Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 17 & 19 October 2012

Question: E12-212

OUTCOM 1: Population Health

Topic: TGA

Type of Question: Written Question on Notice

Number of pages: 2

Senator: Senator Di Natale

Question:

a) Has the Aspen Pharmaceuticals incident, which saw Aspen appealing to the Administrative Appeals Tribunal to prevent the TGA from removing medicines containing dextropropoxyphene (DPP) from the Australian Register of Therapeutic Goods, exposed a critical loophole in TGA regulation, and does the TGA anticipate that other companies now exploit this loophole to bypass TGA regulation?

b) Is it possible to put a dollar value on the work undertaken by the TGA in defending its decision to remove DPP from the Therapeutic Goods Register?

c) To what degree has ensuring consumer safety through the pursuit of a ban on DPP diverted TGA resources from other consumer safety activities?

Answer:

a) No. The provisions allowing a person affected by a decision to cancel a medicine from the Australian Register of Therapeutic Goods (ARTG) internal review by the Therapeutic Goods Administration (TGA) and then review by the Administrative Appeals Tribunal (AAT) are set out in the Therapeutic Goods Act and the Administrative Appeals Tribunal Act.

Section 60 of the *Therapeutic Goods Act 1989* (the TG Act) provides a mechanism where a person whose interests are affected by certain initial decisions, including a decision to cancel a product from the ARTG, can seek an internal review of the decision. A section 60 internal review is carried out by another officer within the TGA as delegate of the Minister. If the person is not satisfied with the section 60 decision, then there is a further mechanism, provided by section 60 of the TG Act and the *Administrative Appeals Tribunal Act 1975* (the AAT Act), for a person to seek review of the decision in the AAT.

In the present case the sponsor sought a section 60 internal review of the decision to cancel Di-Gesic and Doloxene. Following the result of the section 60 internal review, confirming the initial cancellation decision, the sponsor exercised its right to apply to the AAT for further review of the decision. The AAT provides for an independent merits review of administrative decisions. The AAT takes a fresh look at a decision and, based on all the evidence before the AAT and decides what is the "best or preferable decision" in the circumstances. This involves reconsidering the facts, law and policy relating to a decision as well as any further evidence put before the AAT.

The AAT reviews a wide range of decisions made by Australian Government ministers, Departments, Agencies and some other tribunals. The AAT aims to provide a review mechanism that is fair, just, economical, informal and quick. Both individuals and government agencies use the services of the AAT. Although a Commonwealth agency, the AAT is independent of the person or organisation that made the decision subject to review.

The exercise of those rights does not represent a "loophole" to bypass TGA regulation.

b) The AAT matter is ongoing with a final hearing scheduled for 27 and 28 February 2013. As at 31 October 2012, the estimated cost to TGA was $0.758 million (excluding GST), including $0.140 million for costs of counsel.

c) Pursuing the cancellation of dextropropoxyphene-based products from the ARTG has had a minimal resource impact on the TGA. The TGA has continued to undertake its wide ranging post market review and investigation activities to ensure the ongoing safety of therapeutic goods being supplied in Australia.