



Therapeutic Goods (Declared Goods) Order 2019

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

Dated 18 October 2019

Dr Jane Cook
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

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1 Name

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

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Note: This table relates only to the provisions of this instrument as originally made.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) manufacture;
- (c) presentation;
- (d) supply;
- (e) therapeutic device;
- (f) therapeutic goods; and
- (g) therapeutic use.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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.

Schedule 1—Therapeutic goods

Note: See section 5.

Part 1—Therapeutic goods

Goods that are therapeutic goods

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

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	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	when used, advertised or presented for supply for therapeutic use: (a) as an iron supplement; and (b) in a single use sachet

Schedule 2—Not therapeutic goods

Note: See section 6.

Part 1—Not therapeutic goods

Note This Part is reserved for future use.

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

Goods that are not 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	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 (other than apparel specified in item 5), including fitted support or insulating garments	when used solely to: (a) aid physical comfort; or (b) relieve discomfort
5	non-sterile protective or safety apparel or equipment	when used: (a) in the home; or (b) for occupational or recreational use
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
