



Therapeutic Goods Administration (TGA) consultation: options for future regulation of low risk products

May 2016

The Dietitians Association of Australia (DAA) is the national association of the dietetic profession with over 6000 members, and branches in each state and territory. DAA is a leader in nutrition and advocates for food and nutrition for healthier people and healthier nations. DAA appreciates the opportunity to respond to the TGA consultation on options for the regulation of low risk products.

[Redacted text]



DAA interest in this consultation

As the leading nutrition and dietetic organisation in Australia, the Dietitians Association of Australia (DAA) is interested in the regulation of oral vitamins and minerals, and rehydration or formulated sports products. DAA considers the quality and safety of any product consumed orally (i.e. food, vitamin, mineral, rehydration or sports nutrition product) to be of utmost importance and makes the following recommendations to the TGA as part of this consultation.

Vitamins and Minerals

DAA considers it important to uphold robust regulations on the manufacturing, safety and sale of all vitamins (including both water-soluble and fat-soluble vitamins) and minerals in Australia. People who are in genuine need of a vitamin or mineral supplement should be given a high level of confidence in the product, knowing that high standards of quality and manufacturing apply, as these people are likely to be more vulnerable to adverse consequences of adulterants or reduced levels of active ingredients. As such, **DAA supports Option 1 – to maintain the status quo regulation of vitamins and minerals.** DAA does not support Options 2 & 3, which have the potential to result in the production of lower quality vitamin and mineral products if manufacturing standards are not appropriate.

Rehydration or formulated sports products

DAA agrees that rehydration products are a complicated product type due to their similarity with sports drinks. Adding to this complication is the release of some new-to-market rehydration products that contain a mix of electrolytes, plus other active ingredients, such as prebiotics and zinc. Up until recently, rehydration products haven't typically included any other active ingredients aside from electrolytes. **DAA therefore supports the recommendation put forward by the TGA to review rehydration products that are entered in the ARTG** with the aim of ensuring that there is clear demarcation between sports drinks, which are more appropriately regulated as foods, and other oral rehydration products with a specific therapeutic purpose.