



Therapeutic Goods Amendment (Declared Goods) Order 2019

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

Dated 31 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 Amendment (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Note: This table relates only to the provisions of this instrument as originally made.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 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Declared Goods) Order 2019

1 Part 2 of Schedule 1 (at the end of the table)

Add:

- 3 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 used, advertised, or presented for supply:
- (a) for therapeutic use; or
 - (b) 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 folate metabolism;
 - (e) preventing, curing or alleviating folate deficiency;
- and that therapeutic use can be taken to relate to a substance mentioned in paragraph (a) in column 2 of this item