (Prohibited Exports) Regulations 1958

OUR VISION

Our vision is for **effective regulation of controlled drugs to prevent illicit supply and use, while maintaining access to essential medications**. This links with the Department's vision of **better health and wellbeing for all Australians, now and for future generations**.

OUR STRATEGIC INTENT

By regulating the import, export and manufacture of controlled drugs as part of Australia's obligations under International Drug Conventions, we contribute to meeting the department's aim to protect the health, safety and wellbeing of all Australians. We do this by identifying risks to human health and the environment, and managing those risks to prevent harm through education and effective, proportionate compliance activities.

In line with the government's and the community's expectations, we will maintain a best practice and contemporary regulatory environment, boost productivity through reducing unnecessary regulatory burden allowing for increased operational flexibility for industry, and work with international partners to share information and identify opportunities to improve the quality of regulation.

We will continually monitor the environment in which the ODC operates to ensure our regulatory approaches keep pace with changes in technology, industry practices, international regulation and community expectations.

We will use an informed, risk-based approach to licence holder compliance, and identify industry trends and data to proactively assist entities to remain compliant and prevent non-compliance.

The development, management and review of our regulation is guided by the Health Regulatory Policy Framework, which identifies a set of common principles to underpin the department's approach of best practice regulation:

1. Continuous improvement and building trust.
We will:

- adopt a whole of system perspective to regulation, continuously improving our performance, capability, and culture to build trust and confidence in our regulatory system.

2. Risk-based and data-driven.
We will:

- manage risks proportionately, apply treatments which are specific to the prevailing risks and maintain essential safeguards while minimising unnecessary regulatory burden, and leverage data and digital technology to support those we regulate to comply and grow.

3. Collaboration and engagement.
We will:

- be transparent and responsive communicators, implementing regulations in a modern and collaborative way
- recognise that we have a shared responsibility for the stewardship of our regulatory systems
- adopt a whole of system view to regulation and take a proactive and collaborative approach to the delivery of the regulatory functions which the department oversees.

OUR STRATEGIC OBJECTIVES

The common principles the underpin the department's approach of best practice regulation provide a platform for the ODC to develop and implement the following strategic objectives:

1. Ensure compliance with international obligations
2. Enhance stakeholder engagement and collaboration
3. Promote compliance with regulatory requirements
4. Reform ODC's Business Processes and Systems

STRATEGIC OBJECTIVE 1 – ENSURE COMPLIANCE WITH INTERNATIONAL OBLIGATIONS

We support Australia's obligations and provide leadership and advice, both domestically and internationally, in relation to the regulation of controlled drugs. The safety and wellbeing of the Australian community will be maintained by meeting our international obligations for the control of narcotic drugs through effective regulation.

GUIDING PRINCIPLES

1.1 Meet our international obligations for the import, export and manufacture of controlled drugs, cultivation of cannabis and use of precursor chemicals.

1.2 Liaise with international authorities to ensure smooth trade and the resolution of issues under the conventions.

OUR FOCUS FOR 2024-25

a. Ensuring the cultivation, manufacture, production and supply of cannabis and other narcotic drugs are for scientific and medical use and in accordance with international drug treaties and domestic legislation.

b. Managing the domestic production and import of medicinal cannabis in accordance with international drug treaties, avoiding stockpiling in excess of market demand.

c. Introducing measures to improve the oversight of imported stock levels, similar to those required of domestic cultivators.

d. Meeting timeframes for reporting obligations to the International Narcotics Control Board.

e. Making timely updates to domestic drug controls due to changes to international drug treaties.

f. Engaging with international stakeholders to identify emerging issues and international developments.

g. Responding to trade issues to ensure no disruption to access to essential medications.

STRATEGIC OBJECTIVE 2 – ENHANCE STAKEHOLDER ENGAGEMENT AND COLLABORATION

We will be open and responsive to feedback about our processes and regulatory decisions. We engage regularly with many stakeholders and offer a range of mechanisms for the public and regulated entities to engage with us and provide feedback.

GUIDING PRINCIPLES

2.1	Be responsive to stakeholder enquiries.
2.2	Actively communicate with and educate stakeholders on their regulatory obligations and about the role of the ODC.
2.3	Meaningfully engage with stakeholders to understand their concerns and issues prior to making recommendations.
2.4	Collaborate with domestic and international stakeholders building on our relationships with them to address regulatory issues and understand the impact of changing policies, practices, and services.

OUR FOCUS FOR 2024-25

a. Engaging and collaborating with stakeholders impacted by our regulatory decisions to promote transparency of our regulatory processes. Responding to stakeholder enquires in a timely and effective manner and providing opportunities for stakeholders to raise concerns and issues to have them appropriately addressed.

b. Continuing to develop and publish new and improved education, guidance and engagement material, including new website content, to assist regulated entities to understand the role of the ODC and to understand and meet their regulatory obligations.

c. Consulting with state and territory regulators to develop guidance for ODC medicinal cannabis permit holders on sourcing propagating material from state and territory hemp license holders.

d. Providing high quality advice to the Government about controlled drugs and medicinal cannabis regulation, through various mechanisms including the Medicinal Cannabis Expert Working Group.

e. Working with stakeholders across the Australian Government and state and territory authorities to make recommendations on the future of the commercial importation of kava, following the completion of the pilot program for the commercial importation of kava in December 2023.

STRATEGIC OBJECTIVE 3 – PROMOTE COMPLIANCE WITH REGULATORY REQUIREMENTS

We take a risk-based approach to regulation and compliance so that resources are applied to areas of greater risk or concern to enhance community confidence in the regulation of controlled drugs. We will ensure that the importation of controlled substances, vapes and kava products adheres to regulatory standards. Data collected from monitoring activities will be used to identify trends in non-compliance and inform compliance priorities and education activities. In doing this we will manage risks proportionately.

GUIDING PRINCIPLES

3.1	Data and intelligence are used to identify risks of non-compliance and inform compliance strategy.
3.2	Processes are transparent and documented using an evidence-based approach.
3.3	Compliance issues are identified and assessed proportionally with the risk being managed.
3.4	Serious, deliberate, and repeated non-compliance is addressed through infringement, civil action and criminal prosecution.

OUR FOCUS FOR 2024-25

a. Taking a proportionate and risk-based approach to regulatory decisions and the monitoring and compliance of the import of vape products, the import, export and manufacture of controlled drugs, the cultivation of cannabis, and the use of precursor chemicals.

b. Continuing to increase the number of compliance inspections for cultivation, production and manufacture of medicinal cannabis and other narcotics under the *Narcotic Drugs Act 1967*. This will include an industry awareness campaign on reporting obligations.

c. Strengthening compliance activities with a focus on driving innovation, developing supporting tools, and using data and intelligence to inform compliance activities.

d. Ensuring timeliness standards are maintained for completion of Inspection reports and undertake quality assurance activities on those reports.

e. Reviewing and updating the ODC 2023-25 Compliance and Enforcement Framework.

f. Undertaking compliance and education activities to assist licence and permit holders understand their obligations and promote compliance with regulatory requirements, with a particular focus on timely notification to the ODC for variations or change of circumstances by regulated entities

g. Collaborating effectively with Commonwealth and state and territory health and law enforcement agencies to form a strong evidence-base for strong regulatory decision making as appropriate.

h. Maintaining the ODC's Risk Management Framework document and risk model to ensure risks, controls and treatments are appropriately updated to support regulatory activity. This will provide industry with transparency on ODC's continual approach to risk-led monitoring and compliance activities.

i. Undertaking relevant training to ensure staff are qualified and have the capability to undertake compliance activities.

STRATEGIC OBJECTIVE 4 – REFORM ODC'S BUSINESS PROCESSES AND SYSTEMS

We will continuously improve our processes and performance and make regulatory decisions in the context of our international obligations, applicable legislation and impacts on the regulated community. This will include building staff capability and a culture that identifies and implements improved business practices.

Ensuring the ODC's systems and processes are effective will support both the industry and the ODC regulatory activities whilst aligning with other transformation reforms across the department.

GUIDING PRINCIPLES

4.1 Regulatory decisions are made in accordance with published timeframes.

4.2 Regulatory reforms are proposed to Government when evidence of benefit is determined, or when risks can be appropriately managed.

4.3 We will continuously improve business services, processes and digital systems to ensure they are fit for purpose.

OUR FOCUS FOR 2024-25

a. Continuing to meet timeframes within published performance targets or indicative timeframes published on the ODC website, by reviewing processes, continuously improving our performance and engagement with stakeholders.

b. Progressing the implementation of modern digital tools that make it easier for industry to complete business transactions and staff to process applications and transactions. This includes the Transformation Project delivering the first set of Narcotic Drugs Act Licence Application Forms on the Health Business Services Portal, for Medicinal Cannabis and Narcotic Drugs Manufacture, as well as Case Management System functionality for ODC staff. Throughout the remainder of 2024/25, the Project will continue to implement the ODC's suite of business content to improve related processes for the ODC to:

    - better manage and track applications,
    - add capability to the case management system,
    - manage risk and compliance activities, and
    - provide more transparency regarding ODC's regulatory and compliance activities.

c. Building capability through training and cross-skills development and promoting an impartial, flexible and innovative workforce.

d. Ensuring routine compliance inspections are completed within 2 months.

REPORTING

The four strategic objectives in this plan have been prepared consistent with the Government's expectations on how the ODC will achieve its regulatory outcomes, carry out its regulatory functions, and exercise its powers.

Reporting of our performance against the Business Plan will be included in the Department's Portfolio Budget Statements and Annual Report and will comprise both qualitative and quantitative performance data to outline how we performed as a regulator.