



Final decisions and reasons for decisions by a delegate of the Secretary to the Department of Health

31 August 2016

(ACMS meeting – March 2016)

Notice under subsections 42ZCZS and 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary to the Department of Health hereby gives notice of the delegate's final decisions for amending the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons - SUSMP*) under subsections 42ZCZS and 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations). This notice also provides the reasons for each decision and the date of effect (implementation date) of the decision.

The delegate's final decision and reasons relate to:

- A scheduling proposal for cannabis and tetrahydrocannabinols initially referred to the March 2016 meeting of the Advisory Committee on Medicines Scheduling (ACMS#17).

Scheduling proposals referred to the expert advisory committees

Pre-meeting public notice

A 'pre-meeting' public notice inviting submissions on the scheduling proposals referred to the expert advisory committees was published on 20 January 2016 on the TGA website at: [Public notice about scheduling](#).

Redacted versions of public submissions received in response to the public notice will be published on or after the date of this notice at: [Public submissions on scheduling matters](#).

Interim decisions

The delegate's interim decision and reasons for decisions on recommendations by the ACMS#17 were published on 20 January 2016 at <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-acms-and-accs-meeting-march-2016>. This public notice also invited further comment from those parties who made a valid submission in response to the original invitation for submissions.

Further submissions from parties other than those who made a valid submission in response to the original invitation or the applicant, or those received after the closing date, may not be considered by the delegate.

Edited versions of valid public submissions received in response to the interim decisions will be published at [Public submissions on scheduling matters](#).

Final decisions

In accordance with subsection 42ZCZR of the Regulations, if a delegate makes an interim decision on an application, the delegate may make a final decision either confirming, varying or setting aside the interim decision, but only after considering any valid submissions received in response to the interim decisions.

Matters not referred to an advisory committee

A delegate may decide not to refer a scheduling proposal to an expert advisory committee for advice and instead may make a delegate-only decision. When deciding not to refer a matter to a committee, the delegate considers the scheduling guidelines as set out in the [Scheduling Policy Framework for Chemicals and Medicines](#) (SPF, 2015).

Publishing of the amendments to the Poisons Standard

The amendments to the Schedules, Appendices or other parts of the Poisons Standard are published electronically on the [Federal Register of Legislation](#) as amendments to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) prior to the date of effect (implementation date) of the final decisions. Further information, including links to the Poisons Standard on the [Federal Register of Legislation](#), is available at [SUSMP](#).

Part A - Final decision on a matter referred to an expert advisory committee

Summary of delegate's final decision

Substances	Final Decision
Cannabis and Tetrahydrocannabinols	<p>SCHEDULE 9 – AMEND ENTRIES</p> <p>CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), except:</p> <ul style="list-style-type: none"> a) when separately specified in these Schedules; or b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or c) in hemp seed oil for purposes other than internal human use containing 50 mg/kg or less of cannabinoids. <p>TETRAHYDROCANNABINOLS and their alkyl homologues, except:</p> <ul style="list-style-type: none"> a) when included in Schedule 4 or Schedule 8; or b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or c) in hemp seed oil containing 50 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements: <ul style="list-style-type: none"> i) Not for internal use; or ii) Not to be taken; or d) in products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols. <p>SCHEDULE 8 – NEW ENTRIES</p> <p>CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when:</p> <ul style="list-style-type: none"> a) cultivated or produced, or in products manufactured¹, in accordance with the <i>Narcotic Drugs Act 1967</i>; and/or b) for use in products manufactured in accordance with the <i>Narcotic Drugs Act 1967</i>; and/or c) imported as therapeutic goods, or for use in therapeutic goods, for

¹ "Cultivation", "production" and "manufacture" have the same meaning as in the *Narcotic Drugs Act 1967*

supply, in accordance with the *Therapeutic Goods Act 1989*; and/or

- d) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*,

except when:

- i) it is a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or
- ii) separately specified in Schedule 4; or
- iii) separately specified in the NABIXIMOLS entry in this Schedule; or
- iv) in hemp seed oil for purposes other than internal human use containing 50 mg/kg or less of cannabinoids.

TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when:

- a) included in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
- b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or
- c) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*,

except when:

- i) it is a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or
- ii) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements:
 - (A) Not for internal use; or
 - (B) Not to be taken; or
- iii) in products for purposes other than for internal human use containing 50 mg/kg or less of tetrahydrocannabinols; or
- iv) separately specified in the NABIXIMOLS entry in this Schedule.

APPENDIX D, ITEM 1 – NEW ENTRIES

CANNABIS for human use.

TETRAHYDROCANNABINOLS for human use.

APPENDIX K – NEW ENTRIES

CANNABIS

TETRAHYDROCANNABINOLS

INDEX – AMEND ENTRIES

CANNABICHROMENE

	<p>cross reference: NABIXIMOLS, CANNABIS</p> <p>CANNABIDIOL cross reference: NABIXIMOLS, CANNABIS</p> <p>CANNABIDIOLIC ACID cross reference: NABIXIMOLS, CANNABIS</p> <p>CANNABIDIVAROL cross reference: NABIXIMOLS, CANNABIS</p> <p>CANNABIGEROL cross reference: NABIXIMOLS, CANNABIS</p> <p>CANNABINOIDS cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS</p> <p>CANNABINOL cross reference: NABIXIMOLS, CANNABIS</p> <p>CANNABIS cross reference: CANNABIS SATIVA, HEMP, HEMP SEED OIL, TETRAHYDROCANNABINOLS</p> <p>TETRAHYDROCANNABINOLIC ACID cross reference: NABIXIMOLS, TETRAHYDROCANNABINOLS</p> <p>TETRAHYDROCANNABINOLS cross reference: CANNABIS, HEMP SEED OIL, NABIXIMOLS</p> <p>TETRAHYDROCANNABIDIVAROL cross reference: NABIXIMOLS, TETRAHYDROCANNABINOLS</p> <p>Implementation date: 1 November 2016</p>
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1. Scheduling proposal referred to the March 2016 meeting of the Advisory Committee on Medicines Scheduling (ACMS#17)

1.1 Cannabis and Tetrahydrocannabinols

Scheduling proposal

The medicines scheduling delegate (the delegate) has referred the following scheduling proposal for consideration by the Advisory Committee on Medicines Scheduling (ACMS):

- 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 (THCs) where they are 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
 - imported in accordance with the Customs (Prohibited Imports) Regulations 1956.
- except** when included elsewhere in Schedule 8 or Schedule 4.

- Cannabis and Tetrahydrocannabinols 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".

Substance summary

Cannabis is a term used to describe a range of varieties of the *Cannabis* genus. The *Cannabis* plant produces a resin containing compounds called cannabinoids. Some cannabinoids possess psychoactive properties.

Cannabis 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 present in *Cannabis* is cannabidiol that is associated with claims relating to use as an analgesic, anticonvulsant, muscle relaxant, anxiolytic, neuroprotective, anti-oxidant and anti-psychotic.

Nabiximols is a specific extract of *Cannabis sativa* which contains a range of cannabinoids, of which tetrahydrocannabinols and cannabidiol in approximately equal proportions comprise not less than 90% of the total cannabinoid content. Nabiximols are registered for use in Australia as a buccal spray preparation (Sativex®) as an adjunctive treatment for the symptomatic relief of neuropathic pain in multiple sclerosis in adults.

Nabilone is a synthetic cannabinoid used as an anti-emetic in the treatment of nausea and vomiting caused by chemotherapy and also for patients who are not responsive to conventional anti-emetic treatments.

Scheduling status

Cannabis and cannabinoids are currently listed in Schedules 4, 8 and 9, as well as being listed in Appendix D and Appendix K, as follows:

Schedule 9 Entries

CANNABIS **except:**

- a) when separately specified in these Schedules; or
- b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre.

TETRAHYDROCANNABINOLS and their alkyl homologues **except:**

- c) when separately specified in this Schedule;
- d) when included in Schedule 4 or Schedule 8;
- e) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with a warning statement:
 - i) Not for internal use; or
 - ii) Not to be taken; or
- f) in products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols.

SYNTHETIC CANNABINOMIMETICS except when separately specified in these Schedules.

2-[(1R,3S)-3-HYDROXYCYCLOHEXYL]-5-(2-METHYLNONAN-2-YL)PHENOL

*(Cannabicyclohexanol or CP 47,497 C8 homologue).

Schedule 4 Entries

CANNABIDIOL in preparations for therapeutic use containing 2 per cent or less of other cannabinoids found in cannabis.

Schedule 8 Entries

DRONABINOL (delta-9-tetrahydrocannabinol) when prepared and packed for therapeutic use.

NABILONE

NABIXIMOLS (botanical extract of *Cannabis sativa* which includes the following cannabinoids: tetrahydrocannabinol, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acid, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinol and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content) in a buccal spray for human therapeutic use.

Appendix Entries

Appendix D, Part 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 and Ageing under section 19 of the Therapeutic Goods Act 1989.*

DRONABINOL (delta-9-tetrahydrocannabinol).

Appendix D, Part 1 – *Poisons available only from or on the prescription or order of an authorised medical practitioner.*

NABIXIMOLS

Appendix K

DRONABINOL (delta-9-TETRAHYDROCANNABINOL)

NABIXIMOLS

PART 1 - INTERPRETATION

“**Hemp seed oil**” means the oil obtained by cold expression from the ripened fruits (seeds) of *Cannabis sativa*.

Scheduling history

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

The scheduling of cannabis and its extracts has been considered by the National Drugs and Poisons Scheduling Committee (NDPSC) on a number of occasions. Currently, cannabis is a Schedule 9 substance, i.e., a prohibited substance which may be abused or misused and the manufacture, possession, sale or use of which is prohibited by law. An exemption exists for cannabinoid substances listed in lower schedules, and for processed hemp fibre and its products containing 0.1 percent or less of tetrahydrocannabinol.

Dronabinol (delta-9-tetrahydrocannabinol) was considered by the NDPSC in 1994 following a recommendation that it be included in Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), for use in patients with advanced HIV disease with irreversible weight loss. At the time the NDPSC agreed to include dronabinol in Schedule 8 for therapeutic use.

Nabilone was considered at the July 1984 NDPSC meeting and included in Schedule 8 following that meeting. It is used as an anti-emetic in the treatment of nausea and vomiting caused by chemotherapy, primarily for patients who are not responsive to conventional anti-emetic treatments.

In 2009 the NDPSC considered scheduling requirements for the product Sativex®, which contained CBD and small amounts of other cannabinoids, and its access under jurisdictional laws and the Special Access Scheme (SAS). Members agreed that it was appropriate to allow access to Sativex® and suggested that a pragmatic approach would be to create a Schedule 8 entry for this specific formulation, in conjunction with an Appendix D, paragraph 3 listing to facilitate its use within the various jurisdictions.

Nabiximols was considered by the committee in October 2009 for inclusion as a specific entry after an issue was raised that some jurisdictions were unable to allow SAS access to the substance as it was captured under Schedule 9. The Committee agreed on the Schedule 8 listing with specific reference to buccal sprays.

In May 2010, Nabiximols was included in Schedule 8 and Appendices D and K. The Appendix D, Part 3 entry was made to limit access through the SAS. The Appendix K entry was agreed due to its sedating effects.

In March 2013, the committee advised that a change in the Appendix D entry for Nabiximols from Paragraph 3 to Paragraph 1 would be appropriate noting the requirement for specialist oversight for safe prescribing of the drug.

Pre-meeting public submissions

35 submissions were received. 27 submissions supported the proposal, 4 submissions opposed, 3 submissions did not state a position, and 1 submission was for information only.

The public submissions will be made available following publication of this notice at <https://www.tga.gov.au/scheduling-delegates-decisions-public-submissions>.

ACMS advice to the delegate

The ACMS advised that both cannabis and tetrahydrocannabinols, including their extracts, be down-scheduled from Schedule 9 to Schedule 8 for human therapeutic use of cannabis products where the cannabis has been obtained in accordance with the *Narcotic Drugs Act 1967* and, where relevant, the Customs (Prohibited Imports) Regulation 1956.

The committee agreed to recommend a new Appendix D, Part 1 entry to provide for substances to be available only from or on the prescription or order of a medical practitioner authorised under State or Territory legislation.

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the Committee included: a) the risks and benefits of the use of a substance; b) the purposes for which a substance is to be used and the extent of use of a substance; c) the toxicity of a substance; d) the dosage, formulation, labelling, packaging and presentation of a substance; e) the potential for abuse of a substance; f) any other matters that the Secretary considers necessary to protect the public health.

The advice comprised of the following:

- There is growing clinical trial use of cannabis-based products for an increasing range of therapeutic conditions. Schedule 8 is appropriate for safety profile providing a suitable level of oversight (for low risk of dependence when compared to opioids) and safety for these medicines.
- In clinical trials there is moderate-quality evidence to support use of cannabinoids in the treatment of chronic pain and spasticity as well as low-quality evidence of benefit in chemotherapy-related nausea, vomiting, weight gain in HIV, sleep disorders and Tourette syndrome. These conditions require diagnosis, management and monitoring under an appropriate medical practitioner. Many cannabis-based products are being developed as therapeutic products and tested in clinical trials to enhance the evidence base for efficacy.
- In some individuals high doses can cause psychoactive effects (euphoria, hallucinations etc) however cannabinoids pose a lower risk of toxicity or abuse than other existing Schedule 8 drugs such as opioids and amphetamines.
- Dosage, formulations and presentation of medicinal products are unknown at this time. However, products will have to be labelled in accordance with Schedule 8 requirements. Formulations will be dependent upon the clinical need.
- There is potential for misuse and/or abuse as with all other Schedule 8 controlled drugs. However, cannabis has low risk of physical dependence, but it may be a pathway to more addictive drugs. Abuse of the substance may have long term effects particularly in young people. Moving to Schedule 8 will allow some improved access under jurisdictional laws for patients who have been prescribed medicinal cannabis products. It will also provide greater ability to undertake research and clinical trials to gather further evidence of therapeutic efficacy.

Delegate's considerations

The delegate considered the following in regards to this proposal:

- Scheduling proposal;
- Public submissions received;
- ACMS advice;
- Section 52E of the *Therapeutic Goods Act 1989*;

- Scheduling factors²;
- Other relevant information.

Delegate's interim decision

The delegate's interim decision is to create:

- new Schedule 8 entries for Cannabis and Tetrahydrocannabinols (being extracts, or derivatives of extracts, of cannabis) for human therapeutic use, and
- new Appendix D Item 1 entries for Cannabis and Tetrahydrocannabinols, and
- new Appendix K entries for Cannabis and Tetrahydrocannabinols.

For both Cannabis and Tetrahydrocannabinols the Schedule 8 entries are further restricted to substances:

- where the cultivation, production and manufacture of the substances in Australia is only under the *Narcotic Drugs Act 1967*, and
- where the substances are imported into Australia under the Customs (Prohibited Imports) Regulations 1956 with any further production or manufacture of the substances in Australia being under the *Narcotic Drugs Act 1967*, if required.

The new Appendix D Item 1 entries for Cannabis and Tetrahydrocannabinols place an additional control on the substances such that the substances will only be “available from or on the prescription or order of an authorised medical practitioner” where the medical practitioner has been authorised by the “appropriate authority” as defined in Part 1 paragraph 1(1) of the SUSMP which are generally senior health executives of the states and territories.

The new Appendix K entries for Cannabis and Tetrahydrocannabinols are because of the potential sedation effect of these substances and place a requirement for products including these substances to be labelled with a warning regarding their sedation potential.

The proposed implementation date was 1 June 2016.

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate included: a) the risks and benefits of the use of the substance; b) the purposes for which a substance is to be used and the extent of use of a substance; c) the toxicity of the substance; d) the dosage, formulation, labelling, packaging and presentation of a substance; e) the potential for abuse of a substance; and f) any other matters that the Secretary considers necessary to protect public health.

The reasons for the decision are:

- There is an increasing use of cannabis and cannabis extracts (including Tetrahydrocannabinols) in clinical trials in Australia and overseas. The current Schedule 9 status of the substances produces barriers to clinical trials being undertaken across Australia and by creating Schedule 8 entries for these substances their availability for clinical trials is improved, within the restrictions of Schedule 8 substances.
- There is some evidence to support the use of cannabinoids in the treatment of some conditions when these conditions are not adequately treated by other medications.
- In these cases the current Schedule 9 entries preclude individuals being able to access appropriate cannabinoid products for appropriate clinical justified conditions except through clinical trials where they can be conducted. By creating the Schedule 8 entries and the Appendix D Item 1

² [Scheduling Policy Framework for Medicines and Chemicals](#) (SPF, 2015)

entries individuals will be able to have appropriate cannabinoid products including these substances prescribed where the medical practitioner is appropriately authorised to prescribe them.

- The proposed Schedule 8 entry for Cannabis includes the plant, its seeds, its extracts and derivatives of the extracts.
- The proposed Schedule 8 entry for Tetrahydrocannabinols is for Tetrahydrocannabinols extracted from, or derived from the extracts, of cannabis and does not include synthetic Tetrahydrocannabinols.
- The restrictions on the Schedule 8 entries to substances cultivated, produced and manufactured under the *Narcotic Drugs Act 1967* ensures that the substances are being legally cultivated, produced and manufactured in Australia within the controls of the Act.
- The restrictions do allow products containing these substances to be Schedule 8 when imported under the Customs (Prohibited Imports) Regulations 1956 and when any further production or manufacture occurs under the *Narcotic Drugs Act 1967*, if required.
- It should be noted that any supply and import of products containing these substances is still required to comply with the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990. Therefore any product containing these substances not on the Australian Register of Therapeutic Goods will need an exemption or approval to be legally supplied under the *Therapeutic Goods Act 1989*.
- It should be noted that for these substances any use outside of the specific schedule entries will make the substances Schedule 9.

Schedule entries

Schedule 9

Retain existing entry:

CANNABIS except:

- a) when separately specified in these Schedules; or
- b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre.

Amend entry

TETRAHYDROCANNABINOLS and their alkyl homologues except:

- a) when included in Schedule 4 or Schedule 8;
- b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre.
- c) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with a warning statement:
 - i) Not for internal use; or
 - ii) Not to be taken; or
- d) in products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols.

Schedule 8 – New Entries

CANNABIS (including seeds, extracts and derivatives of extracts) for human therapeutic use, including that plant or any part of the plant when prepared or packed for that use, when:

- a) cultivated, produced or manufactured in accordance with the *Narcotic Drugs Act 1967*; and
- b) if relevant, imported in accordance with the Customs (Prohibited Imports) Regulations 1956, **except** when:
 - c) separately specified in Schedule 4; or
 - d) separately specified in the NABIXIMOL entry in this Schedule

TETRAHYDROCANNABINOLS being extracts, or derivatives of extracts, of cannabis, for human therapeutic use, when:

- a) produced or manufactured in accordance with the *Narcotic Drugs Act 1967*; and
- b) if relevant, imported in accordance with the Customs (Prohibited Imports) Regulations 1956 **except** when:
 - c) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with a warning statement:
 - i) Not for internal use; or
 - ii) Not to be taken; or
 - d) in products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols, or
 - e) separately specified in the NABIXIMOL entry in this Schedule.

Appendix D – New item 1 entries

CANNABIS

TETRAHYDROCANNABINOLS

Appendix K - New entries

CANNABIS

TETRAHYDROCANNABINOLS

Public submissions on the interim decision

No public submissions were received on the interim decision.

Delegate's final decision

Following consideration of the interim decision, consultation with state and territory governments and the advice from the ACMS, the medicines delegate has confirmed the interim decision to create new Schedule 8 entries for cannabis and tetrahydrocannabinols with amendments to the S9 entries. The delegate has revised the wording of the entries to ensure clarity of the entries.

The final decision is to amend the Schedule 9 entries for cannabis and tetrahydrocannabinols and create new Schedule 8 entries for cannabis and tetrahydrocannabinols with listings for cannabis and tetrahydrocannabinols in Appendix D (1) and Appendix K.

The delegate has confirmed that the reasons for the final decision are in keeping with those for the interim decision.

The matters under subsection 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate included: a) the risks and benefits of the use of the substance; b) the purposes for which a substance is to be used and the extent of use of a substance; c) the toxicity of the substance; d) the dosage, formulation, labelling, packaging and presentation of a substance; e) the potential for abuse of a substance; and f) any other matters that the Secretary considers necessary to protect public health.

The reasons given by the delegate comprised the following:

- There is an increasing use of cannabis and cannabis extracts (including Tetrahydrocannabinols) in clinical trials in Australia and overseas. The current Schedule 9 status of the substances produces barriers to clinical trials being undertaken across Australia and by creating Schedule 8 entries for these substances their availability for clinical trials is improved, within the restrictions of Schedule 8 substances.
- There is some evidence to support the use of cannabinoids in the treatment of some conditions when these conditions are not adequately treated by other medications.
- In these cases the current Schedule 9 entries preclude individuals being able to access appropriate cannabinoid products for appropriate clinically justified conditions except through clinical trials where they can be conducted. By creating the Schedule 8 entries and the Appendix D Item 1 entries individuals will be able to have appropriate cannabinoid products including these substances prescribed where the medical practitioner is appropriately authorised to prescribe them.
- The proposed Schedule 8 entry for Cannabis includes seeds, extracts, resins, the plant, any part of the plant.
- The proposed Schedule 8 entry for Tetrahydrocannabinols is for Tetrahydrocannabinols extracted from, or derived from the extracts, of *Cannabis* and does not include synthetic Tetrahydrocannabinols.
- The restrictions on the Schedule 8 entries to substances cultivated, produced and manufactured under the *Narcotic Drugs Act 1967* ensures that the substances are being legally cultivated, produced and manufactured in Australia within the controls of *the Act*.
- The restrictions do allow products containing these substances to be Schedule 8 when imported under the Customs (Prohibited Imports) Regulations 1956 and when any further production or manufacture occurs under the *Narcotic Drugs Act 1967*, if required.
- It should be noted that any supply and import of products containing these substances is still required to comply with the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990. Therefore any product containing these substances not on the Australian Register of Therapeutic Goods will need an exemption or approval to be legally supplied under the *Therapeutic Goods Act 1989*.
- It should be noted that for these substances any use outside of the specific schedule entries will make the substances Schedule 9.

The implementation date is **1 November 2016**.

Schedule entry

SCHEDULE 9 - AMEND ENTRIES

CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), **except**:

- a) when separately specified in these Schedules; or
- b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or
- c) in hemp seed oil for purposes other than internal human use containing 50 mg/kg or less of cannabinoids.

TETRAHYDROCANNABINOLS and their alkyl homologues, **except**:

- a) when included in Schedule 4 or Schedule 8; or
- b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or
- c) in hemp seed oil containing 50 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements:
 - iii) Not for internal use; or
 - iv) Not to be taken; or
- d) in products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols.

SCHEDULE 8 - NEW ENTRIES

CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when:

- a) cultivated or produced, or in products manufactured³, in accordance with the *Narcotic Drugs Act 1967*; and/or
- b) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
- c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or
- d) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*,

except when:

- i) it is a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or
- ii) separately specified in Schedule 4; or
- iii) separately specified in the NABIXIMOLS entry in this Schedule; or
- iv) in hemp seed oil for purposes other than internal human use containing 50 mg/kg or less of cannabinoids.

³ "Cultivation", "production" and "manufacture" have the same meaning as in the *Narcotic Drugs Act 1967*

TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when:

- a) included in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
- b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or
- c) in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*,

except when:

- i) it is a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic Goods Regulations 1990 applies; or
- ii) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements:
 - (A) Not for internal use; or
 - (B) Not to be taken; or
- iii) in products for purposes other than for internal human use containing 50 mg/kg or less of tetrahydrocannabinols; or
- iv) separately specified in the NABIXIMOLS entry in this Schedule.

APPENDIX D, ITEM 1 – NEW ENTRIES

CANNABIS for human use.

TETRAHYDROCANNABINOLS for human use.

APPENDIX K – NEW ENTRIES

CANNABIS

TETRAHYDROCANNABINOLS

INDEX – AMEND ENTRIES

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CANNABIDIOLIC ACID

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Part B - Final decision on matters not referred to an expert advisory committee

Summary of delegate's final decision

Substance	Final Decision
Nabiximols	<p>Schedule 8 - Amend Entry</p> <p>NABIXIMOLS (botanical extract of <i>Cannabis sativa</i> which includes the following cannabinoids: tetrahydrocannabinols, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acids, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinols and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content) in a buccal spray for human therapeutic use.</p> <p>Implementation date: 1 November 2016</p>

2.1 Nabiximols

Delegate's Scheduling proposal

The delegate considered amending the Schedule 8 nabiximols entry to ensure consistency in the context of the changes made in relation to the scheduling decision changes for cannabis and tetrahydrocannabinols.

Current scheduling status

The current Schedule 8 entry for Nabiximols is as follows:

NABIXIMOLS (botanical extract of *Cannabis sativa* which includes the following cannabinoids: tetrahydrocannabinol, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acid, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinol and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content) in a buccal spray for human therapeutic use

Delegate's considerations

The delegate considered the following in regards to this proposal:

- Scheduling proposal;
- Section 52E of the *Therapeutic Goods Act 1989*;
- Scheduling factors⁴;
- Other relevant information.

Delegate's final decision

The final decision is to amend the Schedule 8 entry for nabiximols.

⁴ [Scheduling Policy Framework for Medicines and Chemicals](#) (SPF, 2015)

This decision was an editorial amendment to clarify that the nabiximols entry used the correct terminology for tetrahydrocannabinols by adding an 's' to tetrahydrocannabinol.

The reasons given by the delegate comprised the following:

- To ensure consistency with the scheduling decisions for cannabis and tetrahydrocannabinols.

The implementation date is **1 November 2016**.

Schedule entry

SCHEDULE 8 – AMEND ENTRY

NABIXIMOLS (botanical extract of *Cannabis sativa* which includes the following cannabinoids: tetrahydrocannabinols, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acids, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinols and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content) in a buccal spray for human therapeutic use.