

Consultation on proposed clarification of goods-containing-folate-substances

Mylan has considered the TGA's proposal to declare goods containing folate substances as therapeutic goods in certain circumstances.

Mylan's position is that the proposed declaration should not be made for at least the following reasons.

1. The regimes already in place are adequate to assess and determine whether a good is a Food for Special Medical Purposes ("FSMP") in accordance with Food Standard 2.9.5 or for therapeutic use in accordance with the Therapeutic Goods Act.
 - In accordance with Food Standard 2.9.5, FSMPs are effectively foods limited to use in dietary management. Foods which are formulated and represented as being for the dietary management of obesity and overweight or an infant formula product are specifically excluded (2.9.5-2(2)).
 - Amongst a list of other substances in Columns 1 and 2 of the tables to S29-20 and S29-7, Folic Acid and Calcium L-methylfolate are permitted forms of Folate that may be added to FSMPs in accordance with 2.9.5-6 (1)(a) and (b).
 - Importantly, 2.9.5-4 prohibits a therapeutic use claim in relation to FSMPs, that is, a claim must not:
 - (a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or
 - (b) compare the food with a good that is:
 - (i) represented in any way to be for therapeutic use; or
 - (ii) likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.
2. The TGA is empowered to act on a case-by-case basis in the event of misrepresentation of a food as therapeutic goods or non-compliant goods. The Therapeutics Advertising Code (No. 2) 2018 also provides the TGA with a complaints mechanism to ensure that the marketing and advertising of therapeutic goods, amongst other things, is socially responsible and does not mislead or deceive consumers.
3. The Food standards ANZ, Standard 1.2.7 (Nutrition, health and related claims) set out in legislation the use of nutrition content and health claims on food labels and advertisements.
4. In addition to the general Competition and Consumer protection laws regime. As such, if FSMPs are represented as therapeutic goods or for therapeutic use, the TGA has recourse to engage with the advertiser/supplier of those goods on a case-by-case basis.

Mylan is concerned that the TGA's motivation to make the proposed declaration with respect to goods containing folate substances is unclear in view of the Therapeutic Goods and Food Standard regimes already in place and more specifically, that folate has been singled out from other permitted forms of substances that may be added to FSMPs. As such, the TGA's proposal is likely to result in an inconsistent approach to FSMPs and Schedule 2 of the proposed Declaration adds an unnecessary layer of confusion and complexity.

Further, Schedules 1, 3 and 4 are currently placeholders for future use and as such further consultation will be required.

Mylan however, is supportive of all measures to ensure that therapeutic goods and FSMPs are appropriately regulated, supplied and advertised to consumers.

Mylan is available for further consultation with the TGA.