Standing Committee on Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 14 (written)

Topic: Provision of annual reports by Medical Vision Australia.

Hansard Page: N/A

On 25 May 2012 Senator Siewert wrote to Dr Brian Richards, Acting National Manager of the Therapeutic Goods Administration (TGA) and asked:

The committee received evidence that Medical Vision Australia were required to provide annual reports for the first three years following inclusion of the products on the Australian Register of Therapeutic Goods (ARTG) in 2004. These reports were not provided until April 2010 when the recall of PIP breast implants was undertaken and when TGA commenced its investigation.

- Could you inform the committee of what steps, if any, were taken by the TGA to ensure that the reports were provided in a timely manner?
- If steps were taken, what reasons did Medical Vision Australia give for not providing the reports?

Answer:

The requirement to supply annual reports for the first three years of a product's market life is applied as a condition of inclusion in the Australian Register of Therapeutic Goods to higher risk medical devices. The obligation is on the sponsor to send these reports to the TGA. The requirement is set out in detail in TGA guidance documents which are available on the TGA website. Up until 2011, the TGA did not actively monitor whether or not reports were being provided. In 2011, the TGA instigated a procedure whereby it now actively seeks reports from any sponsor who has failed to provide their annual report.

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ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 15 (written)

Topic: Laboratory testing of PIP implants.

Hansard Page: N/A

On 25 May 2012 Senator Siewert wrote to Dr Brian Richards, Acting National Manager of the Therapeutic Goods Administration (TGA) and asked:

With regard to the testing of PIP implants your website states that in 2010 the TGA conducted a range of laboratory tests on gel-filled breast implants manufactured by Poly-Implant Prothèse (PIP).

- Could you inform the committee whether these experiments included tests that would provide data on how the implants were likely to behave after being implanted?

Answer:

The tests performed by the TGA, and other regulators, are designed to measure conformance of the unimplanted device with relevant standards for performance and toxicity. There are no international standards for performance of implanted breast implants.