

## Addisons FocusPapers

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### **Proposed Section 7 Declaration: Products in Capsule, Tablet or Pill Form are Therapeutic Goods (Medicines)**

**Deadline for submissions: Monday 30 November 2009**

The Therapeutic Goods Administration (“TGA”) is proposing changes to the *Therapeutic Goods Act 1989* (“Act”) that would result in the form of a product being a key factor in determining whether it constitutes a medicine or a food.

#### **Food/Medicine Interface**

Currently, the regulatory regimes relating to foods and medicines often overlap. For example:

- there are food standards for many substances that may be marketed as medicines, such as formulated products categorised as supplementary sports foods and edible oils (for example fish oil, flaxseed oil); and
- there are some medicines which have the properties of foods.

The TGA and the Food Standards of Australia and New Zealand (“FSANZ”), consider that confusion exists for importers, manufacturers, consumers and government regulators as to which regulatory regime (and legislation) applies. In other words, it is necessary for relevant parties to determine whether:

- the product is classified as a medicine, in which case the product will require listing or registration with the TGA and must comply with the Act; or
- the product is classified as a food, in which case the product will need to comply with the FSANZ Code (and the relevant State and Territory Food Acts).

These authorities take the view that the confusion that exists between foods and medicines increases where certain foods are packaged in capsule, tablet or pill form. This view is reached on the basis that the form of the packaging/presentation of the product creates the impression that the product is a medicine and consumers may consider that such foods have been assessed by the TGA when, in fact, this has not occurred.

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## **Proposed Section 7 Declaration**

The proposal to issue a declaration (under Section 7 of the Act) will attempt to resolve many of the issues and clarify regulatory requirements in relation to the food/medicine interface issue.

This will result in any products packaged in capsule, tablet or pill form being deemed to be classified as a medicine.

## **How this may affect you?**

If you are manufacturing, importing, marketing or selling certain food products in capsule, tablet or pill form, the proposed Section 7 Declaration will cause those products to be classified as medicines (unless they are unmedicated confectionary): they will require listing or registration with the TGA and compliance with the Act.

This will result in many products sold currently as foods in capsule, tablet or pill form which are not currently listed by the TGA being required to be listed by the TGA in order to be marketed and sold in Australia. This will impact on suppliers of various products, including food products and sports supplements.

Any submissions to the TGA on this issue must be made by **30 November 2009**.

**For more information relating to the Proposed Section 7 Declaration, please contact:**

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