



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

May 2017

(ACCS, ACMS and Joint ACCS-ACMS meetings – November 2016)

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

The delegates of the Secretary to the Department of Health hereby give notice of 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 subsection 42ZCZS 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 delegates' final decisions and reasons relate to:

- scheduling proposals initially referred to the November 2016 meeting of the Joint Advisory Committee on Chemicals and Medicines Scheduling (Joint ACCS-ACMS#14)

Scheduling proposals referred to the expert advisory committees

Pre-meeting public notice

On 22 September 2016, under subsection 42ZCZK of the *Therapeutic Goods Regulations 1990* (the Regulations), the delegate published a pre-meeting public notice [Consultation: Proposed Amendments to the Poisons Standard – Joint ACCS and ACMS meeting, November 2016](#) on the TGA website which specified the proposed amendments to the current Poisons Standard and invited public comment.

The pre-meeting consultation period was open for public comment for 20 business days and closed on 20 October 2016.

In accordance with subsection 42ZCZL of the Regulations redacted versions of public submissions will be published at [Public submissions on scheduling matters](#) on or after the date of this notice.

Interim decisions

November 2016 Joint ACCS-ACMS#14

On 2 February 2017, in accordance with subsection 42ZCZN of the Regulations, the delegate made an interim decision on an application and under subsection 42ZCZP of the Regulations, the [scheduling](#)

[delegate's interim decisions and invitation for further comment: ACCS/ACMS, November 2016](#) and the reasons for the decision was published on TGA website. Further submissions were also invited from the applicants and parties who made valid pre-meeting submissions. The invitation to make submissions was open for 10 business days and closed on 16 February 2017.

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

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

According to subsections 42ZCZT/42ZCZU of the Regulations 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), available at [SPF, February 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 (FRL) 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 FRL, is available at [SUSMP](#).

Glossary

Abbreviation	Name
AAN	Australian Approved Name
AC	Active constituent
ACCC	Australian Competition and Consumer Commission
ACCM	Advisory Committee on Complementary Medicines (formerly Complementary Medicine Evaluation Committee [CMEC])
ACNM	Advisory Committee on Non-prescription Medicines (formerly Medicines Evaluation Committee [MEC])
ACPM	Advisory Committee on Prescription Medicines (formerly Australian Drug Evaluation Committee [ADEC])
ACSOM	Advisory Committee on the Safety of Medicines (formerly Adverse Drug Reactions Advisory Committee [ADRAC])
ADEC	Australian Drug Evaluation Committee (now Advisory Committee on Prescription Medicines [ACPM])
ADI	Acceptable daily intake
ADRAC	Adverse Drug Reactions Advisory Committee (now Advisory Committee on the Safety of Medicines [ACSOM])
AHMAC	Australian Health Ministers' Advisory Council
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
ARfD	Acute reference dose
ASCC	Australian Safety and Compensation Council
ASMI	Australian Self-Medication Industry
ARTG	Australian Register of Therapeutic Goods

Abbreviation	Name
CAS	Chemical Abstract Service
CHC	Complementary Healthcare Council of Australia
CMEC	Complementary Medicine Evaluation Committee (now Advisory Committee on Complementary Medicines [ACCM])
CMI	Consumer Medicine Information
COAG	Councils of Australian Governments
CRC	Child-resistant closure
CTFAA	Cosmetic, Toiletry & Fragrance Association of Australia
CWP	Codeine Working Party
DAP	Drafting Advisory Panel
ECRP	Existing Chemicals Review Program
EPA	Environmental Protection Authority
ERMA	Environmental Risk Management Authority (New Zealand)
FAISD	First Aid Instructions and Safety Directions
FDA	Food and Drug Administration (United States)
FOI	Freedom of Information Act 1982
FSANZ	Food Standards Australia New Zealand
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
GIT	Gastro-intestinal tract
GP	General practitioner
HCN	Health Communication Network

Abbreviation	Name
IMAP	Inventory Multi-tiered Assessment Prioritisation
INN	International Non-proprietary Name
ISO	International Standards Organization
LC ₅₀	The concentration of a substance that produces death in 50 per cent of a population of experimental organisms. Usually expressed as mg per litre (mg/L) as a concentration in air.
LD ₅₀	The concentration of a substance that produces death in 50 per cent of a population of experimental organisms. Usually expressed as milligrams per kilogram (mg/kg) of body weight.
LOAEL	Lowest observed adverse effect level
LOEL	Lowest observed effect level
MCC	Medicines Classification Committee (New Zealand)
MEC	Medicines Evaluation Committee (now Advisory Committee on Non-prescription Medicines [ACNM])
MOH	Ministry of Health (New Zealand)
NCCTG	National Coordinating Committee on Therapeutic Goods
NDPSC	National Drugs and Poisons Schedule Committee
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification & Assessment Scheme
NOAEL	No observed adverse effect level
NOEL	No observable effect level
NOHSC	National Occupational Health & Safety Commission
OCM	Office of Complementary Medicines
OCS	Office of Chemical Safety (formerly Office of Chemical Safety and Environmental Health [OCSEH])

Abbreviation	Name
OCSEH	Office of Chemical Safety and Environmental Health (now Office of Chemical Safety [OCS])
ODA	Office of Devices Authorisation
OMA	Office of Medicines Authorisation (formerly Office of Prescription and Non-prescription Medicines)
OOS	Out of session
OTC	Over-the-counter
PACIA	Plastics and Chemicals Industries Association
PAR	Prescription animal remedy
PBAC	Pharmaceutical Benefits Advisory Committee
PEC	Priority existing chemical
PGA	Pharmaceutical Guild of Australia
PHARM	Pharmaceutical Health and Rational Use of Medicines
PI	Product Information
PIC	Poisons Information Centre
PSA	Pharmaceutical Society of Australia
QCPP	Quality Care Pharmacy Program
QUM	Quality Use of Medicines
RFI	Restricted flow insert
SCCNFP	Scientific Committee on Cosmetic and Non-Food Products
SCCP	Scientific Committee on Consumer Products
STANZHA	States and Territories and New Zealand Health Authorities

Abbreviation	Name
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
SVT	First aid for the solvent prevails
TCM	Traditional Chinese medicine
TGA	Therapeutic Goods Administration
TGC	Therapeutic Goods Committee
TGO	Therapeutic Goods Order
TTHWP	Trans-Tasman Harmonisation Working Party
TTMRA	Trans-Tasman Mutual Recognition Agreement
WHO	World Health Organization
WP	Working party
WS	Warning statement

Contents

Part A - Final decisions on matters referred to an expert advisory committee 9

1. Scheduling proposals referred to the November 2016 meeting of the Joint Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS#14) 9

Summary of delegate's final decisions _____ 9

1.1 Cannabis _____ 14

Part A - Final decisions on matters referred to an expert advisory committee

1. Scheduling proposals referred to the November 2016 meeting of the Joint Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS#14)

Summary of delegate's final decisions

Substance	Final decision
Cannabis, tetrahydrocannabinols and cannabidiol	<p>Schedule 9 – Current Entry</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>Schedule 8 – Current Entry</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 supply, in accordance with the <i>Therapeutic Goods Act 1989</i>; and/or d) in therapeutic goods supplied in accordance with the <i>Therapeutic Goods Act 1989</i>, <p>except when:</p> <ul style="list-style-type: none"> 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

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

Substance	Final decision
	<p>Schedule; or</p> <p>iv) in hemp seed oil for purposes other than internal human therapeutic use containing 50 mg/kg or less of cannabinoids.</p> <p>Schedule 9 – Amend Entry</p> <p>TETRAHYDROCANNABINOLS and their alkyl homologues, except:</p> <p>a) when included in Schedule 4 or Schedule 8; or</p> <p>b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or</p> <p>c) in hemp seed oil containing 50 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements:</p> <p>i) Not for internal use; or</p> <p>ii) Not to be taken; or</p> <p>Schedule 8 – Amend Entry</p> <p># TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when:</p> <p>a) included in products manufactured in accordance with the <i>Narcotic Drugs Act 1967</i>; and/or</p> <p>b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the <i>Therapeutic Goods Act 1989</i>; and/or</p> <p>c) in therapeutic goods supplied in accordance with the <i>Therapeutic Goods Act 1989</i>,</p> <p>except when:</p> <p>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</p> <p>ii) in hemp seed oil, containing 50 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements:</p> <p>A) Not for internal use; or</p> <p>B) Not to be taken; or</p> <p>iii) separately specified in the NABIXIMOLS entry in this Schedule.</p>

Substance	Final decision
	<p>Schedule 4 – Current Entry</p> <p>CANNABIDIOL in preparations for therapeutic use containing 2 per cent or less of other cannabinoids found in cannabis.</p> <p>Appendix D, Item 1 – Current Entries</p> <p>CANNABIS for human use.</p> <p>TETRAHYDROCANNABINOLS for human use.</p> <p>Appendix K – Current Entries</p> <p>CANNABIS</p> <p>TETRAHYDROCANNABINOLS</p> <p><i>Implementation date of 1 October 2017.</i></p> <p>Schedule 9 – Amend Entry</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 total cannabinoids, including 20 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. <p>Schedule 8 – Amend Entry</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 manufactured², 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 supply, in accordance with the <i>Therapeutic Goods Act 1989</i>; and/or

² “Cultivation”, “production” and “manufacture” have the same meaning as in the *Narcotic Drugs Act 1967*

Substance	Final decision
	<p>d) in therapeutic goods supplied in accordance with the <i>Therapeutic Goods Act 1989</i>,</p> <p>except when:</p> <ul style="list-style-type: none"> 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. <p>Schedule 9 –Amend Entry</p> <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 for purposes other than internal human use containing 50 mg/kg or less of total cannabinoids, including 20 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. <p>Schedule 8 –Amend Entry</p> <p># TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when:</p> <ul style="list-style-type: none"> a) included in products manufactured in accordance with the <i>Narcotic Drugs Act 1967</i>; and/or b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the <i>Therapeutic Goods Act 1989</i>; and/or c) in therapeutic goods supplied in accordance with the <i>Therapeutic Goods Act 1989</i>, <p>except when:</p> <ul style="list-style-type: none"> i) it is in 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 the NABIXIMOLS entry in this Schedule.

Substance	Final decision
	<p>Schedule 4 – Amend Entry</p> <p>CANNABIDIOL in preparations for therapeutic use containing 2 per cent or less of total other cannabinoids found in cannabis.</p> <p>APPENDIX D, ITEM 1 – Current entries</p> <p>CANNABIS for human use.</p> <p>TETRAHYDROCANNABINOLS for human use.</p> <p>APPENDIX K – Current entries</p> <p>CANNABIS</p> <p>TETRAHYDROCANNABINOLS</p> <p>Index – Amend entries</p> <p>CANNABICHROMENE cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS</p> <p>CANNABIDIOL cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS</p> <p>CANNABIDIOLIC ACID cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS</p> <p>CANNABIDIVAROL cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS</p> <p>CANNABIGEROL cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS</p> <p>CANNABINOIDS cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS</p> <p>CANNABINOL cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS</p> <p>CANNABIS cross reference: CANNABIS SATIVA, HEMP, HEMP SEED OIL, TETRAHYDROCANNABINOLS</p> <p>TETRAHYDROCANNABINOLIC ACID cross reference: NABIXIMOLS, TETRAHYDROCANNABINOLS, CANNABIS</p> <p>TETRAHYDROCANNABINOLS cross reference: CANNABIS, HEMP SEED OIL, NABIXIMOLS</p>

Substance	Final decision
	<p>TETRAHYDROCANNABIDIVAROL cross reference: NABIXIMOLS, TETRAHYDROCANNABINOLS, CANNABIS</p> <p><i>Implementation date of 1 June 2018.</i></p>

1.1 Cannabis

Referred scheduling proposal

The medicines scheduling delegate in view of the upcoming rescheduling of cannabis and tetrahydrocannabinols (THCs) proposes to consider:

The final decision for cannabis provides for hemp seed oil to be exempt from Schedules 8 and 9 when the levels of total cannabinoids are 50 mg/kg or less.

Due to further information provided after the publication of the final decision, the scheduling delegate is undertaking further consideration. This proposal seeks to determine whether this cut-off for total cannabinoids is appropriate for hemp seed oil, and the delegate is requesting additional information on the levels of cannabinoids (including tetrahydrocannabinols) in hemp seed oil. The delegate is also proposing to add to the cannabis entries regarding the hemp seed oil exception the following:

“when labelled with either of the following warning statements:

- i. Not for internal use; or
- ii. Not to be taken.”

Current scheduling status

Cannabis and cannabinoids are currently listed in Schedules 4, 8 and 9, and in Appendix D and Appendix K.

Hemp seed oil is defined in the Interpretation of the Poisons Standard as follows:

PART 1 - INTERPRETATION

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

Following the 31 August 2016 final scheduling decision for cannabis and tetrahydrocannabinols to be implemented on 1 November 2016, the entries for cannabis, tetrahydrocannabinols and nabiximols are listed in Schedules 8 and 9, and Appendix D and Appendix K as follows:

Schedule 9

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.³

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:
 - 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

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 manufactured⁴, 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 therapeutic 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:

³ The November 2016 Poisons Standard contains an error, referring to 'cannabinols' instead of 'cannabinoids' under the Schedule 9 cannabis entry at item c. This was corrected in the February 2017 update to be consistent with the August 2016 decision, pending the outcome of the advice of the committees.

⁴ "Cultivation", "production" and "manufacture" have the same meaning as in the *Narcotic Drugs Act 1967*

- 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.

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.

Schedule 4

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

Appendix D, Item 1

CANNABIS for human use.

TETRAHYDROCANNABINOLS for human use.

Appendix K

CANNABIS

TETRAHYDROCANNABINOLS

Index

CANNABICHROMENE

cross reference: NABIXIMOLS, CANNABIS

CANNABIDIOL

cross reference: NABIXIMOLS, CANNABIS

CANNABIDIOLIC ACID

cross reference: NABIXIMOLS, CANNABIS

CANNABIDIVAROL

cross reference: NABIXIMOLS, CANNABIS

CANNABIGEROL

cross reference: NABIXIMOLS, CANNABIS

CANNABINOIDS

cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

CANNABINOL

cross reference: NABIXIMOLS, CANNABIS

CANNABIS

cross reference: CANNABIS SATIVA, HEMP, HEMP SEED OIL, TETRAHYDROCANNABINOLS

TETRAHYDROCANNABINOLIC ACID

cross reference: NABIXIMOLS, TETRAHYDROCANNABINOLS

TETRAHYDROCANNABINOLS

cross reference: CANNABIS, HEMP SEED OIL, NABIXIMOLS

TETRAHYDROCANNABIDIVAROL

cross reference: NABIXIMOLS, TETRAHYDROCANNABINOLS

Relevant scheduling history

Cannabis

In August 1999, the committee reviewed the status of its foreshadowed proposal to amend the Schedule 9 entry for cannabis to exempt from scheduling cannabis when grown commercially for fibre production and manufactured goods containing hemp fibre. It was seen that such a proposal would provide uniformity in controls exerted by state and territory governments. A general exemption for hemp fibre and hemp fibre products could be made. The committee considered a general exemption for hemp fibre and hemp fibre products could be made. The exemption would allow sale of such hemp fibre and manufactured products in all jurisdictions.

Tetrahydrocannabinols

In May 1998, the committee considered additional technical and regulatory information relating to a request to exempt from Schedule 9 tetrahydrocannabinols when in hemp seed oil and products for external use when containing 50 mg/kg or less of tetrahydrocannabinols (THC). The committee supported the proposal that hemp seed oil and products containing hemp seed oil should be exempt from the Schedule 9 entry for tetrahydrocannabinols when containing 50 mg/kg of THC and when for external use.

Nabiximols (sativex®)

In October 2009, the committee considered an entry specific for *Cannabis sativa* extract, nabiximols, after the issue was raised at the June 2009 meeting that certain jurisdictions were unable to allow SAS access to the substance as it was captured under Schedule 9. As discussed in June, the committee members agreed on the Schedule 8 listing. The committee also agreed that the Schedule 8 entry should limit the allowed presentation to buccal sprays as this would further reinforce the very restricted scope of this entry and would require any new presentation to be brought to the attention of the committee.

In May 2010, nabiximols were included in Schedule 8 and Appendices D and K. The committee advised that nabiximols needed to be added to Appendix D, Item 3 to limit access through SAS Category A. This addition would allow restricted access to nabiximols only, not to cannabis extracts, but would not prohibit use for clinical trials provided by an authorised prescriber only. The committee agreed to not restrict the Schedule 8 nabiximols entry by indication (for Multiple Sclerosis). Members additionally agreed that it would be appropriate to include nabiximols in Appendix K due to sedating effects.

In March 2013, the committee considered a proposal to reschedule nabiximols from Item 3 of Appendix D to Item 1 of Appendix D of the SUSMP and amended Appendix D to include the entry of nabiximols.

In August 2016, the delegate amended the nabiximols entry in line with the August 2016 decision for cannabis and tetrahydrocannabinols to use the plural 's' for tetrahydrocannabinols and their acids.

Cannabis and tetrahydrocannabinols

In March 2016, the committee considered a proposal to amend the Schedule 9 entries and create new Schedule 8 entries for cannabis and tetrahydrocannabinols with Appendix D, Part 1 and Appendix K warnings. The committee supported the proposal and in August 2016, the Medicines Scheduling Delegate decided to amend the scheduling entries for cannabis, tetrahydrocannabinols and nabiximols, with an implementation date of 1 November 2016.

Minutes of these meetings are available on Govdex (Dashboard/Advisory committee on Medicines Scheduling/Meeting/Minutes).

Scheduling application

This was a delegate-initiated application. The delegate's proposed amendments to the Poisons Standard are as follows:

Schedule 9 – Amend entry

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 X mg/kg or less of cannabinoids when labelled with either of the following warning statements:
 - i) Not for internal use; or
 - ii) Not to be taken.

Schedule 8 – Amend entry

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 manufactured⁵, 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

⁵ "Cultivation", "production" and "manufacture" have the same meaning as in the *Narcotic Drugs Act 1967*

- iv) in hemp seed oil for purposes other than internal human therapeutic use containing X mg/kg or less of cannabinoids when labelled with either of the following warning statements:

A) Not for internal use; or

B) Not to be taken.

Appendix D, Item 1

CANNABIS for human use.

Appendix K

CANNABIS

The reason for the proposal is:

- Currently hemp seed oil has no restriction on cannabinoid content other than 50 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements:
 - i) Not for internal use; or
 - ii) Not to be taken

Australian regulatory information

Narcotics Drugs Act and importation

Under the *Narcotic Drugs Act 1967* (the ND Act) a 'drug' includes all extracts of cannabis (including hemp) from cannabis plants. 'Extracts' do not include extracts from cannabis/hemp seed.

The manufacture of a drug that includes (or is from) a cannabis plant, can only be authorised under a manufacture licence in limited circumstances under the ND Act. As outlined under Section 11K, the Secretary must refuse to grant a manufacture licence if not satisfied on reasonable grounds with one of the following (these are set out in paragraphs 11K(2)(b) and (c), respectively), unless the drug is for the purpose of research in relation to medicinal cannabis products:

- that the drug is a medicinal cannabis product that will be:
 - i) supplied for the purposes of use in a clinical trials that is, or is likely to be approved under the *Therapeutic Goods Act 1989* (the TG Act) or notified to the Secretary under that Act; or
 - ii) otherwise supplied in accordance with an approval or authority under the TG Act; or
 - iii) supplied by a pharmacist in a public hospital in accordance with the TG Act;
- that the drug is a medicinal cannabis product that is registered within the meaning of the TG Act under section 25 of that Act.

Therefore extracts of cannabis (or hemp), or the manufacture of drugs from cannabis plants, may only be for the purposes of the aforementioned activities.

Extracts for food, cosmetics, veterinary use (including pet food) are not permitted.

Cannabis, cannabinoids, cannabis resins, tetrahydrocannabinols, cannabis seeds, cannabis plants and parts of cannabis plants are prohibited imports under the *Customs (Prohibited Imports) Regulations 1956*. Cannabis and THC's that are in Schedule 9 will not be granted an import permit, unless a State or Territory Health Department agency also authorises/grants the applicant a permission to possess, hold or supply cannabis or THC's listed under Schedule 9 of the current Poisons Standard.

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.

Hemp seed oil as defined in Part 1 Interpretation, Paragraph (1) of the Poisons Standard is the oil obtained by cold expression from the ripened fruits (seeds) of *Cannabis sativa*. Hemp oil, is distinct from hemp seed oil and includes extracts from the flowering tops or leaves or any other part of the Cannabis plant other than the ripened fruit (seeds).

Information in the public domain, including websites and literature articles⁶ report cannabinoids are not synthesised within the hemp seed. However, traces of delta-9-tetrahydrocannabinol and cannabidiol contamination of the seed may occur due to residual contamination of the outside of the seed coat, even under good agricultural/manufacturing practice. Rigorous cleaning methods, including washing, sieving and shelling, may help reduce or remove any cannabinoid contamination of seeds.

Reported gas chromatography (GC) analytical composition data of hemp seed oil (variety Fedora-19) from Leizer, *et al*, (2000) includes significant portions of polyunsaturated fatty acids such as linoleic acid, oleic acid, stearic acid eichosanoic acids and palmitic acid, with more than 80% of the content being unsaturated fatty acids. Other trace compounds reported include Vitamin E (tocopherols), β -sitosterol, and terpenes (e.g. myrcene and caryophyllene) and salicylates.

⁶ [P1042 - Low THC Hemp Seeds as Food](#) and Leizer, C. *et al*, [The Composition of Hemp Seed Oil and Its Potential as an Important Source of Nutrition \(pdf,145kb\)](#), J. Nutraceuticals, Functional & Medical Foods 2000 2(4) 35 – 53

TABLE 1. Hemp Seed Oil Macrocomposition

Components	Reported (Deferne and Pate, 1996; Callaway and Laakkonen, 1996)	Results
<i>Fatty Acids</i>		
	(% w/w)	(% w/w)
Linoleic Acid (18:2ω6)	50-70	52-62
α-Linolenic Acid (18:3ω3)	15-25	12-23
Oleic Acid (18:1ω9)	10-16	8-13
Palmitic Acid (16:0)	6-9	5-7
Stearic Acid (18:0)	2-3	1-2
γ-Linolenic Acid (18:3ω6)	1-6	3-4
Eicosanoic Acid (20:0)	0.79-0.81*	0.39-0.79
Eicosenoic Acid (20:1)	0.39-0.41*	0.51
Eicosadienoic Acid (20:2)	0.00-0.09*	0.00
<i>Natural Products</i>		
Cannabidiol	nr	10 mg/kg
Δ^9-tetrahydrocannabinol	50 mg/kg**	nd
Myrcene	nr	160 mg/L
β-Caryophyllene	nr	740 mg/L
β-Sitosterol	nr	100-148 g/L [‡]
α-Tocopherol	7-80 ppm ^{†,††}	tr
γ-Tocopherol	710-870 ppm ^{†,††}	468 mg/L
Methyl salicylate	nr	tr

* as reported for variety FIN-314

** as reported by Grotenherman et al. (1998)

† as reported by Blade (1997)

†† as reported by HYChem Corporation, Henry Yard, personal communication

‡ total sterol content measured as β -sitosterol

nr—not reported in cold pressed oil

nd—not detectable (lower limits of detection could not be determined without THC standard)

tr—trace amounts

Given this information, hemp seed oil products should not contain significant amounts of cannabinoids. The presence of cannabinoids in hemp seed oil is considered to arise from either a contamination or adulteration, rather than be naturally occurring.

Pre-meeting public submissions

Three (3) public submissions were received for cannabis. Of these, two (2) were opposed to the proposed amendments, and one (1) proposed an additional amendment. The main points were:

- Concern that the level of caution concerning cannabis and its constituents is far higher than warranted given the suggested therapeutic benefit;
- The US legislation is being approved to allow personal use in addition to medical use;
- Multiple studies show that CBD is safe, and it is not appropriate to set any limit in hemp seed oil;
- Concern that there is ambiguity in the current Schedule 9 entries for cannabis and tetrahydrocannabinols (THCs) and that the scheduling of low-THC hemp and hemp seed oils should also be exempt (less than 50 mg/kg);
- Concern that products not intended for therapeutic use (e.g. cosmetics and dog food) will be captured in the Schedule 8 and Schedule 9 entries and whether this is appropriate;
- One submission proposed that Schedule 9 entries for cannabis and tetrahydrocannabinols both be amended to include the following entry: “d) in products for the purpose other than internal human consumption use containing 50 mg/kg or less of tetrahydrocannabinols”.

Summary of Joint ACCS-ACMS advice to the delegate

The committee advised that the Schedule 9 and Schedule 8 entries for cannabis and Schedule 9 entry for tetrahydrocannabinols be amended as follows:

Schedule 9 –Proposed Amended Entry

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 **20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids when labelled with either of the following warning statements:**
 - i) Not for internal use; or
 - ii) Not to be taken.
- d) in products for the purposes other than internal human use containing 20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids.

Schedule 8 – Proposed Amended Entry

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 manufactured⁷, 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 therapeutic use containing **20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids when labelled with either of the following warning statements:**
 - A) Not for internal use; or**
 - B) Not to be taken.**

⁷ “Cultivation”, “production” and “manufacture” have the same meaning as in the *Narcotic Drugs Act 1967*

Schedule 9 –Proposed Amended Entry

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~~20 mg/kg or less of tetrahydrocannabinols **and 50 mg/kg or less of total cannabinoids** when labelled with either of the following warning statements:
 - i) Not for internal use; or
 - ii) Not to be taken; or
- d) in products for purposes other than internal human use containing ~~50~~20 mg/kg or less of tetrahydrocannabinols **and 50 mg/kg or less of total cannabinoids**.

Schedule 8 – Proposed Amended Entry

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 in 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~~20 mg/kg or less of tetrahydrocannabinols **and 50 mg/kg or less of total cannabinoids** 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.

The committee recommended that the schedule entry for cannabidiol be amended in Schedule 4 of the Poisons Standard to include a consistent hemp seed oil exemption:

Schedule 4 – Proposed Amended Entry

CANNABIDIOL in preparations for therapeutic use containing 2 per cent or less of other cannabinoids found in cannabis, **except when**:

- a) in hemp seed oil for purposes other than internal human use containing 20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids when labelled with either of the following warning statements:
 - i) Not for internal use; or
 - ii) Not to be taken.

- b) in products for the purposes other than internal human use containing 20 mg/kg or less of tetrahydrocannabinols and 50 mg/kg or less of total cannabinoids.

The committee recommended an implementation date of **1 June 2017**.

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 reasons for the advice comprised the following:

- There is low risk associated with the concentration of cannabinoids permitted under the exceptions.
- Hemp seed oil contains fatty acids considered useful as skin conditioners and topical use is low risk, particularly if the level of psychoactive cannabinoid is minimal.
- Low THC hemp seed oil has been used in cosmetic and pet food products. Limiting human use to 'external only' mitigates against risk of internal consumption of cannabinoids, particularly tetrahydrocannabinols and cannabidiol.
- The risk of toxicity is minimal in the concentrations permitted under the exceptions. Most of the toxicity associated with cannabis is due to the tetrahydrocannabinols (THCs) content.
- The toxicity will be low if the THC content is low. International jurisdictions have cut-off limits lower than 50 mg/kg; some jurisdictions have as low as 10 mg/kg.
- Label warning statements 'not for internal use' or 'not to be taken' would apply and make it clear that the products are not for human internal use.
- Including specific instructions about "Not for internal use" and/or "Not to be taken" makes it clear that oral formulations are not exempted from scheduling.
- There does not appear to be any evidence of misuse or abuse of the products that currently contain low concentrations of tetrahydrocannabinols/cannabinoids.
- Limiting the tetrahydrocannabinols content for exemption from scheduling reduces the risk of abuse and diversion.
- The amendments to the schedule entries would provide clarity and avoid any ambiguity about the products intended to be captured.
- There is merit in having consistent exemptions across all cannabis and tetrahydrocannabinols entries in Schedules 8 and 9 and the Schedule 4 entry for cannabidiol.

Delegate's considerations

The delegate considered the following in regards to this application:

- Scheduling proposal
- Public submissions received
- ACCS-ACMS advice
- Section 52E of the *Therapeutic Goods Act 1989*
- [Scheduling Policy Framework](#) (SPF 2015)

- Other relevant information.

Delegate's interim decision

The delegate's interim decision was that:

- a) the Schedule 8 and 9 entries for cannabis and tetrahydrocannabinols be amended to remove the text 'internal' relating to human use
- b) the 'hemp seed oil' clauses in the Schedule 9 entries for cannabis and tetrahydrocannabinols be amended to:
 - i) limit total cannabinoid content to 50 mg/kg including a new limit for tetrahydrocannabinols of 20 mg/kg
 - ii) restrict use in humans
 - iii) include labelling with either of the following warning statements 'not for internal use' or 'not to be taken'
- c) the Schedule 8 cannabis and tetrahydrocannabinols entries be amended by deleting the exemptions for 'hemp seed oil' and 'products'
- d) the Schedule 9 entry for tetrahydrocannabinols be amended by deleting the exemption for 'products'
- e) the Schedule 4 entry for cannabidiol be amended to include clarification in relation to total content of other cannabinoids.

The amended wording for the Schedule 8 and Schedule 9 entries for cannabis and tetrahydrocannabinols and the Schedule 4 entry for cannabidiol are as follows:

Schedule 9 – Amend Entry

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 human use containing 50 mg/kg or less of total cannabinoids, including 20 mg/kg or less of tetrahydrocannabinols, when labelled with either of the following warning statements:
 - i) Not for internal use; or
 - ii) Not to be taken.

Schedule 8 – Amend Entry

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 manufactured⁸, 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

⁸ "Cultivation", "production" and "manufacture" have the same meaning as in the *Narcotic Drugs Act 1967*

- 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.

Schedule 9 – Amend Entry

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 for purposes other than human use containing 50 mg/kg or less of total cannabinoids, including 20 mg/kg or less of tetrahydrocannabinols when labelled with either of the following warning statements:
 - i) Not for internal use; or
 - ii) Not to be taken.

Schedule 8 – Amend Entry

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 in 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 the NABIXIMOLS entry in this Schedule.

Schedule 4 – Amend Entry

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

Appendix D, item 1 – Current entries

CANNABIS for human use.

TETRAHYDROCANNABINOLS for human use.

Appendix K – Current entries

CANNABIS

TETRAHYDROCANNABINOLS

The proposed implementation date is **1 June 2017**.

The delegate considered the relevant matters under section 52E (1) of the *Therapeutic Goods Act 1989*: (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 reasons for the interim decision are the following:

- The delegate acknowledge the committee's advice.
- There is low risk associated with the concentration of cannabinoids permitted under the exceptions. The toxicity will be low if the THC content is low. International jurisdictions have cut-off limits lower than 50 mg/kg; some jurisdictions have as low as 10 mg/kg.
- Low THC hemp seed oil has been used in cosmetic and pet food products. Limiting human use to 'external only' mitigates against risk of internal consumption of cannabinoids, particularly tetrahydrocannabinols and cannabidiol. Hemp seed oil contains fatty acids considered useful as skin conditioners and topical use is a low risk, particularly if the level of psychoactive cannabinoid is minimal.
- Label warning statements 'not for internal use' or 'not to be taken' would apply and make it clear the products are not for human internal use. Including specific instructions about "Not for internal use" and/or "Not to be taken" makes it clear that oral formulations are not exempted from scheduling.
- There does not appear to be any evidence of misuse or abuse of the products that currently contain low concentrations of tetrahydrocannabinols/cannabinoids. Limiting the tetrahydrocannabinols content for exemption from scheduling reduces the risk of abuse and diversion.
- The amendments to the schedule entries would provide clarity and avoid any ambiguity about the products intended to be captured. There is merit in having consistent exemptions across all cannabis and tetrahydrocannabinols entries in Schedules 8 and 9 and the Schedule 4 entry for cannabidiol, in particular the limits for total cannabinoids and tetrahydrocannabinols.
- The product exemption applying to products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols is being omitted as this is inconsistent with the operation of the *Narcotic Drugs Act 1967* (the ND Act) and may be breaching Australia's obligations under the *Single Convention on Narcotic Drugs 1961* (the Single Convention). Any manufacture of drugs would be regulated under ND Act, and would require the manufacturer to be holding a manufacture licence and a permit. In view of the recent amendments to the ND Act, the Secretary must refuse to grant a manufacture licence involving cannabis, unless satisfied on reasonable grounds that at least one of the circumstances set out in subsection 11K(2) of the ND Act is met. Thus the end use of the manufactured cannabis under the ND Act is limited for a person to be granted a manufacture licence, irrespective of the concentration of cannabis in the end product to be supplied. Similarly, the cultivation and production of cannabis or cannabis resins are regulated under the ND Act.
 - Any person who manufactures, cultivates cannabis plants or produces cannabis or cannabis resins without a licence may be committing an offence under the Criminal Code Act. Any importation of drugs would be regulated under the *Customs (Prohibited Imports) Regulations 1956*.
 - The Single Convention does not apply to the cultivation of cannabis plants exclusively for industrial purposes (fibre and seed) or horticultural purposes. However, it applies to the cultivation of cannabis plants for the production of cannabis or cannabis resins, and requires

amongst others that the manufacture of drugs be under licence, subject to exemptions, and that trade in and distribution of drugs be under licence, subject to exemptions.

- The cannabidiol Schedule 4 entry covers only therapeutic use. Therefore non-therapeutic use falls under other Schedule entries for cannabis.
- The cannabidiol entry amendment is to clarify that the cannabidiol must contain at least 98 per cent cannabidiol relative to the total amount of other cannabinoids in the cannabidiol.
- Amending the Schedule 9 entries for cannabis and tetrahydrocannabinols to introduce specific limits for total cannabinoids including tetrahydrocannabinols.
- NICNAS have advised that there are no cannabinoids approved as ingredients in cosmetics (i.e. external human use). Therefore there is no requirement for an exemption, as no approved products exist. This would lead to removal of the exemptions for hemp seed oil from the tetrahydrocannabinols and cannabis Schedule 8 entries and removal of the exemptions for products from the tetrahydrocannabinols and cannabis Schedule 9 and Schedule 8 entries.
- Food is not considered as part of this decision.

Public submissions on the interim decision

Three (3) submissions were received and these opposed the interim decision. The main points of the submissions were:

- The proposed amendments in the interim decision differ from those in the proposal, as well as from the current and previous entries for cannabis and tetrahydrocannabinols. All submissions asserted that the interim decision will have an unjustified effect of capturing certain previously lawful products in Schedule 9, such as hemp seed oil cosmetic products, effectively ending the hemp seed oil industry.
- In light of recent and ongoing policy developments with respect to cannabis, the submissions suggested that the committee and the scheduling delegates are rushing to implement changes to the Poisons Standard and are doing so without the required level of careful consideration and public consultation.
- The submissions asserted that there are flaws in the changes to the existing exceptions and cannabinoid content limits proposed in the interim decision, and suggests that these should be the subject of wider industry consultation before any final decision is made.
- A submission recommended that product and hemp seed oil exceptions be removed from each of the Schedule 8 entries, that the limits for hemp seed oil and other products of 50 mg/kg or less of tetrahydrocannabinols be reinstated, and that no limits for other cannabinoids should apply.

Delegate's final decision

Following consideration of the interim decision, advice from the ACMS, and consideration of the submissions received, the delegate has confirmed the interim decision to amend the Schedule 9 and Schedule 8 entries for cannabis and tetrahydrocannabinols. The delegate has revised the wording of the entries to ensure clarity of the entries.

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

The delegate's final decision is that:

- a) the Schedule 8 and 9 entries for cannabis and tetrahydrocannabinols to retain the text 'internal' relating to human use

- b) the 'hemp seed oil' clauses in the Schedule 9 entries for cannabis and tetrahydrocannabinols be amended to:
 - i) limit total cannabinoid content to 50 mg/kg including a new limit for tetrahydrocannabinols of 20 mg/kg
 - ii) include labelling with either of the following warning statements 'not for internal use' or 'not to be taken'
- c) the Schedule 8 cannabis and tetrahydrocannabinols entries be amended by deleting the exemptions for 'hemp seed oil' and 'products'
- d) the Schedule 9 entry for tetrahydrocannabinols be amended by deleting the exemption for 'products'
- e) the Schedule 4 entry for cannabidiol be amended to include clarification in relation to total content of other cannabinoids.

The matters under section 52E (1) of the *Therapeutic Goods Act 1989* considered relevant by the delegate 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; and f) any other matters that the Secretary considers necessary to protect the public health.

The reasons given by the delegate comprised the following:

- There is low risk associated with the concentration of cannabinoids permitted under the exceptions. The toxicity will be low if the THCs content is low. International jurisdictions have cut-off limits lower than 50 mg/kg; some jurisdictions have as low as 10 mg/kg.
- Low THC hemp seed oil has been used in cosmetic and pet food products. Limiting human use to 'external only' mitigates against risk of internal consumption of cannabinoids, particularly tetrahydrocannabinols and cannabidiol. Hemp seed oil contains fatty acids considered useful as skin conditioners and topical use is a low risk, particularly if the level of psychoactive cannabinoid is minimal.
- Label warning statements "Not for internal use" or "Not to be taken" would apply and make it clear the products are not for human internal use. Including specific instructions about "Not for internal use" and/or "Not to be taken" makes it clear that oral formulations are not exempted from scheduling.
- There does not appear to be any evidence of misuse or abuse of the products that currently contain low concentrations of tetrahydrocannabinols/cannabinoids. Limiting the tetrahydrocannabinols content for exemption from scheduling reduces the risk of abuse and diversion.
- The amendments to the schedule entries would provide clarity and avoid any ambiguity about the products intended to be captured. There is merit in having consistent exemptions across the cannabis and tetrahydrocannabinols entries in Schedule 9, in particular the limits for total cannabinoids and tetrahydrocannabinols.
- The product exemption applying to products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols is being omitted as this is inconsistent with the operation of the *Narcotic Drugs Act 1967* (the ND Act) and may be breaching Australia's obligations under the *Single Convention on Narcotic Drugs 1961* (the Single Convention). Any manufacture of drugs would be regulated under the ND Act, and would require the manufacturer to be holding a manufacture licence and a permit. In view of the recent amendments to the ND Act, the Secretary must refuse to grant a manufacture licence involving cannabis, unless satisfied on reasonable grounds that at least one of the circumstances set out in subsection 11K(2) of the ND

Act is met. Thus the end use of the manufactured cannabis under the ND Act is limited for a person to be granted a manufacture licence, irrespective of the concentration of cannabis in the end product to be supplied. Similarly, the cultivation and production of cannabis or cannabis resins are regulated under the ND Act.

- Any person who manufactures, cultivates cannabis plants or produces cannabis or cannabis resins without a licence may be committing an offence under the Criminal Code Act. Any importation of drugs would be regulated under the *Customs (Prohibited Imports) Regulations 1956*.
- The Single Convention does not apply to the cultivation of cannabis plants exclusively for industrial purposes (fibre and seed) or horticultural purposes. However, it applies to the cultivation of cannabis plants for the production of cannabis or cannabis resins, and requires amongst others that the manufacture of drugs be under licence, subject to exemptions, and that trade in and distribution of drugs be under licence, subject to exemptions.
- The cannabidiol Schedule 4 entry covers only therapeutic use. Therefore non-therapeutic use falls under other Schedule entries for cannabis.
- The cannabidiol entry amendment is to clarify that the cannabidiol must contain at least 98 per cent cannabidiol relative to the total amount of other cannabinoids in the cannabidiol.
- Amending the Schedule 9 entries for cannabis and tetrahydrocannabinols to introduce specific limits for total cannabinoids including tetrahydrocannabinols in hemp seed oil.
- NICNAS have advised that there are no cannabinoids approved as ingredients in cosmetics (i.e. external human use). Therefore there is no requirement for an exemption, as no approved products exist. This would lead to removal of the exemptions for hemp seed oil from the tetrahydrocannabinols and cannabis Schedule 8 entries and removal of the exemptions for products from the tetrahydrocannabinols and cannabis Schedule 9 and Schedule 8 entries.
- Food is not considered as part of this decision.

Additional reasons for the final decision are the following:

- The delegate noted the public submissions, however, has confirmed that the final decision as amended and reasons for the final decision are in keeping with those for the interim decision.
- The submissions received have highlighted that there is currently a level of confusion regarding the difference between hemp seed oil and hemp oil. The Poisons Standard provides the following definition of hemp seed oil:

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

Thus, hemp seed oil can only be made from hemp seeds, and not any other part of the Cannabis plant. Hemp seeds naturally contain only trace amounts of tetrahydrocannabinols and cannabinoids, however a very small quantity of tetrahydrocannabinols and cannabinoids are permitted to allow for any minor contamination with other parts of the Cannabis plant. Hemp oil, on the other hand, can be made from any part of the cannabis plant. As flowers and leaves are high in tetrahydrocannabinols and other cannabinoids, they are captured by the Schedule 9 entries for Tetrahydrocannabinols and Cannabis. It is for this reason that hemp seeds are exempt from the *Narcotic Drugs Act 1967*, and the *Single Convention on Narcotic Drugs 1961*, while hemp oil is captured by the *Narcotic Drugs Act 1967* and the *Single Convention on Narcotic Drugs 1961*.

- A submission raised the issue of Beta Caryophyllene (BCP) being a cannabinoid from their perspective and hence affecting the scheduling of this substance. Research by the secretariat has confirmed that Beta Caryophyllene is a terpene that is a selective agonist of cannabinoid receptor

type-2 (CB₂) and for the purposes of this scheduling entry, the delegate does not define BCP as a cannabinoid.

- It is also noted that Health Canada has a List of Ingredients that are Restricted for Use in Cosmetic Products (<http://www.hc-sc.gc.ca/cps-spc/cosmet-person/hot-list-critique/hotlist-liste-eng.php#c2>) which includes the following entry:

Cannabis sativa	8016-24- Hemp seed oil	8; seed oil 89958- 21-4	10 µg/g THC (delta-9-tetrahydrocannabinol), as per the <i>Industrial Hemp Regulations.</i>
------------------------	---------------------------	----------------------------------	---

This restricted level for THC in cosmetics is equivalent to 10mg/kg.

- Cannabidiol products with 98% of the cannabinoids in the products being cannabidiol are Schedule 4 for therapeutic use. As cannabidiol is absorbed through the skin it is not appropriate that hemp seed oil should have be allowed to have any significant amounts of cannabidiol, noting that there should only be very minimal amounts in hemp seed oil.
- In view of this, it is appropriate to have maximum amounts of cannabinoids and tetrahydrocannabinols in hemp seed oil noting there should only be very minimal amounts, if any in the hemp seeds from which the oil is sourced.
- As noted previously it is not appropriate to have any other '*products for purposes other than internal human use*' exempt due to the issues around the ND Act and Single Convention.
- The delegate noted that Food Standards Australia New Zealand (FSANZ) has recently reached a decision on the use of low THC hemp seeds as food. The Poisons Standard applies access restrictions on all poisons where there is a potential risk to public health and safety. Food that is covered by a food standard issued by FSANZ, and complies with the food standard, is exempted from the Poisons Standard by its' inclusion in Appendix A. While this was taken into consideration by the scheduling delegate, it was not the reason for this scheduling decision, and may be reconsidered at a later date.

Schedule 9 – Amend Entry

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 total cannabinoids, including 20 mg/kg or less of tetrahydrocannabinols, when labelled with either of the following warning statements:
 - i) Not for internal use; or
 - ii) Not to be taken.

Schedule 8 – Amend Entry

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

- h) cultivated or produced, or in products manufactured⁹, in accordance with the *Narcotic Drugs Act 1967* and/or
- i) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967* and/or
- j) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or
- k) 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.

Schedule 9 – Amend Entry

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 for purposes other than internal human use containing 50 mg/kg or less of total cannabinoids, including 20 mg/kg or less of tetrahydrocannabinols, when labelled with either of the following warning statements:
 - i) Not for internal use; or
 - ii) Not to be taken.

Schedule 8 – Amend Entry

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 in 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 the NABIXIMOLS entry in this Schedule.

⁹ “Cultivation”, “production” and “manufacture” have the same meaning as in the *Narcotic Drugs Act 1967*

Schedule 4 – Amend Entry

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

Appendix D, item 1 – Current entries

CANNABIS for human use.

TETRAHYDROCANNABINOLS for human use.

Appendix K – Current entries

CANNABIS

TETRAHYDROCANNABINOLS

Index

CANNABICHROMENE

cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

CANNABIDIOL

cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

CANNABIDIOLIC ACID

cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

CANNABIDIVAROL

cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

CANNABIGEROL

cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

CANNABINOIDS

cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

CANNABINOL

cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

CANNABIS

cross reference: CANNABIS SATIVA, HEMP, HEMP SEED OIL, TETRAHYDROCANNABINOLS

TETRAHYDROCANNABINOLIC ACID

cross reference: NABIXIMOLS, TETRAHYDROCANNABINOLS, CANNABIS

TETRAHYDROCANNABINOLS

cross reference: CANNABIS, HEMP SEED OIL, NABIXIMOLS

TETRAHYDROCANNABIDIVAROL

cross reference: NABIXIMOLS, TETRAHYDROCANNABINOLS, CANNABIS

Implementation dates are as follows:

1. **1 October 2017** to remove “in products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols.” from the tetrahydrocannabinols Schedule 9 and Schedule 8 entries.
2. **1 June 2018** for all other changes.