

## Regulation of our Products

### **Regulatory Overview**

Vitamin, mineral, herbal and other health supplements are referred to as Complementary Medicines by the Australian government, and are regulated as therapeutic goods under the control of the Therapeutic Goods Administration (TGA) within the Commonwealth Department of Health and Ageing.

All medicines in Australia, both complementary and conventional, must be manufactured under pharmaceutical standards of good manufacturing practice (GMP). All medicines must be on the Australian Register of Therapeutic Goods (ARTG) as either listed or registered.

All prescription medicines and the majority of over-the-counter (OTC) pharmaceutical medicines are registered and labelled 'AUST R', while the majority of complementary medicines are listed and are labelled 'AUST L'. Registered medicines have been evaluated by the TGA for quality, safety and efficacy, listed medicines have been similarly assessed - only not for efficacy. Companies making claims for efficacy however, must hold evidence that supports these claims. Any high-level claim of efficacy for a serious disease requires registration and TGA assessment.

In contrast, vitamin, mineral, herbal and other health supplements in the United States are regulated as dietary supplements. The U.S. Food and Drug Administration (FDA) is not involved in the assessment or certification of these types of products.

This places Australia at the forefront of complementary medicine regulation and ensures that Australian consumers and consumers purchasing Australian Products have medicines produced at a high level of quality control.