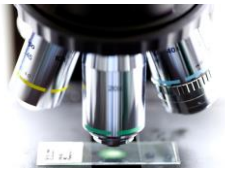




Technical Alert

The Office of Drug Control: Medicinal Cannabis Consultation Session

Dear Member,

CMA was recently invited to attend an information session held by the Department of Health's Office of Drug Control (ODC) regarding licensing for the domestic cultivation and manufacture of medicinal cannabis products. This follows on from recent amendments to the *Narcotic Drugs Act 1967*, enabling the domestic cultivation of cannabis for medicinal and related research purposes that will come into operation later in the year.

Domestic cultivation of medicinal cannabis will enable sufficient quantities of raw materials to be available to meet the needs of local manufacturers, and will ensure that quality control measures on medicinal cannabis-derived products can be enforced to protect patient safety.

Please find below a summary of the information provided at the meeting, held in Sydney on 12 July 2016. Presentation slides will be available at www.odc.gov.au after 20 July 2016.

Key Dates

29 February 2016: The *Narcotic Drugs Amendment Bill 2016* was passed by Parliament to enable the cultivation of cannabis for medicinal and related research purposes in Australia.

31 May 2016: TGA decision to reschedule cannabis from Schedule 9 (prohibited) to Schedule 8 (controlled substance) of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

30 October 2016: The amended *Narcotic Drugs Act 1967* will come into effect. In the period between now and 30 October, a detailed regulatory framework is being put in place, enabling applications for licences and permits for cultivation, production and manufacture of medicinal cannabis products. From this date, licence application forms will be accepted by the ODC; this date is also the deadline for states to decide on patients groups.

Market Size

- University of Sydney Business School paper titled "*Medicinal Cannabis in Australia: Science, Regulation & Industry*" estimates that initial demand could be as high as 8,000 kg of the product worth more than $100 million per year, enough to service between 20,000 and 100,000 patients.
- This corresponds to 51,000 square metres or 5 hectares of greenhouse space or 15 hectares of broad acreage farming.

- Patient groups will be decided on a state by state basis, however, four key patient groups have been identified at a federal level. These four groups of patients cover epilepsy, multiple sclerosis, cancer and terminal patients.

Market Access

Licenses

Prerequisites in order to obtain a license will include:

- a 'fit and proper' test for license applicants;
- applicants must prove financial viability;
- security, transportation, storage and disposal facilities must meet requirements set by ODC;
- seed to sale tracking technology; and
- self reporting systems for identifying and communicating breaches to ODC.

Cultivator

A cultivator will need to hold either a medicinal cannabis licence or a cannabis research licence granted by the ODC under the ND Act to cultivate cannabis for medicinal or related research purposes.

- One license will be required and will be issued by ODC
    - must have contract with manufacturer
    - one year duration, renewable.

Manufacturer

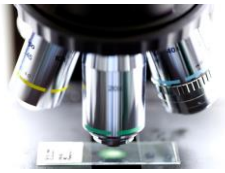
- May require up to three licenses
    - one from ODC granted under the *Narcotic Drugs Act 1967*
    - one from the TGA granted under the *Therapeutic Goods Act 1989*
    - one from the relevant state/territory jurisdiction (usually the Health Department)

Patients

- Medical practitioners can register with the Authorised Prescriber Scheme (APS) to become a provider of unregistered products:
    - only available to specialists in early stage.
- Patient Special Access Scheme (SAS) allows medical practitioners to seek permission to grant unregistered products on a case by case basis.

Permits

- Outlines the types and quantities of cannabis to be produced.
- New permits will be granted when there is evidence of unmet demand provided to ODC by manufacturer.
- Permits limit national inventory to 6 month supply:
    - Requirement under single convention, monitored by International Narcotics Control Board (INCB).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Fees and charges

- Fees to be set by cost-recovery model according to Australian Government Cost Recovery Guidelines.
- Fee structure to be approved by state and federal parliaments.

CMA economic analysis

CMA is pleased with the overall momentum and political support in regards to the creation of a medicinal cannabis framework. Although this development provides exciting opportunities for our industry there are a number of underlying concerns with the proposed system. Our first concern is the long-term competitive structure of the industry.

The system creates market concentrating forces such as:

- Borrowing constraints emerging from one year licenses,
- Creating contractual relationship with silent firm may require a costly specialist intermediary,
- Heavy compliance burden and fixed fee structure gives larger firms cost advantage, and
- Limits to international trade due to international obligations and conventions.

Our second concern is the state by state variation in patient groups. Although we acknowledge the need for systematic flexibility and an active role for state governments, this system may lead to incomplete data and stakeholder confusion.

Our third and final concern is that the new framework does not adequately utilize preexisting industrial hemp capabilities. Ignoring established supply chains and expertise will delay the maturation of the industry and ultimately lead to higher consumer prices.

ENDS