

**Senate Community Affairs Committee**

**ANSWERS TO ESTIMATES QUESTIONS ON NOTICE**

**HEALTH AND AGEING PORTFOLIO**

**Supplementary Budget Estimates 2012-2013, 17 & 19 October 2012**

**Question: E12-015**

**OUTCOME 1: Population Health**

**Topic: CANCELLATION OF DEXTROPROPOXYPHENE PRODUCTS FROM THE ARTG (ASPEN PHARMACARE AUSTRALIA PTY LTD)**

**Type of Question:** Hansard Page 23, 17 October 2012

**Number of pages:** 1

**Senator:** Senator Di Natale

**Question:**

- a) How much work is involved for the TGA in terms of prosecuting this case?
- b) Can you put a dollar value on the resources it has consumed, including the costs of counsel?

**Answer:**

- a) Presenting the case of the Minister for Health and Ageing in the Administrative Appeals Tribunal (AAT) in relation to the decision of the Minister's delegate to cancel Di-Gesic and Doloxene from the Australian Register of Therapeutic Goods has involved the Therapeutic Goods Administration (TGA) in the following:
  - engagement and briefing of external solicitors and counsel,
  - preparation for and attendance at AAT hearings,
  - meetings with the sponsor of the products, Aspen Pharmacare Australia Pty Ltd,
  - reconsideration by the TGA decision maker,
  - the commissioning and consideration of advice from the Advisory Committee on the Safety of Medicines and the Advisory Committee on Prescription Medicines,
  - the seeking and considering of advice from the Royal Australasian College of Physicians, the Royal Australasian College of Surgeons, the Pain Management Faculty of the Royal Australasian College of Anaesthetists and the Australian College of Emergency Medicine, and
  - contributions by TGA legal and medical staff.
- 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.