

New Food Medicine Interface Guidance Tool Published

Delegates who attended this year's CMA (CHC) Regulatory Obligations Seminar were able to hear from Ms Trisha Garrett, Head of the Office of Complementary Medicines TGA, who addressed a series of slides relating to the issues experienced at the food-medicine interface.

The TGA has actively been working with Food Standards Australia New Zealand (FSANZ), State Food Regulators and The Department of Health to identify and resolve issues experienced at the interface. It was considered that much of the ambiguity could be resolved through the development of a clear guidance tool based in law and greater formal involvement of the TGA in food forums.

The Food-Medicine Interface (FMI) Guidance Tool was developed to assist users to work through a series of questions sequentially to interperate the relevant definitions in the *Therapeutic Goods Act 1989* (Act) as to whether a particular product was likely to be a therapeutic good or not. The FMI Tool has received endorsement by States and Territories and is designed to facilitate importers, manufacturers and suppliers to determine whether their products are foods or therapeutic goods and for regulators when they need to know whether the TGA is responsible for regulating a product or not.

If a product is judged to be a therapeutic good, the TGA may for example take action if the product is not included in the Australian Register of Therapeutic Goods (ARTG) or otherwise not exempt or approved under the Act. The TGA could also publish an Alert to order the recall of a product should the product pose a potential health risk. In cases where the product in question is judged not to be a therapeutic good, the TGA may remove the product from the Register (under section 9F) and contact relevant state and territory food regulators for appropriate action.

Resources:

- The FMI Guidance Tool has now been published to the TGA website and is available [here](#)
- FMI Guidance Tool Explanatory Material [here](#)
- TGA presentations given at the CHC Regulatory Obligations Seminar 2014 can be located [here](#)

Ends