



Therapeutic Goods (Declared Goods) Order 2019

I, John Skerritt, as delegate of the Secretary of the Department of Health, make the following order.

Dated

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

DRAFT

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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 made.	

Note: This table relates only to the provisions of this instrument as originally made.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

In this instrument:

Act means *Therapeutic Goods Act 1989*.

5 Declared goods—therapeutic goods

The goods or classes of goods specified in Schedule 1 to this instrument are declared to be therapeutic goods.

6 Declared goods—therapeutic goods when used, advertised, or presented for supply in a particular way

The goods or classes of goods specified in column 2 of an item in the table in Schedule 2 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.

7 Declared goods—not therapeutic goods

The goods or classes of goods specified in Schedule 3 to this instrument are declared not to be therapeutic goods.

8 Declared goods—not therapeutic goods when used, advertised, or presented for supply in a particular way

The goods or classes of goods specified in column 2 of an item in the table in Schedule 4 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.

Note This Schedule is reserved for future use.

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

Note: See section 6.

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: (a) contain one or more of the following folate substances: (i) folic acid; or (ii) folinic acid; or (iii) levomefolic acid; or (iv) any other form of folate that may be characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer; and (b) are represented as being food for special medical purposes, or being for dietary management of a disease disorder or medical condition; 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	when the goods are: (a) used, advertised, or presented for supply, for therapeutic use; or (b) used, advertised, or presented for supply, in a way that is likely to be taken to be for therapeutic use; including, but not limited to, one or more of the following therapeutic uses: (c) preventing, curing or alleviating depression; (d) curing or alleviating an inborn error of metabolism; (e) preventing, curing or alleviating folate deficiency; and that therapeutic use can be taken to relate to a folate substance mentioned in paragraph (a) in column 2 to this item

Schedule 3—Not therapeutic goods

Note: See section 7.

Note This Schedule is reserved for future use.

Schedule 4—Not therapeutic goods when used, advertised, or presented for supply in a particular way

Note: See section 8.

Note This Schedule is reserved for future use.