

Chapter 1

The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants

Terms of Reference

1.1 On 8 February 2012 the Senate referred the following matter to the Senate Community Affairs Committees for inquiry and report by 31 May 2012:

The role of the Government and the Therapeutic Goods Administration (TGA) regarding the approval and monitoring of medical devices listed on the Australian Register of Therapeutic Goods, including:

- (a) the TGA's approval, monitoring, withdrawal and follow-up of the Poly Implant Prothese (PIP) breast implants;
 - (b) the procedures the TGA has in place to continuously monitor relevant information in relation to device manufacturers and sponsors, including the legal or approval issues both in Australia and overseas;
 - (c) information provided to the Government in relation to the PIP breast implants;
 - (d) the impact of PIP breast implant failures on Australian patients;
 - (e) the procedures the TGA has in place to assess the risk to Australian patients if devices available in Australia are the subject of warnings or withdrawals overseas;
 - (f) the procedures the TGA has in place to communicate device information (including withdrawal information) to the general public, with a focus on affected patients; and
 - (g) the ability of the TGA to undertake or commission research in relation to specific areas of concern regarding devices, such as metal-on-metal implants.
- (2) That, in conducting its inquiry, the committee should consider:
- (a) the report and findings of the 2011 Community Affairs References Committee inquiry into medical devices; and
 - (b) any action the Government and TGA has taken or intends to take in relation to the 2011 report and recommendations.

Conduct of the current inquiry

1.2 The inquiry was advertised 29 February 2012 in *The Australian*, and through the internet. The committee invited submissions from the Commonwealth Government and interested organisations.

1.3 The committee received 50 submissions from organisations and individuals (listed at Appendix 1). In addition, the committee received responses in relation to potential adverse reflection.

1.4 A public hearing was held in Canberra on 9 May 2012. A list of stakeholders who appeared before the committee is set out in Appendix 2.

1.5 Submissions, additional information, the Hansard transcript of evidence and responses to potential adverse reflection (contained in submissions or expressed at the public hearing) may be accessed through the committee's website at:

http://aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_ctte/implants_2012/index.htm.

Note on references

1.6 References in this report are to individual submissions as received by the committee, not to a bound volume. References to the committee Hansard are to the proof Hansard. Page numbers may vary between the proof and the official Hansard transcript.

Acknowledgements and notes

1.7 The committee sincerely thanks all submitters and witnesses for their contribution and participation in the inquiry process. The committee particularly wishes to extend its gratitude to individuals who shared their personal accounts regarding PIP breast implants during this inquiry.

Australian sponsor, Medical Vision Australia

1.8 The Australian sponsor of PIP breast implants, Medical Vision Australia Pty Ltd, was invited to appear before the committee to assist with this inquiry, however this invitation was declined. The committee also sought written evidence from Medical Vision Australia; however this opportunity was also declined. Despite numerous attempts to contact them, both in writing and via phone, Medical Vision Australia representatives have not engaged with the committee during this inquiry. The committee received an explanation through the legal firm representing Medical Vision Australia that all invitations are declined due to pending legal matters. The committee is disappointed that Medical Vision Australia did not participate in the inquiry.

Proposed legal action in Australia

1.9 The committee notes the proposed class action in South Australia which is being prepared by law firm Tindall Gask Bentley on behalf of patients who have received PIP breast implants in Australia. There are reports of over 500 women being

part of this class action¹ and the committee received a number of submissions from individuals that may be plaintiffs in this class action. The committee wishes to thank the women and legal firm for their participating in this inquiry.

Previous inquiry regarding medical devices

1.10 On 16 June 2011 the Senate referred the regulatory standards for the approval of medical devices in Australia for inquiry and report. The committee received 34 submissions, and held a public hearing for this inquiry on 27 September 2011. The committee tabled their report for this inquiry on 22 November 2011.

1.11 The report, and the 21 recommendations from this inquiry can viewed on the committee's website at:

http://aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_cte/medical_devices/report/index.htm

1.12 The Australian Government has not yet provided a formal response to this 2011 inquiry report on medical devices.

Structure of the report

1.13 This report is comprised of 5 Chapters.

- Chapter 2 provides background regarding PIP breast implants in Australia, the TGA's role in registering and monitoring PIP breast implants for use in Australia, and an overview of the international response to the recall of this medical device.
- Chapter 3 explores the main issues regarding the handling of the PIP breast implants situation that were raised throughout the inquiry of in light of the evidence received.
- Chapter 4 outlines the impact PIP breast implants have had on Australian patients in light of the evidence which the committee received.
- Chapter 5 provides a summary of issues raised throughout the inquiry and provides recommendations made by the committee.

1 Jordanna Schriever, *540 women register for class action against breast implant maker*, 23 March 2012, The Advertiser, <http://www.adelaidenow.com.au/ipad/women-register-for-class-action-against-breast-implant-maker/story-fn6bqphm-1226302149137> (viewed 13 April 2012).