



Therapeutic Goods (Declared Goods) Order 2020

I, Jane Cook, as delegate of the Secretary of the Department of Health, make the following order.

Dated [day][month][year]

Dr Jane Cook **DRAFT ONLY—NOT FOR SIGNATURE**
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

Contents

1 Name.....	1
2 Commencement	1
3 Authority.....	1
4 Definitions	1
5 Declared goods¾ therapeutic goods	2
6 Declared goods¾ not therapeutic goods	2
Schedule 1—Therapeutic goods	3
Part 1—Therapeutic goods	3
Part 2—Therapeutic goods when used, advertised, or presented for supply in a particular way	4
Schedule 2—Not therapeutic goods	6
Part 1—Not therapeutic goods	6
Part 2—Not therapeutic goods when used, advertised, or presented for supply in a particular way	7

1 Name

This instrument is the *Therapeutic Goods (Declared Goods) Order 2020*.

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	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made.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 section 7 of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

- (a) advertise;
- (b) current Poisons Standard;
- (c) directions for use;
- (d) presentation;
- (e) supply;
- (f) therapeutic goods; and
- (g) therapeutic use.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

capsule has the same meaning as in TGO 101.

Permissible Ingredients Determination means the determination under section 26BB of the Act, as in force from time to time.

Note: The permissible ingredients determination is published on the Federal Register of Legislation at <https://www.legislation.gov.au>.

pill has the same meaning as in TGO 101.

relevant substance means any of the following substances, where the substance is not included in a schedule to the current Poisons Standard or expressly identified on the WADA prohibited list:

- (a) β -methylphenylethylamine (BMPEA) (*Acacia rigidula*);
- (b) dendrobium (*Dendrobium nobile*);
- (c) methylliberine;
- (d) N-phenethyl dimethylamine (*Eria jarensis* extract).

Food Standards Schedule 29 means the *Australia New Zealand Food Standards Code – Schedule 29 – Special purpose foods*, as in force from time to time.

Note: The *Australia New Zealand Food Standards Code – Schedule 29 – Special purpose foods* is published on the Federal Register of Legislation at <https://www.legislation.gov.au>.

tablet has the same meaning as in TGO 101.

TGO 101 means the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019*, as in force from time to time.

Note: TGO 101 is published on the Federal Register of Legislation at <https://www.legislation.gov.au>.

WADA (short for World Anti-Doping Agency) has the same meaning as in the *Australian Sports Anti-Doping Authority Act 2006*.

WADA Prohibited List means the list identifying prohibited substances and prohibited methods published by WADA, as in force or existing at the time this instrument commences.

Note: The WADA prohibited list is published on the WADA website at <https://www.wada-ama.org/en>.

5 Declared goods—therapeutic goods

- (1) The goods or classes of goods specified in Part 1 of Schedule 1 to this instrument are declared to be therapeutic goods.
- (2) The goods or classes of goods specified in column 2 of an item in the table in Part 2 of Schedule 1 to this instrument, when used, advertised, or presented for supply, in a way specified in column 3 of that item, are declared to be therapeutic goods.

6 Declared goods—not therapeutic goods

- (1) The goods or classes of goods specified in Part 1 of Schedule 2 to this instrument are declared not to be therapeutic goods.
- (2) The goods or classes of goods specified in column 2 of an item in the table in Part 2 of Schedule 2 to this instrument, when used, advertised, or presented for supply, in a way specified in column 3 of that item, are declared not to be therapeutic goods.

Note: See section 5.

Part 1—Therapeutic goods

Note This Part is reserved for future use.

DRAFT

Part 2—Therapeutic goods when used, advertised, or presented for supply in a particular way

Goods that are therapeutic goods when used, advertised, or presented for supply in a particular way

Column 1	Column 2	Column 3
Item	Goods or classes of goods	Use, advertising or presentation
1	<p>goods for oral administration that are represented (expressly or by implication) as being for the improvement or maintenance of physical or mental performance in sport, exercise or any other recreational activity, and which:</p> <p>(a) contain, or are represented (expressly or by implication) to contain, one or more of the following (however described or named):</p> <p>(i) a substance included in a schedule to the current Poisons Standard;</p> <p>(ii) a substance expressly identified on the WADA Prohibited List;</p> <p>(iii) a relevant substance;</p> <p>(iv) a substance with equivalent pharmacological action to a substance mentioned in subparagraph (i), (ii) or (iii), including those that may be characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer;</p> <p>(v) an ingredient in an amount that exceeds any limit for the ingredient specified in the Permissible Ingredients Determination when used in accordance with the directions for use in relation to the goods;</p> <p>(vi) an amino acid in an amount that exceeds any limit for the amino acid specified in section S29—18 of the Food Standards Schedule 29 when used in accordance with the directions for use in relation to the goods;</p> <p>(vii) a substance in an amount that exceeds any limit for the substance specified in section S29—19 of the Food</p>	<p>when the goods are used, advertised, or presented for supply:</p> <p>(a) for therapeutic use; or</p> <p>(b) in a way that is likely to be taken to be for therapeutic use;</p> <p>including, but not limited to, one or more of the following therapeutic uses:</p> <p>(c) gaining muscle;</p> <p>(d) increasing mental focus;</p> <p>(e) increasing metabolism;</p> <p>(f) increasing stamina;</p> <p>(g) increasing testosterone levels, reducing oestrogen levels or otherwise modifying hormone levels;</p> <p>(h) losing weight or fat;</p> <p>(i) preparing for workout;</p> <p>(j) recovering from workout</p>

Standards Schedule 29 when used
in accordance with the directions
of use in relation to the goods; or

(b) are manufactured in the dosage form of
a tablet, capsule or pill

DRAFT

Note: See section 6.

Part 1—Not therapeutic goods

Note This Part is reserved for future use.

DRAFT

Part 2—Not therapeutic goods when used, advertised, or presented for supply in a particular way

Note This Part is reserved for future use.

DRAFT