Australian Government
Department of Health

Information Briefing
For Information

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To: **Minister Ley**

cc: **Minister Nash**
[redacted]
Lisa Studdert

Subject: Medicinal Cannabis Down-scheduling proposal

Purpose: To advise you of a delegate-initiated proposal to down-schedule medicinal cannabis when supplied and used in accordance with the *Narcotic Drugs Act 1967* and the *Therapeutic Good Act 1989*

Urgency: The proposal to down- schedule will be made public on 21 January 2016, in order to allow the required public consultation process to be undertaken.

Clearance:

Contact Officer:	*Bill Turner*	*Assistant Secretary, Office of Drug Control*	Ph: s22 [redacted]
Clearance Officer:	*John Skerritt*	*Deputy Secretary, Regulatory Services Group*	*Clearance Officer Signature* 16/1/2015

Key Issues:

1. Cannabis and Tetrahydrocannabinols (THC) are currently in Schedule 9 of the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)).
2. In some states and territories, being in Schedule 9 either creates an absolute barrier to supplying and using cannabis or cannabinoids for medicinal purposes, or creates legislative and practical difficulties in the implementation of a regulatory regime. For example, Schedule 9 status may prevent handling or transport of medicinal cannabis products and the prescribing by a medical practitioner.
3. Medicines scheduling decisions are made by a senior medical officer, acting as a delegate of the Secretary of the Department. The delegate has initiated a process to consult with the states and territories and the public on a proposal to down-schedule substances in medicinal cannabis products when supplied and used in accordance with the *Narcotic Drugs Act 1967* (soon to be amended to permit the cultivation of cannabis for medicinal and related scientific purposes) and the *Therapeutic Goods Act 1989*.
4. As you know, we are currently finalising a Bill to amend the Narcotic Drugs Act for introduction in early February. The Bill, if passed by Parliament, would amend the Act to enable cultivation of cannabis for use in medicinal products to be supplied through

provisions of the Therapeutic Goods Act (clinical trials, authorised prescriber, special access scheme).

5. State and territory drugs and poisons legislation interacts with these provisions, with scheduling being a key control on access (for instance, determining whether supply of a medicine requires a prescription etc). States and territories could unilaterally schedule cannabis and other cannabinoids in a way that that would permit them to provide access; however, it is preferable that the Commonwealth provide leadership by amending the SUSMP in a manner that the states and territories could adopt in a consistent fashion. This would allow, to the extent possible, supply and access to medicinal cannabis products to be managed uniformly across the country.
6. Initial discussions with senior State and Territory Health Department representatives indicate support for the proposal that the Commonwealth down-schedule cannabis products (mostly now in Schedule 9 (Prohibited substances), although they will provide more detailed comment as part of the planned public consultations.
7. In order for potential changes to be implemented by Spring 2016, the proposal needs to be discussed at the meeting of the Advisory Committee on Medicines Scheduling (ACMS) on 15/16 March 2016. It is necessary to post a public notice that allows 4 weeks for public submissions on the proposal on 21 January 2016. The consultation period is specified in the *Therapeutic Goods Regulations* 1990.

Background:

We are currently finalising draft legislation that will enable the cultivation of cannabis for medicinal and related scientific purposes for introduction in the week commencing 8 February. The proposed amendments to the Narcotic Drugs Act will provide a comprehensive, robust and secure system for the cultivation of cannabis and the manufacture of medicinal cannabis products.

However, the supply of these products will be controlled both under the Therapeutic Goods Act and existing state and territory legislation. The primary control at the state and territory level is the Poisons Standard. Even though the Poisons Standard is a Commonwealth legislative instrument made under the Therapeutic Goods Act, it is given legal effect by states and territories through their own poisons/drugs legislation. Because of the differing structures of the relevant state/territory legislation medicines scheduling is not consistent nationally. For example, some states have allowed pathways for therapeutic use of Schedule 9 substances (which cannabis currently is), while other states have an absolute prohibition on access to Schedule 9 substances.

At least two states have proposed unilateral amendment of their schedules to enable access to medicinal cannabis as a means of facilitating access to medicinal cannabis products, but the wider view is that it would be preferable that there be a Commonwealth decision to down-schedule. This gives a better opportunity for consistent approaches and also demonstrates Commonwealth leadership.

The scheduling delegate has proposed to down-schedule cannabis substances, when used in specified ways, consistent with legal cultivation and manufacture within Australia or legal import into Australia, to Schedule 8 (Controlled drug) (the proposed public notice is at **Attachment 1**). If a down- scheduling decision is made, and adopted by those states, the effect of this would be to remove existing state prohibitions (and provide more flexibility in state controls). It would also have the effect of better enabling patients prescribed with a medicinal cannabis product in a state/territory to travel interstate without the risk of breaking criminal laws, depending on the state/territory legislation.

The proposed change to scheduling will be integrated with additional controls over cannabis, extracts derived from botanical cannabis and THC, including the requirement for Australian produced/manufactured medicinal cannabis products to be manufactured in accordance with the Narcotic Drugs Act (as proposed to be amended).

Imported products would need to be imported in accordance with the Customs (Prohibited Imports) Regulations 1956, which requires an importer to be licensed.

In addition, we are seeking public comment on the following possible additional controls:

- limiting prescribing to state/territory authorised medical practitioners; or
- limiting access to through a clinical trial, Special Access Scheme Category B or Authorised Prescribers, access routes allowed under the Therapeutic Goods Act; or
- creating a new entry 'Poisons available only from or on the order of a specialist physician'.

The final decision on the proposal will be informed by a four week public consultation and discussions at the ACMS meeting 15/16 March 2016. The expected timeline is as follows:

- Public notice - 21 January
- Public submissions submitted by 18 February
- ACMS meeting - 15/16 March
- Interim decision with proposed implementation date made public with request for submissions on the interim decision – early April
- Submissions on interim decision submitted by 2 weeks from publication of interim decision – 2 weeks after publication of interim decision
- Publication of final decision and implementation date – early May
- Implementation date (when in the Poisons Standard) could be 1 June 2016.

This would allow a decision to be made in a time that is consistent with the expected commencement of the operation of the new provisions in the Narcotic Drugs Act for cultivation (particularly in Victoria) around September/October 2016.

The final operation of the decision will depend on the time taken for states and territories to adopt the changes. Some states directly reference the Poisons Standard so adoption is automatic; while for others, regulatory change is needed to give the decision effect. The additional controls might also require state/territory regulatory changes.

Questions and Answers about the proposal for public communication are attached. These have been reviewed by the Department's media advisor. .

Attachments:

Attachment 1. Public notice

Attachment 2. Questions and Answers on Cannabis Down Scheduling Proposal

Attachment 1

Scheduling proposal for cannabis – Public notice

Proposal to enable appropriate access to medicinal cannabis products by creating new Schedule 8 entries for the following substances for internal human therapeutic use:

- Cannabis (plant and flowering tops),
- Botanically derived extracts (or derivatives) of cannabis, and
- Tetrahydrocannabinols (THC) botanically derived from cannabis.

including when prepared or packed for therapeutic use, and where the substances:

- have been produced or manufactured in accordance with the *Narcotic Drugs Act 1967*; or
- have been imported in accordance with the *Customs (Prohibited Imports) Regulations 1956.*

except when included elsewhere in Schedule 8 or Schedule 4.

Cannabis and THC would remain Schedule 9 substances:

- for human therapeutic use when it does not fit the above criteria, or
- when not for human therapeutic use, or
- Does not fit any other current exceptions.

Options for additional controls on these substances through an entry in Appendix D of the SUSMP could include one of the following:

- restriction of access to state/territory authorised medical practitioners (current Item 1 - Poisons available only from or on the prescription or order of an authorised medical practitioner); or
- restricting access to :
    - clinical trials conducted under the TG Act when unapproved products including these substances are used i.e. Clinical trial Notification (CTN) or Clinical Trial Exemption (CTX); and
    - supply as an unapproved product through the TGA Special Access Scheme Category B or the Authorised Prescriber Scheme similar to the current Item 3 (Poisons available only from or on the prescription or order of a medical practitioner authorised or approved by the Secretary of the Commonwealth Department of Health under section 19 of the *Therapeutic Goods Act 1989*.); or
- restricting access by creating an entry such as "Poisons available only from or on the order of a specialist physician".

Cannabis re-scheduling proposal – Questions and Answers

What is proposed?

It is proposed that the Standard for the Uniform Scheduling of Medicines and Poisons (the SUSMP or the Poisons Standard) be amended to place some cannabis-derived substances, when used in particular ways, in Schedule 8 of the Standard.

Potential down-scheduling to S8 still allows very strict controls on access to the substances. A number of other therapeutically used-substances which have risk of addiction or criminal diversion such as cocaine or morphine are also included in schedule 8.

Cannabis and THC (a psycho-active component of cannabis) currently sit in Schedule 9, which means access for their use is extremely restricted.

Why is this being proposed?

On 17 October 2015, the Commonwealth Government announced that it will seek parliamentary approval of amendments to the *Narcotic Drugs Act 1967* to establish a national scheme to allow the cultivation of cannabis for medicinal purposes. However, the access to these products - including handling, transportation and storage - is controlled by their scheduling status under the Poisons Standard. Most cannabis products are currently listed in Schedule 9 of the Poisons Standard which makes supply of product grown and manufactured in Australia very difficult and, in some states, potentially impossible. This scheduling proposal **complements the planned amendments to the Narcotic Drugs Act** and aims to simplify access for those qualified for such access, while keeping appropriate controls in place to prevent these products from being diverted to illicit uses.

What is the scheduling process?

Scheduling is the national system for applying access restrictions on human and veterinary medicines as well as a range of chemicals where there is a potential risk to public health and safety. Substances are scheduled according to the degree of risk and the level of control required over availability to protect consumers.

While decisions on medicines scheduling are made by a delegate, who is a senior medical officer, in the Commonwealth Department of Health, the implementation of scheduling decisions is the responsibility of state and territory governments. The state and territory government are responsible for imposing legislative controls on the supply of substances and the controls these governments impose usually flow from the schedule in which the poison is located.

The policy is outlined in the Australian Health Ministers' Advisory Council Scheduling Policy Framework found at https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals.

The proposal will be referred to the Advisory Committee on Medicines Scheduling (ACMS) for advice, and after publication on the TGA website (www.tga.gov.au) today (21 January 2016), public comment is invited prior to committee consideration by close of business 18 February.

After the Committee considers the re-scheduling proposal, public comment and background papers, they will provide a recommendation to the senior medical officer.

Does this public notice mean that substances derived from cannabis will definitely be down-scheduled?

No. The scheduling decision will be made by a senior medical officer (in the capacity as a delegate of the Secretary of the Commonwealth Department of Health). Comments are being sought prior to a meeting of the Advisory Committee on Medicines Scheduling in March 2016. The Committee is made up of independent experts as well as state and territories representatives that provide advice to the scheduling delegate. The scheduling delegate will make an interim decision based on the comments made and the advice from the Committee.

What is the role of states and territories in this?

An entry in the Poisons Standard has no legal effect unless it is adopted through state and territory drugs and poison legislation. If approved, the proposal aims to support a consistent approach that all states and territories can apply to allow the supply of medicinal cannabis in their jurisdiction. It will be up to the individual states and territories how they might wish to implement any final decision.

Why can't the *Therapeutic Goods Act 1989* be used to guarantee a consistent approach to supply of medicinal cannabis products?

The role of the Therapeutic Goods Act relates to the regulation of the supply of therapeutic goods and works in tandem with state and territory legislation on the access to scheduled particular substances. This proposal is designed to facilitate the access pathways already available under the Therapeutic Goods Act for unregistered products.

The Therapeutic Goods Act makes provision for the use of unregistered medicines in certain cases where there is medical opinion that it is justified, such as through the Authorised Prescriber Scheme, where a medical practitioner can be authorised by the TGA to prescribe a specific medicine to a specific patient group.

It also allows for the conduct of clinical trials, which are necessary to test new medicines to enable them to be registered by the TGA for general use.

When will a decision be made?

Following the meeting of the ACMS in March, an interim decision will be published seeking further comment. A final decision would then be made before the end of May 2016 and published with an implementation date, if appropriate.

However, implementation of the decision in individual states and territories will depend on when and how it the decision adopted into state and territory legislation.