

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-031

OUTCOME 1: Population Health

Topic: COST RECOVERY

Written Question on Notice

Senator Siewert asked:

The TGA's current funding is fully cost-recovered from industry.

- a) How does the TGA manage the perceived conflict of interest presented by its cost recovery arrangements?
- b) Has there been any discussion about a portion of its funding coming from the Government, as is usual in other countries, to reduce the potential perceived conflict of interest?

Answer:

- a) The principle of recovery of the costs of regulation from the regulated industry, rather than the taxpayers, has been supported for many years in the Commonwealth by various governments.

The cost recovery arrangements in place at the TGA, and the requirements of decision made under the *Therapeutic Goods Act 1989* ensure that there is no link between the funding mechanism of the TGA and its regulatory decision making.

The Australian Government approves the fees and charges levied for regulatory functions undertaken by the TGA on an annual basis. These fees and charges are publically gazetted as a disallowable instrument in the Australian Parliament.

This type of cost recovery arrangement is common to other Commonwealth regulators such as Australian Pesticides and Veterinary Medicines Authority (APVMA) and Civil Aviation Safety Authority (CASA) and is a way of ensuring that taxpayers are not subsidising the cost of regulatory functions that are utilised by companies seeking to gain commercial benefit from selling therapeutic goods.

- b) The funding arrangements for therapeutic goods regulation vary in different parts of the world. A number of overseas regulators with similar regulatory frameworks for therapeutic products to that of TGA have full or partial cost recovery. There is a full cost recovery in Australia and the UK, though both the US and Canada have partial cost recovery. At the same time there is full cost recovery in some therapeutic product sectors but not in other product sectors, for example, Medicines and Healthcare Products Regulatory Agency, UK has full cost recovery for medicines and not for medical devices. Interestingly, Canada has just passed legislation to increase its proportion of funding via cost recovery.

The issue of future funding a portion of the TGA costs is a matter for the government.