



# **Therapeutic Goods (Declared Goods) Order 2019**

made under section 7 of the  
*Therapeutic Goods Act 1989*

## **Compilation No. 3**

**Compilation date:** 30 November 2020

**Includes amendments up to:** F2020L01204

Prepared by the Department of Health, Canberra

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## About this compilation

### This compilation

This is a compilation of the *Therapeutic Goods (Declared Goods) Order 2019* that shows the text of the law as amended and in force on 30 November 2020 (the **compilation date**).

The notes at the end of this compilation (the **endnotes**) include information about amending laws and the amendment history of provisions of the compiled law.

### Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register ([www.legislation.gov.au](http://www.legislation.gov.au)). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

### Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

### Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

### Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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## 1 Name

This instrument is the *Therapeutic Goods (Declared Goods) Order 2019*.

## 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 subsection 3(1) of the Act, including the following:

- (a) advertise;
- (b) current Poisons Standard;
- (c) manufacture;
- (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.

*pill* has the same meaning as in TGO 101.

*Prohibited List* means *The World Anti-Doping Code International Standard Prohibited List* (January 2020) published by the World Anti-Doping Agency, as in force or existing at 30 November 2020.

Note: The Prohibited List is published on the World Anti-Doping Agency (WADA) website at <https://www.wada-ama.org/en>.

*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 Prohibited List:

- (a) dendrobium (*Dendrobium nobile*);
- (b) methylliberine.

*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*.

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

*Trefriw Wells mineral water* means naturally-occurring mineral water sourced from Trefriw Wells Spa in the United Kingdom.

## 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.

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- (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.

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## Schedule 1—Therapeutic goods

Note: See section 5.

### Part 1—Therapeutic goods

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#### Goods that are therapeutic goods

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Column 1	Column 2
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Item	Goods or classes of goods
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1	goods that are or contain Cellasene
2	goods that: (a) contain fibre; and (b) are manufactured in the dosage form of a tablet, capsule or pill
3	goods that: (a) contain, or are promoted to contain, isolated b-hydroxy-b-methylbutyrate (HMB) or its salts; and (b) are manufactured in the dosage form of a tablet, capsule, pill or powder
4	goods that: (a) contain shark cartilage; and (b) are manufactured in the dosage form of: (i) a tablet, capsule or pill; or (ii) a powder, where that powder is not a wholesale product for use as an ingredient in food

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## 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
1A	<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 recreational activity, and that:</p> <p>(a) contain, or are represented (expressly or by implication) to contain, one or more of the following substances (however described or named):</p> <p>(i) a substance included in a schedule to the current Poisons Standard; or</p> <p>(ii) a substance expressly identified on the Prohibited List that is added as an ingredient to the goods; or</p> <p>(iii) a relevant substance that is added as an ingredient to the goods; or</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; or</p> <p>(b) on or after 30 November 2023, are supplied in the dosage form of a tablet, capsule or pill, other than those goods containing glucose only</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>
1	goods that are labelled or promoted for cosmetic purposes	when used, advertised or presented for supply for oral consumption
2	goods that contain Trefriw Wells mineral water	<p>when used, advertised or presented for supply for therapeutic use:</p> <p>(a) as an iron supplement; and</p> <p>(b) in a single use sachet</p>
3	<p>goods that:</p> <p>(a) contain one or more of the following folate substances:</p> <p>(i) folic acid; or</p> <p>(ii) folinic acid; or</p> <p>(iii) levomefolic acid; or</p> <p>(iv) any other form of folate that may be</p>	<p>when 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>



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<p>characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer; and</p> <p>(b) are represented as being food for special medical purposes, or being for dietary management of a disease, disorder or medical condition;</p> <p>whether or not the recommended single dose of the goods contains sufficient macronutrients to feed, either exclusively or partially, the person for whom the dose is intended</p>	<p>(c) preventing, curing or alleviating depression;</p> <p>(d) curing or alleviating an inborn error of folate metabolism;</p> <p>(e) preventing, curing or alleviating folate deficiency;</p> <p>and that therapeutic use can be taken to relate to a substance mentioned in paragraph (a) in column 2 of this item</p>
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## **Schedule 2—Not therapeutic goods**

Note: See section 6.

### **Part 1—Not therapeutic goods**

*Note* This Part is reserved for future use.

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

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### Goods that are not therapeutic goods when used, advertised, or presented for supply in a particular way

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Column 1	Column 2	Column 3
Item	Goods or classes of goods	Use, advertising or presentation
1	deodorant preparations	when used: (a) for dermal application; or (b) with therapeutic devices
2	depilatory preparations	when used for dermal application
3	non-prescription spectacles	when used solely for: (a) magnification of images; or (b) sun protection
4	non-sterile apparel including fitted support or insulating garments	when used solely to: (a) aid physical comfort; or (b) relieve discomfort
6	soaps and detergents, other than medicated soaps and detergents	when used for cleansing skin or hair
7	spa water or natural mineral water	when the goods are not used, advertised or presented for supply for therapeutic use
8	substances for use in the purification or treatment of drinking water	when the goods are not used, advertised or presented for supply for therapeutic use
9	unmedicated dental chewing gum	when advertised or presented for supply, the only benefits claimed to result from the use of the goods are consequential on improvements to oral hygiene

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## Endnotes

Endnote 1—About the endnotes

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## Endnotes

### Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

### Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

### Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

### Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.

**Endnote 2—Abbreviation key**

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	reloc = relocated
ed = editorial change	renum = renumbered
exp = expires/expired or ceases/ceased to have effect	rep = repealed
F = Federal Register of Legislation	rs = repealed and substituted
gaz = gazette	s = section(s)/subsection(s)
LA = <i>Legislation Act 2003</i>	Sch = Schedule(s)
LIA = <i>Legislative Instruments Act 2003</i>	Sdiv = Subdivision(s)
(md) = misdescribed amendment can be given effect	SLI = Select Legislative Instrument
(md not incorp) = misdescribed amendment cannot be given effect	SR = Statutory Rules
mod = modified/modification	Sub-Ch = Sub-Chapter(s)
No. = Number(s)	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

## Endnotes

### Endnote 3—Legislation history

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### Endnote 3—Legislation history

<b>Name</b>	<b>Registration</b>	<b>Commencement</b>	<b>Application, saving and transitional provisions</b>
<i>Therapeutic Goods (Declared Goods) Order 2019</i>	21 Oct 2019 (F2019L01352)	22 Oct 2019	—
<i>Therapeutic Goods Amendment (Declared Goods) Order 2019</i>	4 Nov 2019 (F2019L01419)	5 Nov 2019	—
<i>Therapeutic Goods Amendment (Declared Goods) Order (No. 1) 2020</i>	23 Apr 2020 (F2020L00465)	24 Apr 2020	—
<i>Therapeutic Goods (Declared Goods) Amendment (Sports Supplements) Order 2020</i>	23 Sep 2020 (F2020L01204)	30 Nov 2020	—

**Endnote 4—Amendment history**

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<b>Provision affected</b>	<b>How affected</b>
s 2 .....	rep LA s 48D
s 4 .....	am F2020L01204
Schedule 1 .....	am F2019L01419, F2020L01204
Schedule 2 .....	am F2020L00465