



Australian Government

Department of Health

Business Plan: January-June 2022

Office of Drug Control



Message from the Deputy Secretary

Welcome to the inaugural Business Plan for the Office of Drug Control (ODC), the first of what will become an annual publication.

This Business Plan sets out our regulation, regulatory reform, stakeholder education and engagement, and compliance agenda for the remainder of the 2021-22 financial year. It supplements the *Health Portfolio Budget Statements* and the *Department of Health Corporate Plan*.

Over the last few years there has been a significant amount of change in relation to the regulation of narcotic drugs in Australia, in particular, due to the growth of medicinal cannabis industry. To ensure the appropriateness of Australia's regulatory framework for medicinal cannabis, in 2019 the Australian Government commissioned a significant review of the scheme, which was undertaken by Professor John McMillan AO. The ODC has been progressively implementing the Review recommendations, culminating in the introduction on 24 December 2021 of a single licence framework with simplified permit arrangements for regulating medicinal cannabis cultivation, production and manufacture activities. These reforms are aimed at reducing the regulatory burden and increasing operational flexibility for industry.

The Government, as part of its Pacific Step-up initiative, recently implemented a two-year pilot program for the commercial importation of kava. The Department of Health, through the ODC, is the lead agency for the kava pilot, which includes a comprehensive evaluation to inform recommendations to Government at the conclusion of the pilot.

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

Role of the Office of Drug Control

The ODC, as part of the Department of Health, regulates and provides advice on controlled drugs to support Australia's obligations under International Drug Conventions.

The ODC's responsibilities include the regulation of the import, export and manufacture of controlled drugs to ensure access to essential medications, the regulation of medicinal cannabis cultivation and production; reporting on activities to the International Narcotic Control Board (INCB); applying amendments to international drug controls in Australia and providing in-depth travel advice regarding travelling with controlled drugs.

The ODC exercises powers conferred through the *Narcotic Drugs Act 1967* and associated regulations:

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

These domestic legislation and regulations give effect to a number of international treaties, including:

- 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.

Principles

As an Australian Government regulator we adhere to the following principles:

- we are committed to maintaining the trust and confidence of the Australian public
- we are accountable to the government and the Australian public, and work cooperatively with the industry we regulate
- we communicate meaningfully with stakeholders including consumers, providing transparency across our regulatory practice
- we assess evidence in making decisions and recognise the value of taking a risk-based approach to regulatory, compliance and enforcement activity
- we perform our functions consistently to ensure predictable outcomes in similar decisions.

Operating environment

As a signatory to international drug conventions, Australia is committed to complying with the obligations within them, including in relation to the import, export and reporting of internationally controlled drugs and precursor chemicals, the manufacture of narcotics drugs, and acting as the single designated agency to licence and control cannabis cultivation. The purpose of the drug conventions is to provide an international framework that recognises the medicinal value of narcotic and psychotropic drugs and ensures that these drugs are available for legitimate purposes.

As part of ensuring Australia meets its international obligations, the ODC works 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.

Our challenge is to ensure that regulation is appropriate to manage risk while not unnecessarily impeding the operations of the entities that we regulate. Our compliance and enforcement

responses will remain proportionate to the risk posed to maintaining the integrity of the regulatory framework. The ODC is committed to enhancing its stakeholder engagement and education activities, including in response to emerging issues and trends, and to assist businesses to comply with their regulatory requirements.

The activities of the ODC are supported through industry cost recovery for its medicinal cannabis activities, and direct Government funding for other activities. We are committed to regularly reviewing our fees and charges to enable government decisions on appropriate charging rates and to ensure consistency with the Australian Government Charging Framework and industry expectations.

Across the globe, the COVID-19 pandemic has had an impact on industry and regulators, requiring innovative solutions to address its impacts. We are continuing to engage and support industry by being adaptable and capitalising on advancements in remote communication.

We will continue to support Australia's obligations and provide leadership, both domestically and internationally, in relation to narcotic drugs regulation.

Priorities

Over the January-June 2022 period, the ODC will be focusing on the following priorities:

Engagement and Collaboration

- Increase engagement with stakeholders, including through regular meetings with industry representatives, information sessions and workshops, and attendance at industry conferences to facilitate better communication between the ODC and our stakeholders.
- Enhance collaboration and strategic engagement with relevant Commonwealth, state and territory agencies on regulatory issues of common interest.
- Manage our business-as-usual activities with industry including: narcotic manufacturing licences and permits; medicinal cannabis licence and permit activities; and the import and export of controlled drugs and related substances.

International obligations

- Continue to meet our international obligations for the import, export and manufacture of controlled drugs, and precursor chemicals, and timeframes for reporting requirements to the International Narcotics Control Board on treaty mandated activities.
- Liaise with international authorities to ensure the smooth trade and resolution of issues under the conventions.
- Continue to support the Government's kava pilot program.

Transparency

- Undertake a review (for Government consideration) of the ODC's current cost model following the implementation of the new single licence and related permit reforms. Outcomes of the review will include the proposal to implement appropriate fees and charges, as well as publishing specific service levels for the processing of medicinal cannabis licence and permit applications.
- Publish the first *Compliance and Enforcement Framework* document, to provide industry with transparency on ODC's approach to monitoring and compliance activities.
- As part of complying with the Government's new Regulator Performance Guide, the ODC will develop and publish a set of Key Performance Indicators (KPIs) for 2022-23. The ODC will continue to publish KPIs and report on achievements against them annually.
- Publish improved guidance for industry, including clear service level standards and assessment timeframes for all licence and permit processes across the ODC.

Manage risk

- Implement a risk-based approach to regulation and compliance, to ensure that resources are applied to areas of greatest risk or concern. Compliance audit activities will continue to monitor whether entities are complying with relevant legislation, policies and procedures in accordance with their licence conditions.
- Continue to undertake planned and unannounced inspections, virtually and on-site in line with our risk-based compliance approach.

Continuous improvement

- Regularly review our procedures and processes to ensure they remain relevant and to identify opportunities for efficiency gains.
- Embed reforms to medicinal cannabis regulation following the move to a single licence and reformed permit framework.
- Undertake a website transformation project to align with whole-of-government hosting and accessibility standards. This will include a full review and update of existing ODC website content, as well as a new and improved look and feel. This work will be completed in the 2022-23 financial year.