

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2011-12, 15 February 2012

Question: E12-233

OUTCOME: 1: Population Health

Topic: ADVERTISING

Written Question on Notice

Senator Di Natale asked:

When would the TGA make a decision to pursue an [advertising complaint] issue like that, as opposed to referring the complaint on to another body?

Answer:

The regulation of advertising of therapeutic goods in Australia is controlled at three levels through regulatory, co-regulatory and self-regulatory systems. The regulatory framework is set out in the *Therapeutic Goods Act 1989* (the Act), Therapeutic Goods Regulations 1990 (the Regulations) and the Therapeutic Goods Advertising Code 2007, which are administered by the Therapeutic Goods Administration (TGA).

The co-regulatory framework provides for certain functions set out in the Regulations to be undertaken by key industry bodies. The “co-regulation” aspect includes the approval of certain consumer advertisements by industry bodies that have been delegated with that power by the Secretary and the consideration of certain advertising complaints by the Complaints Resolution Panel, the members of which include nominees of relevant industry bodies. “Self-regulation” is undertaken by the relevant industry bodies under specified voluntary codes of practice.

The Medicines Australia Code of Conduct sets the standards for the ethical marketing and promotion of prescription-only medicines in Australia. It complements the legislative requirements of the Act and the Regulations. Complaints about the promotion of registered prescription-only medicines may be referred by the TGA to the Medicines Australia to investigate the behaviour of the sponsor. Where a sponsor of a prescription-only medicine has been found to have breached the Code of Conduct, Medicines Australia can impose a range of sanctions, including substantial fines, depending on the breach.