

EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Poisons Standard November 2016

The *Therapeutic Goods Act 1989* (**the TG Act**) provides for the establishment and maintenance of a system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The TG Act also provides for a framework for the state and territory governments to adopt a uniform approach to control the availability and accessibility, and to ensure the safe handling, of medicines and poisons in Australia. The Therapeutic Goods Administration (**the TGA**), which is part of the Department of Health, is responsible for administering the TG Act.

Part 6-3 of the TG Act provides the basis for a uniform system of access controls for goods containing scheduled substances. The scheduling of substances allows restrictions to be placed on their supply to the public, in the interests of public health and safety. The scheduling of substances is aimed at minimising the risks of poisoning from, and the misuse or abuse of, scheduled substances.

Subsection 52D(2) of the TG Act (which is in Part 6-3) provides for the Secretary of the Department of Health, to amend the current Poisons Standard (known as the Standard for the Uniform Scheduling of Medicines and Poisons) or to prepare a document (a new Poisons Standard) that includes schedules containing the names or descriptions of substances, in substitution for the current Poisons Standard.

The Poisons Standard consists of decisions of the Secretary, regarding the classification of poisons into the different Schedules, signifying the degree of control recommended to be exercised over their availability to the public.

The TG Act establishes two expert advisory committees, the Advisory Committee on Medicines Scheduling (the ACMS) (section 52B) and the Advisory Committee on Chemicals Scheduling (the ACCS) (section 52C), which provide advice and make recommendations to the Secretary on matters relating to medicines and chemicals scheduling decisions.

The Schedules contained in the Poisons Standard are referred to under state and territory legislation for regulatory purposes. This enables restrictions to be placed on the supply of scheduled substances to the public, according to the degree of risk associated with them and the degree of control over their availability, in the interest of public health and safety.

The Commonwealth also takes into account the scheduling and classification of substances in the Poisons Standard for regulatory and enforcement purposes under the TG Act.

For example, the TG Act prohibits the publication or broadcasting of advertisements to consumers about prescription medicines containing substances included in

Schedule 4 or 8 of the Poisons Standard, or over the counter medicines containing substances included in Schedule 3 and not included in Appendix H of the Poisons Standard. The advertising of substances included in Schedule 9 or Schedule 10 of the Poisons Standard is also prohibited.

The *Scheduling Policy Framework (the SPF)* provides guidance on whether a decision concerning the Poisons Standard would benefit from being referred to ACMS or ACCS for advice. A copy of the SPF can be found at <https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals>.

The purpose of this instrument is to make a new Poisons Standard (cited as the Poisons Standard November 2016) in substitution for the previous Poisons Standard - Poisons Standard October 2016 (which commenced on 1 October 2016).

The Poisons Standard November 2016 incorporates a number of changes to the Poisons Standard October 2016. These principally involve the entries for cannabis and tetrahydrocannabinols in Schedule 9, and the creation of new entries for cannabis and tetrahydrocannabinols in Schedule 8.

These changes were made following the provision of advice from the ACMS, in accordance with the procedures set out in Subdivision 3D.2 of Part 6 of the Therapeutic Goods Regulations 1990 (**the TG Regulations**) for amending the Poisons Standard when a proposed amendment is referred to an expert advisory committee.

Amendments relating to cannabis and cannabinoids (including tetrahydrocannabinols) scheduling were considered at the March 2016 ACMS meeting, after a delegate-initiated scheduling application to enable appropriate access to medicinal cannabis for human therapeutic use.

Background

Cannabis is a term that covers varieties of the *Cannabis* genus. The *Cannabis* plant produces a resin containing compounds called cannabinoids. Some cannabinoids possess psychoactive properties.

The *Cannabis* plant contains about 60 cannabinoids of which the main active constituent is delta-9-tetrahydrocannabinol. Delta-9-tetrahydrocannabinol reportedly has anti-emetic properties and has been associated with claims relating to use for the control of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional anti-emetics. Another active cannabinoid in *Cannabis* is cannabidiol that has been associated with claims relating to use as an analgesic, anticonvulsant, muscle relaxant, anxiolytic, neuroprotective, anti-oxidant and anti-psychotic.

Scheduling of cannabinoids has been considered on several occasions over the last 30 years. In the period since 1984, nabilone, dronabinol (synthetic delta-9-tetrahydrocannabinol), and nabiximols have been listed in Schedule 8 and cannabidiol in Schedule 4, to enable access for therapeutic use for specific medical conditions.

An invitation for the public to comment on the scheduling proposal in relation to cannabis and cannabinoids was advertised on the TGA website (www.tga.gov.au) from 20 January 2016. The period for consultation closed on 18 February 2016.

The interim decision

The delegate's [interim decision](#) was made on 5 April 2016, after consideration of public comments and consultation with state and territory governments. In this decision, the proposal that was referred to the ACMS meeting was amended from cannabis and cannabinoids, to cannabis and tetrahydrocannabinols. A copy of the interim decision can be found on the TGA website (www.tga.gov.au).

The delegate's interim decision on cannabis and tetrahydrocannabinols was to down-schedule cannabis and tetrahydrocannabinols from Schedule 9 (Prohibited Substances) to Schedule 8 (Controlled Drugs) for human therapeutic use and in specified circumstances, with Appendix D (1) and Appendix K entries. Non-therapeutic use is to remain in Schedule 9.

The interim decision to include Appendix D (1) entries for cannabis and tetrahydrocannabinols places an additional control such that these substances will only be "available from or on the prescription or order of an authorised medical practitioner" and where the medical practitioner has been authorised by the "appropriate authority" as defined in Part 1, Interpretation, Paragraph 1(1) of the Poisons Standard (these are generally senior health executives of the states and territories). An explanation of "appropriate authority" and "authorised prescriber" can be found below.

Inclusion in Appendix K means products containing cannabis and tetrahydrocannabinols must be labelled with a sedation potential warning. This measure was included because of the potential sedation effects of these substances.

An invitation for further public comment on the interim decision was advertised on the TGA website (www.tga.gov.au) from 5 April 2016. The consultation closed on 19 April 2016.

The final decision

The delegate's final scheduling decision on cannabis and tetrahydrocannabinols was made following due consideration of further public comments, and discussion with state and territory governments.

The final decision was to create new Schedule 8 entries for cannabis and tetrahydrocannabinols, and to amend the existing Schedule 9 entries for cannabis and tetrahydrocannabinols. The Appendix D (1) and Appendix K entries from the interim decision have been retained in the final decision on cannabis and tetrahydrocannabinols.

The scheduling decision complements recent amendments to the *Narcotic Drugs Act 1967 (the ND Act)* made by the [Narcotic Drugs Amendment Act 2016](#), and aims to make available for the first time in Australia medicinal cannabis products from

cannabis cultivated in Australia for patients that qualify, while retaining appropriate controls to prevent such products from being diverted to illicit uses.

The effect of this decision is that *Cannabis*, *Cannabis* resin, extracts, cannabinoids or other *Cannabis* products that have been:

- cultivated and produced and/or manufactured in accordance with a licence under the ND Act; or
- imported for use in therapeutic goods, or in a product imported, and supplied in accordance with the TG Act;

and that are for human therapeutic use, will come within the new Schedule 8 entries.

Otherwise, these products would still be covered by the Schedule 9 entry.

There are exceptions to the new Schedule 8 listings for cannabis and tetrahydrocannabinols. One of exceptions refers to products containing *Cannabis* or tetrahydrocannabinols to which item 4, 8, 10, 11 or 12 of Schedule 5A to the TG Regulations applies. Such products are not, when brought into Australia in the circumstances set out in those items, required to be included in the Australian Register of Therapeutic Goods. However, it is not intended that their scheduling status change, i.e. they would be Schedule 9 poisons.

The other exceptions reflect the fact that the specific listings of cannabinoids elsewhere in the Schedules accommodate residual quantities of tetrahydrocannabinols and products that are not intended for internal human use.

Hemp seed oil is as defined in Part 1 Interpretation, Paragraph (1) of the Poisons Standard, and means the oil obtained by cold expression from the ripened fruits (seeds) of *Cannabis sativa*.

Hemp oil is not the same as hemp seed oil. Hemp oil includes extracts from the flowering tops and leaves and any other part of the *Cannabis* plant other than the ripened fruit (seeds). Hemp oil will come within Schedules 8 or 9, depending on whether or not it satisfies the relevant criteria.

The final decision aims to deliver a consistent approach that all state and territory governments can apply to allow the supply of medicinal cannabis. However, it will be up to the individual state and territory governments as to how they adopt and implement the final decision. This will depend on the respective state and territory legislation. The decision to down-schedule also gave due consideration to an implementation date that would allow the state and territory governments time to consider what, if any, changes to their legislation are required.

The final decision also amends the Schedule 9 listing of cannabis and tetrahydrocannabinols to take into account the new Schedule 8 entries for cannabis and tetrahydrocannabinols.

Schedules 8 and 9 – Cannabis

The Poisons Standard Schedule 8 entry for cannabis applies only where cannabis is intended for human therapeutic use and where it satisfies the other specified criteria for its listing in this Schedule.

The Schedule 9 amendment for cannabis includes an exception for processed hemp fibre to contain residual concentrations of tetrahydrocannabinols of up to 0.1 per cent. This means that processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre, are not scheduled. This exclusion of hemp fibre is consistent with Article 28 of the [Single Convention on Narcotic Drugs, 1961](#), to which Australia is a signatory.

Under Part 1, Interpretation, Paragraph (2)(b) of the Poisons Standard, the term ‘substance’ covers a plant and any part of that plant when packed and prepared for therapeutic use, other than a plant included in Schedules 8 or 9. In the November 2016 Poisons Standard, the references to cannabis in the Schedule 8 and Schedule 9 entries are to be interpreted as including the substance when packed and prepared for human therapeutic use.

The term “derivatives” does not appear in the Poisons Standard Schedule 8 or Schedule 9 entries for cannabis or tetrahydrocannabinols because according to Part 1, Interpretation, Paragraph 1(2) of the Poisons Standard, a Schedule entry includes preparations containing the poison in any concentration and all salts, active principles, and derivatives of the poison, and all alkaloids of a plant unless the entry specifically states otherwise.

Cannabis when not covered by the Schedule 8 entry, is otherwise captured by Schedule 9 of the Poisons Standard, and is considered to be prohibited. Synthetic cannabinoids, other than those specifically specified in the Schedules are covered by the Schedule 9 entry.

If a *Cannabis* plant is cultivated by a person in Australia who does not hold a licence and permit under the ND Act or who does have such a licence and permit but who has breached a conditions of such a licence or permit in relation to their cultivation, then any product containing that cannabis or an extract etc. of that cannabis, will be captured by the Schedule 9 entry, not the Schedule 8 entry.

“Cultivation”, “production” and “manufacture” take their meaning from the ND Act where they are defined as follows:

- i) Cultivation of a *Cannabis* plant includes the following:
 - a) to sow a seed of a *Cannabis* plant;
 - b) to plant, grow, tend, nurture or harvest a *Cannabis* plant;
 - c) to graft, divide or transplant a *Cannabis* plant;but does not include the separation of cannabis or cannabis resin from a cannabis plant
- ii) Production means the separation of cannabis and cannabis resin from the plants from which they are obtained. The production of cannabis involves the separation of cannabis flowering or fruiting tops of the *Cannabis* plant (excluding the seeds and leaves when not accompanied by the tops) where the resin has not been extracted.

- iii) Manufacture of cannabis involves all processes, other than production (as defined above), by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs.

Only botanical extracts, seeds and resins from the Cannabis plant and any part of the *Cannabis* plant are captured by the Schedule 8 entry, except when there is a more specific Schedule entry, for example, the Schedule 8 entry for nabiximols or the Schedule 4 entry for cannabidiol.

Extracts and derivatives of equivalent composition that are cannabinoids derived through synthetic means are not captured by this Schedule 8 entry. Nabilone and nabiximols are separately listed in Schedule 8. Synthetic extracts and derivatives are captured under Schedule 9, unless separately specified in another Schedule in the Poisons Standard. For example, outside of the cannabidiol Schedule 4 entry (for therapeutic use), cannabidiol and its acid are captured by the cannabis Schedule 9 entry. Similarly, cannabitol, cannabigerol, and cannabichromene, cannabidivarin and their respective acids are captured by the cannabis Schedule 8 or 9 entries, as alkaloids, active principles and derivatives.

Schedules 8 and 9 – Tetrahydrocannabinols

The tetrahydrocannabinols group entry includes tetrahydrocannabinol isomers and related acids.

The Poisons Standard Schedule 8 entry for tetrahydrocannabinols applies only where tetrahydrocannabinols are intended for human therapeutic use and the other applicable criteria are complied with. Outside of human therapeutic use, tetrahydrocannabinols are otherwise listed in Schedule 9 of the Poisons Standard.

Tetrahydrocannabinols found in hemp seed oil in concentrations less than 50 mg/kg when labelled with a warning statement “Not for internal use” or “Not to be taken” are not scheduled.

Tetrahydrocannabinols found in products in concentrations less than 50 mg/kg for purposes other than internal human use are not scheduled.

The Schedule amendments for tetrahydrocannabinols and cannabis also include an exception for processed hemp fibre that contains residual tetrahydrocannabinols of up to 0.1 per cent. This means that processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols and hemp fibre products, such as rope, manufactured from such fibre are not scheduled, consistent with Article 28 of the [Single Convention on Narcotic Drugs, 1961](#).

Tetrahydrocannabinols are otherwise captured by Schedule 9 of the Poisons Standard.

Only tetrahydrocannabinols that are extracted from the plant and any part of the plant of the genus *Cannabis* are captured by this Schedule 8 entry. Alkyl homologues of tetrahydrocannabinols that are extracted and/or derived botanically and synthetic tetrahydrocannabinols are captured under Schedule 9, unless separately specified in another Schedule of the Poisons Standard. For example, dronabinol has a separate

Schedule 8 entry. Similarly, the Schedule 9 group entry for synthetic cannabinomimetics is a specific listing. Examples of alkyl homologues that are captured by the Schedule 9 entry for tetrahydrocannabinols include tetrahydrocannabidivarin, and its acids.

Inclusion of Cannabis and tetrahydrocannabinols in Item 1 of Appendix D

The inclusion of cannabis and tetrahydrocannabinols in Item 1 of Appendix D, referred to as Appendix D (1), has the effect of restricting the availability of cannabis and tetrahydrocannabinols that are listed in Schedule 8 of the current Poisons Standard. The Schedule 8 cannabis and tetrahydrocannabinols can only be made available from or on the prescription or order of an authorised medical practitioner. The authority can only be issued by an Australian, State, Territory Health department or agency. Thus, not all registered medical practitioners can prescribe these substances or products containing these substances.

Under Part 1 of the Poisons Standard, an “*Appropriate authority*” as it applies to cannabis and tetrahydrocannabinols in Schedule 8 are the following:

- (a) in the Australian Capital Territory, ACT Government Health Directorate;
- (b) in New South Wales, the Secretary of Health;
- (c) in the Northern Territory, the Chief Health Officer of the Department of Health;
- (d) in Queensland, the Chief Executive of Queensland Health;
- (e) in South Australia, the Chief Executive of the Department for Health and Ageing;
- (f) in Tasmania, the Secretary of the Department of Health and Human Services;
- (g) in Victoria, the Secretary to the Department of Health;
- (h) in Western Australia, the Chief Executive Officer of the Department of Health.

An “*authorised prescriber*” in relation to the cannabis and tetrahydrocannabinols under Schedule 8 means a registered medical practitioner authorised by the appropriate authority or such other person authorised by the appropriate authority.

Subject to the operation of relevant state and territory legislation, this would mean that the medical practitioners that can prescribe or order cannabis and tetrahydrocannabinols in a state or territory would be limited to those specifically authorised by the person described as the “appropriate authority” for that jurisdiction.

The delegate’s final decision in relation to these matters was published on the TGA website on 31 August 2016, with the delegate deciding that these decisions will be implemented from 1 November 2016 in the case of each of the substances mentioned above.

The Poisons Standard November 2016 also includes an editorial amendment to the entry for nabiximols in Schedule 8 to reflect the group entry for tetrahydrocannabinols.

This decision was a delegate-only decision that was not open to public consultation, as it was considered (in accordance with the SPF) to be sufficiently straightforward as to not require public consultation.

The Poisons Standard is a legislative instrument for the purposes of the *Legislation Act 2003*. However, section 42 (disallowance) of that Act does not apply (see subsection 52D(4A) of the TG Act). Because it is not disallowable, subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011* does not require that the instrument be accompanied by a statement of compatibility with the human rights recognised under that Act.

The instrument commences on 1 November 2016, which means that the Poisons Standard November 2016 is effective on and from that day.