



**Consumer Healthcare  
Products Australia**

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To Whom it May Concern

**RE: Proposed clarification that goods are therapeutic goods - goods containing folate substances in certain circumstances**

CHP Australia is the leading voice and industry body for **manufacturers and distributors of consumer healthcare products**, which includes non-prescription medicines. We strive to advance consumer health through **responsible Self Care** and were previously known as the Australian Self Medication Industry (ASMI).

Our key priorities for the industry include **improving health literacy, growing the consumer healthcare products industry** and **increasing access to medicines** where appropriate.

CHP Australia welcomes the opportunity to respond to this consultation and supports the application of appropriate and effective regulation. CHP Australia also recognises the challenges presented to regulators by interface areas, including the food-medicine interface, and the difficulties these areas can introduce in balancing consumer access to products with appropriate risk-based regulatory controls.

CHP Australia supports the principle of this proposed clarification that when a good is presented for a therapeutic use it should be regulated as a therapeutic good with the appropriate safety, quality and efficacy controls. In this instance, when goods are claiming to be foods for special medical purposes (FSMP) but not complying with the definition of FSMP in Food Standard 2.9.5 due to the presence of inappropriate therapeutic representations, these should be regulated as therapeutic goods.

The presentation of the proposed Schedule 2 declaration of the Therapeutic Goods (Declared Goods) Order 2019 could lead to some unintended consequences. The *Therapeutic Goods Act* gives the Secretary the authority to declare goods to be therapeutic goods under section 7 of the Act, even if they are also goods for which there is a standard in the Australia New Zealand Food Standards Code. This creates a potential conflict for products containing folate substances that are legitimately sold as FSMP for the dietary management of inborn errors of amino acid, protein, fat or carbohydrate metabolism.

**Advancing consumer health through responsible self care**



In order to avoid unintended consequences, we suggest that consideration be given to amending the wording for Item 1 in column 3, part (d) to specify errors of 'folate' metabolism. The Secretary should also consider adding a Schedule 3 entry so that specific FSMP products that are consistent with Food Standard 2.9.5 are also declared not to be therapeutic goods, for instance, those that provide necessary dietary support for conditions such as Phenylketonuria and Tyrosinaemia.

CHP Australia also notes that the supplier of an FSMP is only able to control their presentation and advertising of a good and not ultimately how the product is used or how it is represented by unrelated third parties. This creates a risk within the wording of the declared goods order, and within the wording of the Act, that a good could meet the criteria under column 3 for being a therapeutic good based on the actions of parties beyond the control of the supplier. Consideration should be given to amending the wording of the proposed conditions under column 3 to mitigate this risk or additional clarification should be included to demonstrate that expectations around use and advertising won't be applied without limit.

CHP Australia remains available to discuss this matter further if there is any additional clarification required of this position.

Regards,