Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

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

Question: E12-030

OUTCOME 1: Population Health

Topic: SENATE INQUIRY INTO THE REGULATION OF MEDICAL DEVICES

Type of Question: Written Question on Notice

Number of pages : 2

Senator: Senator Xenophon

Question:

The Government's response to recommendation 15 also indicates that the Government will be working with the TGA on a review of the processes in place regarding communication with relevant groups, including the general community.

a) Can the department provide more information on this review?

b) When is it likely to be completed and any findings implemented?

c) Will the recent reports of increases in PIP implant ruptures and problems with the use of vaginal mesh - neither of which have resulted in additional comment from the TGA - change the timeline for this review?

d) In response to recommendation 17, the Government states that Australia is participating in a worldwide study of patients who have received the ASR hips. Can the department provide more information on this study?

e) In relation to the Government's response to recommendation 18, can the department explain why voluntary codes of conduct for practitioners are considered robust?

f) Can the department provide any information on when the government may issue a response to the committee inquiry into PIP breast implants?

Answer:

a) and b)

The future arrangements for the Therapeutic Goods Administration's (TGA) communications strategy were announced by the Government in December 2011 through the document TGA Reforms: a blueprint for TGA's future. Implementation of all of the components will take place in phases and will be complete by July 2015. Some aspects have already been delivered, for example the Australian Advisory Council on Therapeutic Goods has been established, a searchable database of adverse events associated with medicines has been released and consultations have been held on an early warning system to alert the general community about potential safety issues with medicines and medical devices. The TGA reports on progress with the reform package on a 6-monthly basis. These reports will be available on the TGA's website.

c) The review will proceed in accordance with the published timelines stated in the Blueprint document. TGA continues to report monthly on its website on issues with Poly Implant Protheses (PIP) breast implants. Statements about concerns with gynaecological meshes were published on the TGA website in October 2012.

d) Professors Henrik Malchau and Orhun Muratoglu, co-directors of the Harris Orthopedic Laboratory at the Massachusetts General Hospital (MGH), will lead a research team to undertake a worldwide Long-Term Multicenter Evaluation of the Articluar Surface Replacement (ASR) Hip System. MGH will be the regulatory sponsor for the study and will coordinate the identification of sites and data collection. MGH will also be responsible for data analysis and will ensure unbiased dissemination of the results. The study is planned to run for seven years, will recruit 5000 patients and will monitor the rate of revision, soft tissue reaction and metal ion levels. It is anticipated that Australia will provide a substantial pool of ASR recipients for the study which will be coordinated by The International Musculoskeletal Research Institute on behalf of MGH.

e) As stated in its response to Recommendation 18, the Government recognises the need for the therapeutic goods industry to strengthen its self-regulatory framework, including codes of conduct, to ensure ethical conduct in the promotion of therapeutic goods to healthcare professions.

To achieve this, the Government is supporting industry associations to incorporate the high level principles and framework developed by the Working Group on Promotion of Therapeutic Products in their codes of conduct, while at the same time improving communication and building shared systems for complaints reporting.

f) The Government is considering the findings of the Senate Committee inquiry into the recall of breast implants manufactured by Poly Implant Prothèse (PIP) and is finalising its response.