

Poisons Amendment (2018 Measures No. 1) Instrument 2018

I, {insert author} make the following instrument. Dated 1st April 2018

{insert author}

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1 Name

This instrument is the Poisons Amendment (2017 Measures No. 2) Instrument 2017

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument		

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Part 1 – Cannabidiol

SCHEDULE 3

Add

CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant);

and

CANNABIDIOL (CBD) in preparations for therapeutic use;

and

TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use;

when:

a) cultivated or produced, or in products manufactured^[1], 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) in hemp seed oil for human consumption pursuant to the Food Standards Australia New Zealand Act 1991 and containing less than 50mg/kg of cannabinoids and/or less than 50mg/kg of tetrahydrocannabinols and/or

e) for purposes other than internal human use containing 5% or less of tetrahydrocannabinols and 10% or less of cannabinoids when labelled with either of the following warning statements:

i. Not for internal use; or

ii. Not to be taken and/or

f) it is wholly derived from a mother plant as defined in the Therapeutic Goods Act 1989 Section 3AA in solution with other material regulated elsewhere in the Poisons Schedule and may not be fortified.

SCHEDULE 4

Repeal

CANNABIDIOL (CBD) 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.

Add

CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant);

and

CANNABIDIOL (CBD) in preparations for therapeutic use;

and

TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use;

when:

a) cultivated or produced, or in products manufactured[1], 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 3 or 9 and/or

e) contains 20% or less of tetrahydrocannabinols and it is wholly derived from a mother plant as defined in the Therapeutic Goods Act 1989 Section 3AA

SCHEDULE 8

Repeal

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 manufactured[1], 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 (imported product); 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.

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.

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 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.

Part 2 - Cannabis

SCHEDULE 9

Repeal

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.

Add

CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared) containing 20% or greater of tetrahydrocannabinols and where

- i) any cannabinoids present are not derived from a natural plant and/or
- ii) cannabinoid levels have been fortified after cultivation;

except:

- a) when separately specified in these Schedules.

Repeal

DRUGS REQUIRED TO BE LABELLED WITH A SEDATION WARNING – Cannabis

Add

DRUGS REQUIRED TO BE LABELLED WITH A SEDATION WARNING –

Cannabis greater than 10% of tetrahydrocannabinols.

Note 1. All legislative instruments and compilations are registered on the Federal Register of Legislation kept under the Legislation Act 2003. See <http://www.legislation.gov.au>