

## Technical Alert

### Folate-containing food for special medical purposes re-classified as therapeutic goods under Section 7 Declaration

#### Summary

On 4 September 2019 the TGA announced a [consultation](#) to clarify whether certain goods containing folate are considered to be food or medicine, and consulted specifically on Amendment Order [[DRAFT Therapeutic Goods \(Declared Goods\) Order 2019](#)], declaring certain folate containing goods as therapeutic goods.

This instrument proposed to include goods that contain folate (and folate derivatives such as folic, levomefolic acid) and which are also promoted for:

- Preventing, curing or alleviating depression, and
- Curing or alleviating an inborn error of metabolism, or
- Preventing, curing or alleviating folate deficiency;

as therapeutic goods.

Most of the feedback received objected to the proposal based on potential loss of access to these goods by consumers and the consequence to their health or financial impacts to companies, investors that may currently supply goods that meet the declaration. (One submitter noted that the TGA were consulted during development of their product and were fully aware of the intention to market as a food.)

The TGA considered the submissions and continued with the Amendment Order which commenced on **5 November 2019**. The practical implication of this decision is that goods meeting the criteria set out in Item Schedule 2 of the order, will be regulated as therapeutic goods. The substances folate, folic acid and levomefolic acid, 5- methyl tetrahydrofolate are listable ingredients, and currently available in listed medicines.

For those companies that manufacture products which meet the criteria (contain folate/folate derivatives and which make those therapeutic claims) and who wish to continue supplying in the Australian marketplace, will need to apply to list or register (whichever is the appropriate pathway based on claims) their medicine on the ARTG.

#### Background

Declared goods orders are made under section 7 of Therapeutic Goods Act 1989 (the Act). These decisions can be made at any time by the Secretary (or their delegate) determining that any good may meet the definition of a therapeutic good as per the Act, even if the product or good is currently captured by legislation elsewhere. For example, in this instance, the types of goods and products



recently declared under the Amendment Order were represented as being a food for special medical purposes (“FSMPs”) and included in Standard 2.9.5 of the Food Standards Code.

More recently [another consultation](#) was launched proposing to declare certain sports supplements as therapeutic goods.

### **Resources**

[TGA announcement](#) declaring folate as therapeutic goods

[Consultation on folate](#)

[Therapeutic Goods \(Declared Goods\) Order 2019](#)

**Members are encouraged to forward any identified issues to [technical@cmaustralia.org.au](mailto:technical@cmaustralia.org.au) for attention by the Committee Secretariat.**

**ENDS**