Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

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

Question: E12-025

OUTCOME 1: Population Health

Topic: TGA – DEVICES SENATE INQUIRY

Type of Question: Written Question on Notice

Number of pages: 2

Senator: Senator Xenophon

Question:

a) In relation to the previous Senate inquiries, what progress has the TGA made in addressing the recommendations specific to the TGA?

b) Does the TGA see this as a priority? If so, what resources are being dedicated to doing so?

c) Can the TGA provide a general timeline for implementation?

Answer:

a) The Government response to the Senate Inquiry into *The regulatory standards for the approval of medical devices in Australia* was tabled on 13 September 2012. This response outlined Therapeutic Goods Administration action to progress a range of recommendations.

The Government has not yet responded to the Senate Inquiry into *The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese breast implants*.

Recommendation 1 of *The regulatory standards for the approval of medical devices in Australia* was accepted by the Government. The TGA Blueprint includes projects on product name and product information on medical devices. In the interim the ARTG is publically available on the TGA website and several changes and improvements were made to the ARTG in May 2012 to improve searchability.

Recommendation 2 was agreed by Government. The first of these reforms implemented from 1 July 2012 was the change of classification of hip, knee and shoulder joint implants (total and partial) from Class IIb (medium-high risk medical devices) to Class III (high risk medical devices), increasing the level of regulatory oversight to better assure the products' safety, quality and performance. Consultation on further reform options for pre-market assessment of higher-risk medical devices is being developed.

Recommendation 7 (in part) and 8 related to adverse event reporting, and the Government agreed in principle to these recommendations. From 1 August 2012 the Database of Adverse Event Notifications has made publicly available on the TGA website. Further work has been outlined in the TGA Blueprint.

Recommendation 9 was agreed by the Government. Details of implementation plans for the twenty-one recommendations of the Transparency Review are outlined in "Delivering reforms – Implementation plan for TGA Reforms: A blueprint for TGA's future", available on the TGA website, with a number of achievements to date:

- On 16 July the Government announced the establishment of the Australian Therapeutic Goods Advisory Council, to be chaired by Australia's Chief Medical Officer, Professor Chris Baggoley (Transparency Review Recommendation 1);

- Significant improvements were made to the ARTG in May 2012 outlined above (under Medical Device Inquiry Recommendation 1, also relevant to Transparency Inquiry Recommendation 5);

- Consultation on proposed regulatory changes to the labelling and packaging of medicines (excluding medical devices) to address consumer safety risks was undertaken between May and August 2012 (Transparency Review Recommendation 14); and

- Release of an on-line system for reporting problems with medical devices in March 2012 (Transparency Review Recommendation 19).

Further, recommendations have been made to establish registers for high risk implantable devices. The Government supports this and as such is consulting with stakeholders in the first phase of implementation.

The Australian Commission on Safety and Quality in Health Care has been appointed by the Department of Health and Ageing to consolidate research and consult with key stakeholders on the technical, governance and funding options relevant to implementation.

b) The reforms outlined in the TGA Blueprint are a priority for the Department and TGA. The reforms will be achieved incrementally over four years, in three phases (through to December 2015).

c) Please refer to the implementation plan.