The Senate

Community Affairs References Committee

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

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5.13 The committee recommends that the TGA include in their advice that it is unclear whether PIP breast implants rupture more than other silicone breast implants and that further testing and investigation of PIP breast implants will continue to inform this advice.

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 action[1] 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_ctte/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).

Chapter 2

Overview of the PIP breast implants situation

Introduction

2.1 This chapter sets out the background of the PIP breast implants in Australia, a description of 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.

PIP breast implants in Australia

2.2 PIP breast implants are medical devices, manufactured by French company Poly Implant Prothèse (PIP), that are composed of a silicone outer shell filled with a silicone gel.[1] It is estimated that 300 000 PIP breast implants were sold worldwide before the company went out of business.[2] The TGA, which is a division of the Department of Health and Ageing, is responsible for monitoring medical devices in Australia, including PIP breast implants.[3] PIP silicone breast implants are known to be used in Australia from 1998[4] until their recall in April 2010. These PIP breast implants were provided in Australia to individual patients by a number of sponsors under the Special Access Scheme (SAS) from 1998/99, and then were sponsored in Australia by Medical Vision Australia Pty Ltd (Medical Vision Australia) between 2002 and 2010.[5] A sponsor of a therapeutic good is defined as:

> The sponsor is the person or company responsible for the importation of medical devices into Australia, and/or the supply of medical devices in Australia, and/or the export of medical devices from Australia, as well as

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1 Department of Health and Ageing, *Consumers Questions and Answers: PIP breast implants*, updated 27 April 2012, p. 1, http://www.health.gov.au/internet/main/publishing.nsf/content/2DB01EA9F428C399CA2579F1001F3DE9/$File/Q&A-TGA-Factsheet-2012.pdf (accessed 11 May 2012).

2 Reuters, *No need for routine removal of breast implants: UK*, 6 January 2012, http://www.reuters.com/article/2012/01/06/us-implants-britain-idUSTRE8051EU20120106 (accessed 16 April 2012).

3 Therapeutic Goods Administration, *Australian Regulatory Guidelines for Medical Devices*, May 2011, p. 20, http://www.tga.gov.au/pdf/devices-argmd.pdf (accessed 21 May 2012).

4 *Consumers Questions and Answers: PIP Implants*, Therapeutic Goods Administration website 12 January 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120107.htm (accessed 16 April 2012).

5 Department of Health and Ageing, *Submission 30*, p. 5.

> making application to the TGA to have their device included in the ARTG [Australian Register Therapeutic Goods].[6]

2.3 An exact figure for how many Australian women currently have PIP breast implants is unclear for some of the following reasons:

- The current breast implant registry works on an opt-out basis, therefore contains limited statistical information about PIP implants and recipients;
- some women have since had their implants removed;
- not all implants supplied would have been used; and
- it is possible that some women received single implants instead of two.[7]

2.4 The committee received the following summary from the Department of Health and Ageing regarding the actual number of PIP breast implants used in Australia:

> TGA records indicate that around 3 000 PIP implants were approved by the TGA for supply under the SAS scheme or as part of the clinical trial. Based on an audit of distribution records held by Medical Vision Australia, the TGA estimates that around 10 000 PIP silicone gel implants were supplied in Australia while the implants were included on the ARTG, in the period from 2004 until April 2010, when they were recalled and cancelled from the ARTG. The TGA does not, however, have access to data on how many of these 13 000 implants were actually used or remain implanted in patients.[8]

Special Access Scheme arrangements

2.5 The TGA describes the SAS as "arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis".[9] This meant individual patients, with the support of the medical practitioner, were able to access PIP breast implants that were available overseas, but not in Australia.[10]

2.6 The fact that this medical device was supplied in Australia before being registered on the ARTG appears to have caused confusion amongst consumers about

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6 Therapeutic Goods Administration, *Australian Regulatory Guidelines for Medical Devices*, May 2011, p. 26, http://www.tga.gov.au/pdf/devices-argmd.pdf (accessed 21 May 2012).

7 Therapeutic Goods Administration, *PIP breast implants – a summary*, PIP breast implants – An Australian Perspective, 23 March 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120323.htm#summary (accessed 13 April 2012).

8 Department of Health and Ageing, *Submission 30*, p. 9.

9 Therapeutic Goods Administration, *Special Access Scheme*, 9 June 2011, p. 1, http://www.tga.gov.au/hp/access-sas.htm#about (accessed 20 May 2012).

10 Department of Health and Ageing, *Submission 30*, Footnote 2 p. 8.

the supply arrangements for this medical device. As one witness explained to the committee:

> When PIP implants were placed in my body in 2001, I had no knowledge whatsoever that PIP implants were not entered onto the Australian register of Therapeutic Goods (ARTG) and that PIP implants could not be legally supplied in Australia except on an Individual Patient Use basis...[11]

2.7 In order for a patient to be supplied with an unregistered therapeutic good, the patient must provide their informed consent.[12] The committee received some evidence from submitters that this informed consent was not always obtained.

> At no time was I warned that silicone breast implants were considered 'High Risk' devices. In 2001, prior to surgery to replace my ruptured implants, I unwittingly signed the hospital generic 'consent to surgery' form. As it later transpired, my consent was anything but informed.[13]

Committee view

2.8 The committee considers that informed consent for unapproved therapeutic goods is a serious issue that requires urgent reform; however it received limited evidence from submitters who received PIP breast implants before 2004 when the PIP breast implants were not on the Australian Register of Therapeutic Goods. Based on the current evidence, it unfortunately cannot determine how extensive the number of women affected actually is. This in itself is an issue of concern that also requires urgent reform.

Recommendation 1

2.9 The committee recommends that there be rigorous systems put in place to ensure that medical practitioners provide consumers with all the information needed to allow them to give fully informed consent.

Role of the TGA

2.10 As a division of the Department of Health and Ageing (DoHA), the TGA is responsible for regulating the quality of medical devices in Australia. This role is detailed in the committee's 2011 report on the regulatory standards for the approval of medical devices in Australia (2011 report). This report set out the various powers the TGA has in relation to monitoring and withdrawing devices:

> Chapter 4 of the *Therapeutic Goods Act 1989* provides for the regulation of medical devices. The Act provides for various powers in relation to the

11 Name withheld, *Submission 37*, p. 2.

12 Therapeutic Goods Administration, *Access to unapproved therapeutic goods via Special Access scheme*, 16 November 2009, p. 9, http://www.tga.gov.au/hp/access-sas-guidelines.htm (accessed 21 May 2012).

13 Name withheld, *Submission 37*, p. 2.

> regulation of medical devices including the power to issue conformity assessment certificates to manufacturers of a medical device; suspend or revoke conformity assessment certificates in particular circumstances; include a medical device in the ARTG; suspend or cancel entries of devices from the ARTG; obtain information about medical devices; and require the recovery (recall) of medical devices, or to inform the public about medical devices, where the devices do not comply with the requirements of the legislation.[14]

2.11 The committee received evidence from the TGA at the inquiry's public hearing which clarified their role as regulating therapeutic goods for supply, and that they are "not responsible for the regulation of medical practice".[15] This was reiterated in submission from DoHA:

> The TGA's formal regulatory powers to require information about the performance of device extend only to sponsors and manufacturers, not to doctors and consumers.[16]

2.12 The TGA is however responsible for approving devices to be registered on the ATRG. As outlined in the 2011 report, the regulation of medical devices in Australia includes:

> (a) A classification system for medical devices based on different levels of potential risk to the patient.
>
> (b) Manufacturers are required to demonstrate compliance with a set of internationally agreed 'Essential Principles' for the quality, safety and performance of the medical devices.
>
> (c) A requirement that manufacturers implement and maintain a suitable quality management system (QMS) for the design, production, release and post market monitoring of medical devices.
>
> (d) A requirement that medical devices be included in the ARTG unless they are exempt.
>
> (e) Medical devices available on the market are subject to monitoring by the TGA. This monitoring includes a comprehensive incident reporting scheme.[17]

2.13 Australia has a risks-based regulatory framework and the TGA classifies breast implants as a high risk, or Class III, medical device.[18]

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14 Senate Community Affairs References Committee, *The regulatory standards of medical devices in Australia*, November 2011, p. 4.

15 Dr Brian Richards, Therapeutic Goods Administration, *Committee Hansard*, 9 May 2012, p. 29.

16 Department of Health and Ageing, *Submission 30*, p. 5.

17 Senate Community Affairs References Committee, *The regulatory standards of medical devices in Australia*, November 2011, p. 4.

2.14 Under Australia's regulatory framework, the device sponsor is responsible for making an application for a medical device to be included in the ARTG. This application for registration includes supplying a Conformity Assessment Certificate from an appropriate European Commission (EC) Notified Body should a device be manufactured overseas.[19] This regulatory framework aligns with internationally accepted best practice and harmonises Australian regulatory requirements with the recommendations of the medical devices Global Harmonisation Task Force (GHTF). As explained in DoHA's submission to the committee:

> The new regulatory framework strengthened the pre-market process, particularly for high risk devices, through the introduction of a conformity assessment process, and also strengthened post-market vigilance requirements. An application for the inclusion of a new medical device in the ARTG made after 4 October 2002 was required to demonstrate that the device met the new regulatory requirements. Sponsors of existing products registered or listed on the ARTG as at 4 October 2002 were given five years (until 4 October 2007) to transition to the new framework or have their devices cancelled from the ARTG.[20]

Roles and responsibilities in monitoring medical devices

2.15 Once a medical device has been included in the ARTG, it must continue to "meet all the regulatory, safety and performance requirements and standards that were required for the approval".[21] The TGA identifies four key stakeholders involved in improving outcomes for users of medical devices:

> *sponsors*—who are responsible for the legal supply of the device in Australia
>
> *manufacturers* as defined in section 41BG of the *Therapeutic Goods Act 1989* (the Act)
>
> the *TGA*—the Regulator
>
> *users*—consumers and health practitioners who by voluntarily reporting concerns with devices enable issues to be identified and corrective action to be taken[22]

18 Therapeutic Goods Administration, *PIP breast implants – TGA update*, 2 April 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120402.htm (accessed 15 May 2012).

19 Department of Health and Ageing, *Submission 30*, p. 16.

20 Department of Health and Ageing, *Submission 30*, p. 12.

21 Therapeutic Goods Administration, *Australian Regulatory Guidelines for Medical Devices*, Section 22, post-market vigilance and monitoring requirements, May 2011, p. 294.

22 Therapeutic Goods Administration, *Australian Regulatory Guidelines for Medical Devices*, Section 22, post-market vigilance and monitoring requirements, May 2011, p. 294.

Sponsor – Medical Vision Australia

2.16 Medical Vision Australia was the Australian sponsor of PIP breast implants for the French manufacturer PIP. Medical Vision Australia was therefore responsible for keeping up to date information about the performance of the device, including:

> any malfunction or deterioration in the characteristics or performance of the device;
>
> any inadequacy in the design, manufacture, labelling, instructions for use or advertising materials of the device;
>
> any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device that has led to any complaint or problem in relation to the device, no matter how minor;
>
> information that indicates that the device does not comply with the essential principles; and
>
> information that indicates that an overseas issued conformity assessment certificate has been restricted, suspended, revoked or is no longer in effect.[23]

2.17 The committee received evidence from DoHA that a routine condition applied to Class III devices is that the sponsor must provide three consecutive annual reports to the TGA following inclusion of the device in the ARTG. As set out in the Australian Regulatory Guidelines for Medical Devices, these annual reports must:

> ...include all complaints received by the manufacturer relating to problems with the use of the device that have been received by them over the year. Complaints received by the manufacturer relating to the use of the device, including its supply under a different name, in other countries where the device is available must also be included.[24]

2.18 The evidence provided to the committee demonstrated that Medical Vision Australia did not provide the information that would have been contained in the annual reports until April 2010 when the recall of PIP breast implants was undertaken and when TGA commenced its investigation.

> Medical Vision Australia had not provided the required annual reports for the first three years following inclusion of the products on the ARTG. When this oversight was detected, the TGA requested information from the sponsor relevant to its investigation that would otherwise have been provided in these annual reports. This information was received by the TGA in April 2010.[25]

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23 Department of Health and Ageing, *Submission 30*, p. 17.

24 Therapeutic Goods Administration, *Australian Regulatory Guidelines for Medical Devices*, Section 22, post-market vigilance and monitoring requirements, May 2011, p. 298.

25 Department of Health and Ageing, *Submission 30*, p. 28.

2.19 The sponsor's role in monitoring the quality of PIP breast implants was critical to monitoring performance and safety of this device once it was in the Australian market. The sponsor's obligations are outlined in section 41FD of the *Therapeutic Goods Act 1989*, and these obligations include reporting adverse incidents and performance issues to the TGA.

2.20 The committee was informed by the TGA that it did not 'actively monitor' whether annual reports were being provided by sponsors in accordance with their obligations until 2011, and that the TGA has since instigated a procedure to actively seek reports when they are not provided.[26]

Committee view

2.21 The committee is concerned that the sponsor of PIP breast implants did not provide the three annual reports as required when the device was included in the ARTG. With this requirement not being met by the sponsor, it is not known whether issues with this device would have been raised earlier and the current situation avoided.

2.22 It is concerning to the committee that obligations have been placed on sponsors with little or no follow up from the TGA if those obligations were not met. While the system now in place goes some way towards addressing this, it is not acceptable that sponsors have not been held to account for so many years.

2.23 The Committee expresses its disappointment over Medical Vision Australia's decision to decline the invitation to assist in this inquiry. As a result the committee was not in receipt of all of the information it required to fully investigate the matter.

Recommendation 2

2.24 The committee recommends that the TGA review all cases where sponsors have not met their obligations in relation to their listing on the Australian Register of Therapeutic Goods to ensure that these cases do not pose any health risk to the Australian public, and that important data has not been missed.

Recommendation 3

2.25 The committee recommends that the Department of Health and Ageing include as part of their annual report process, information on the TGA's procedures for monitoring requirements placed on Class III medical devices.

26 Therapeutic Goods Administration, response to written question on notice, 25 May 2012 (received 28 May 2012).

TGA – the regulator

2.26 The *Australian Regulatory Guidelines for Medical Devices* sets out what the TGA's monitoring activities are, these include:

- reviews of technical and clinical information to ensure that compliance with the Essential Principles and conformity assessment procedures is demonstrated;
- testing to confirm compliance with the Essential Principles;
- inspections of manufacturer's or sponsor's records and documentation;
- on-site testing of medical devices or taking samples for off-site testing;
- audits of distribution records;
- audits of the traceability of raw materials used in the manufacture of therapeutic goods and tracking of component parts; and
- trend analysis and reporting to sponsors.[27]

2.27 In relation to the PIP breast implants, the TGA reviewed, evaluated and assessed data and conducted an onsite audit of the manufacturer facility in France. The exact details of the TGA's activities are outlined in the chronology at Appendix 3 and the TGA's assessment of PIP implants is also explored in more detail later in this Chapter.

2.28 The TGA also undertakes "ongoing monitoring to ensure that regulatory compliance and safety of the medical devices continues after supply to the Australian market".[28] This monitoring role is explained in further detail in Chapter 3.

2.29 When the TGA and/or a sponsor become aware of information (such as adverse events, malfunctions or faults) about a medical device supplied on the Australian market, either can take action. In relation to PIP breast implants, the TGA worked closely with the sponsor regarding the recall. Events leading up to the recall are in the chronology at Appendix 3.

Users - consumers

2.30 Australian consumers also can play a role in monitoring medical devices. The TGA has a voluntary reporting system for consumers to report faults of issues with medical devices they use.[29] The TGA then investigates these reports. The process for

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27 Therapeutic Goods Administration, *Australian Regulatory Guidelines for Medical Devices*, Section 22, post-market vigilance and monitoring requirements, May 2011, p. 301.

28 Medical Technology Association of Australia, *Submission 15*, p. 6.

29 Medical Technology Association of Australia, *Submission 15*, p. 7.

reporting an adverse event is outlined on the TGA's website and includes an online form for device users.[30]

2.31 Although this avenue of reporting adverse events is available to the public, it appears to the committee that issues regarding consumers' awareness of these processes remain poor, and many consumers would not know where to go if wanted to report an issue with their implants. This issue was highlighted in the committee's 2011 report where recommendations were made to improve processes of post-market surveillance. A copy of the recommendations from the 2011 report is at Appendix 4.

2.32 Some submitters however provided evidence to the committee that they had lodged an adverse event report to the TGA regarding their PIP breast implants and were not satisfied with the response from the TGA in this monitoring process. As one individual explained:

> I submitted an 'adverse event to a medical device' form to the TGA in January 2012 yet, except for a standard email acknowledgement of receipt, I was not asked for further details until April 2012, when I was sent a letter requesting that the TGA contact my treating doctors for further information of my symptoms. This delay is unacceptable, particularly when the TGA were advised in the 'adverse event to a medical device' form that I was so ill from the PIP breast implants, I had been hospitalised.[31]

2.33 Another submitter commented that she became a "statistic"[32] when she lodged an adverse event report to the TGA, and that they may now want to speak with her as part of their investigation. The committee believes the need for formal follow up with consumers once a report has been lodged is vital to increase confidence that action has been taken and encourage future reporting of adverse events.

2.34 It is also important to note that the lack of adverse event reporting by health professionals to the TGA was raised during the committee's previous inquiry into medical devices, with Recommendation 8 (Appendix 4) of that report specifically addressing this issue. It is clear from evidence provided to both the previous inquiry and to this inquiry that consistent, comprehensive adverse event reporting by all parties is required to allow the TGA to act quickly and appropriately when these problems occur.

Adverse events – reports of PIP breast implants rupturing

2.35 Ruptured breast implants is considered an 'expected event' therefore sponsors and manufacturers are not required nor expected to routinely report these events to the

30 Therapeutic Goods Administration, *Users Medical Device Incident Report form*, March 2012, http://reporting.tga.gov.au/mdir/udir03.aspx (accessed 22 May 2012).

31 Name withheld, *Submission 36*, p. 3.

32 Name withheld, *Submission 35*, p. 2.

TGA.[33] However, the committee heard from patients that may view their ruptured implants as an adverse event as it had affected their lives (refer Chapter 4 for more detail). The consumers reporting of this type of event are of course dependent on their awareness of this process and their willingness to engage with this process with the TGA.

2.36 The first adverse report with PIP breast implants occurred in 31 October 2002 (under SAS arrangements).[34] It is not clear from the evidence whether this initial report related to a rupture. Between 2002 and 2010 when the device was recalled, the TGA received 34 reports of adverse events in relation to PIP implants. All except for three reports were from either the sponsor or manufacturer and the majority (25) related to reports of rupture.[35]

2.37 According to recent TGA figures[36] there was as a marked increase in confirmed ruptures in 2012, from 37 confirmed ruptures on 4 January 2012 to 287 confirmed reports of ruptured PIP breast implants on 25 May 2012. Of these 287 reports, 80 were made by consumers, 183 by surgeons and 24 by the supplier.[37]

The TGA's Pre market assessment of PIP breast implants

2.38 In April 2003, the Australian sponsor of PIP breast implants, Medical Vision Australia made an application to the TGA for a Conformity Assessment[38] to be issued to PIP for manufacturing of silicone gel pre-filled breast implants. The TGA cannot exercise any of its regulatory powers outside Australia; however it can conduct an audit of an overseas manufacturing facility through arrangement with that manufacturer.[39] The TGA undertook a conformity assessment review for PIP breast implants over an 18 month period. This review included an onsite audit of the manufacturing facility in France, an examination of the design of the PIP implants, and an assessment of clinical evidence.[40]

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33 Department of Health and Ageing, *Submission 30*, p. 20.

34 Department of Health and Ageing, *Submission 30*, p. 48.

35 Department of Health and Ageing, *Submission 30*, p. 27.

36 Therapeutic Goods Administration, *Poly Implant Prothese (PIP) breast implants – the Australian Perspective*, 4 January 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-120104.htm (accessed 28 May 2012).

37 Therapeutic Goods Administration, *PIP breast implants – TGA update*, 25 May 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120525.htm (accessed 28 May 2012).

38 Refer to the Senate Community Affairs References Committee report, *The regulatory standards of medical devices in Australia*, 22 November 2011 for detailed information on Conformity Assessment Certificate arrangements.

39 Department of Health and Ageing, *Submission 30*, p. 15.

40 Department of Health and Ageing, *Submission 30*, pp. 23-24.

2.39 The TGA conducted the onsite audit of the facility in France 17 – 19 November 2003. This audit determined three major and three minor 'non-conformities' which were explained in DoHA's submission to the committee:

> The first major nonconformity was a problem with construction and maintenance of a cleanroom, where there were gaps in the vinyl flooring, unsealed holes in the wall of the envelope filling room and unsealed edges on benches and storage cabinets. This was a potential problem because of the risk of harbouring microorganisms that could potentially contaminate the product. The second major non-conformity was identified because an external door and internal door to the raw materials receiving area were left open simultaneously, exposing the area to potential contamination or allowing pests to enter. The third major non-conformity related to the company's methods for demonstrating that contamination had not occurred.
>
> While all three of these major non-conformities pointed to the potential for contamination of the finished product, no evidence of contamination was found and the non-conformity finding was issued so that appropriate corrective actions could be put in place to prevent the risk from being realised.
>
> The first of the three minor non-conformities related to failure to apply a unique internal lot number to raw materials, where subsequent deliveries from the manufacturer had the same lot number as an initial delivery. The second minor nonconformity related to incorrectly applying quarantine labels to drums of raw material used to make the shell of the implants. The final minor non-conformity was that photocopies of certain standard operating procedures were found, when the quality management system clearly prohibited the copying of these documents.[41]

2.40 The manufacturer supplied further information relating to these identified non-conformities on 15 December 2003 and the audit report was closed on 23 August 2004.[42] During this time, the manufacturer had obtained a European Commission Conformity Assessment Certificate (March 2004) from a European Notified Body.[43]

2.41 The Australian sponsor also provided clinical data to support the application for registration and at that time, the TGA clinical evaluator noted the data's limitations:

> The clinical data submitted in January 2004 by Medical Vision Australia in support of the conformity assessment certificate application consisted of a trial of 265 patients with a one year follow-up.
>
> The clinical trial was retrospective, unblinded and uncontrolled. It provided safety data extending to one year with respect to the patient group. No ruptures or extrusions were reported in the trial although 12 contractures

41 Department of Health and Ageing, *Submission 30*, p. 24.

42 Department of Health and Ageing, *Submission 30*, p. 48.

43 Department of Health and Ageing, *Submission 30*, p. 48.

> were observed. Thirty three patients experienced other, less frequent adverse events. Data on the number of implants worldwide and the number and types of adverse event reports were received in March 2004. There had been 103562 PIP silicone gel filled implants distributed worldwide at the time of submission. Corresponding adverse event reports numbered 205. With respect to Australian adverse events there were seven reported to the TGA including five ruptures and two gel extrusions/leakage. These data supported the safety profile of the device.
>
> The TGA clinical evaluator noted the limited nature of the clinical data submitted, but also reasoned that arguments for essential similarity with other implants of similar design and materials should be taken into account.
>
> None of the other components of the evaluation raised any major concerns in relation to the efficacy, quality or safety of the PIP silicone gel-filled breast implants.[44]

2.42 The TGA clinical evaluator then referred this application for registration to the Medical Devices Evaluation Committee (MDEC) in September 2004 for decision. As reflected in the Department of Health and Ageing's submission:

> [The] MDEC advised that it had no objection to the inclusion of these implants on the ARTG for cosmetic breast augmentation and postmastectomy breast reconstruction, but recommended that approval should be subject to the provision of comprehensive annual post-market reports to the TGA for evaluation for a period of seven years from the date of approval.[45]

2.43 Despite the recommendation from MDEC, the delegate approved inclusion on ARTG in 2004 but did not impose the requirement for seven annual reports.[46] No further explanation was provided by the Department regarding this decision. It should be noted that the MDEC has now been replaced by the Advisory Committee on Medical Devices which was established on 1 January 2010 through changes made to the *Therapeutic Goods Regulations 1990*.[47]

Committee view

2.44 The committee is concerned that the TGA approved PIP breast implants for inclusion on the ARTG without imposing the requirement for seven years of annual reports as recommended by the Medical Devices Evaluation Committee.

Recommendation 4

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44 Department of Health and Ageing, *Submission 30*, p. 25.

45 Department of Health and Ageing, *Submission 30*, p. 26.

46 Department of Health and Ageing, *Submission 30*, p. 26.

47 Therapeutic Goods Administration, *Advisory Committee on Medical Devices*, http://www.tga.gov.au/about/committees-acmd.htm (accessed 30 May 2012)

2.45 The committee recommends that the TGA put in place measures to ensure that when recommendations made by the Advisory Committee on Medical Devices (formally the Medical Devices Evaluation Committee) are not followed, the delegate needs to set out specific and compelling reasons why the decision was taken.

Registration of PIP breast implants

2.46 The TGA registered PIP breast implants on the ARTG in 2004, with the Conformity Assessment Certificate expiring in October 2009. Medical Vision Australia advised the TGA in 2009 that they had EC certification and that they would "vary the manufacturer's evidence supporting the nine ARTG entries from the TGA certification to EC certification".[48] This variation was accepted by the TGA in September 2009 and the PIP breast implants remained on the ARTG under European recognition arrangements. These arrangements include medical devices being included on the ARTG through a conformity assessment certification which is issued under provisions of a trade facilitation agreement with European countries.[49] These mutual recognition arrangements in relation to conformity assessments are outlined in more detail in the 2011 report.[50]

2.47 On 8 December 2011, the Australian government noted in its response to the TGA Transparency Review that:

> Regulatory provisions relating to the use of third party assessment bodies and increasing premarket scrutiny of implantable medical devices are linked to recommendations of the recent Senate Community Affairs References Committee inquiry into 'The standards for the approval of medical devices in Australia' These remain under consideration and further consultation is planned.[51]

Committee view

2.48 The committee notes the response to the 2011 report has not yet been received and urges the Australian government to consider its response to strengthening premarket assessments in the light of the PIP breast implants issue as a priority.

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48 Department of Health and Ageing, *Submission 30*, p. 26.

49 Department of Health and Ageing, *Submission 30*, p. 12.

50 Senate Community Affairs References Committee, *The regulatory standards of medical devices in Australia*, November 2011, pp. 7-8.

51 Australian Government, *TGA Reforms: A blueprint for TGA's future*, December 2011, p. 11, http://www.tga.gov.au/newsroom/media-2011-tga-reforms-111208.htm (accessed 22 May 2012).

Advice from French Regulator regarding PIP breast implants

2.49 The French regulator, AFSSAPS[52] advised the TGA and Medical Vision Australia on 31 March 2010 of its decision to recall and suspend the marketing of silicone breast implants manufactured by PIP. As explained in the Department of Health and Ageing's submission, this decision was made by the French regulator because it had:

> "registered" an increase in reports regarding implant rupture and local complications and had discovered that the company had used an unauthorised silicone gel in the products.[53]

2.50 Following this advice, Medical Vision Australia withdrew all non-implanted PIP breast implants from the Australian market on 6 April 2010.[54] After recalling the medical device from the Australian market, The TGA removed PIP breast implants from the Australian Register of Therapeutic Goods (ARTG) on 14 April 2010.[55]

2.51 Non-implanted PIP breast implants were recalled from the Australian market in 2010. However the matter did not attract substantial media attention in Australia until further actions were taken in late 2011 by various regulatory bodies overseas. The impact of the media coverage is covered in Chapter 4 of this report, as is the experiences of Australian women with PIP breast implants.

International responses to the PIP breast implant recall

2.52 The PIP manufactured implants caused global concern after advice was issued by the French regulator, AFSSAPS, that these implants contained industrial silicone rather than medical-grade fillers and that they may be more prone to rupture and leakage than other implants. Of most concern were initial reports linking the PIP breast implants to a rare form of cancer known as ALCL. This link has been now been discounted by medical experts in the United Kingdom (UK) and Europe.[56]

2.53 Different countries took different courses of action following the advice about the use of unauthorised materials. France, Belgium, Germany and the Czech Republic all advised women with PIP breast implants to have them removed.[57] The French

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52 Agence française de sécurité sanitaire des produits de santé (now known as National Security Agency of Medicines and Health Products or ANSM).

53 Department of Health and Ageing, *Submission 30*, Attachment 1, p. 49.

54 Therapeutic Goods Administration, *PIP Breast Implants – TGA Update*, 5 April 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120405.htm (accessed 13 April 2012).

55 Department of Health and Ageing, *Submission 30*, p. 8.

56 National Health Service, United Kingdom, *PIP breast implants – latest from the NHS*, 15 May 2012, http://www.nhs.uk/news/2012/01January/Pages/government-review-advises-on-french-pip-breast-implants.aspx (accessed 17 May 2012).

57 *No Routine Removal of PIP breast implants*, 6 January 2012, http://news.sky.com/home/uk-news/article/16143989 (accessed 15 May 2012)

Government in particular advised women to consider having their implants "surgically removed as a non-urgent precautionary measure" and while removal would be paid for by the state, the costs of replacement implants would only be met for those who received the implants as part of reconstructive surgery for breast cancer.[58]

2.54 The UK however has stated there was not enough evidence to direct routine removal of breast implants.[59] This is reflected in the UK House of Commons Health Committee report into PIP breast implants and regulation of cosmetic interventions:

> In the absence of evidence the policy response has become one of judgement and caution rather than scientific imperative.[60]

2.55 The UK National Health Service (NHS) has decided to support the removal of PIP breast implants if the patient decides with her doctor that it is right to do so. However, the UK will only replace the implants if the original operation was done by the NHS.[61]

2.56 The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks released their report on the PIP implant issue on 1 February 2012 and concluded there was no evidence to support a recommendation that women with PIP implants who do not have any problems with their implants should have surgery to remove or replace them.[62]

2.57 In addition to the UK House of Commons report into PIP breast implants, the UK has also initiated multiple reviews regarding this issue. Specifically, the reviews include expert assessments of the evidence relating to the medical risks associated with PIP implants, a review into the actions of the UK's regulatory body responsible for regulating medical devices, the Medicine's and Health Care Products Regulatory Authority (MHRA) and a wider review into the regulation of cosmetic interventions.[63]

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58 Department of Health and Ageing, *Submission 30*, p. 5.

59 UK Medicines and Healthcare products Regulatory Agency press release, *PIP breast implants UK medical devices regulator says no evidence to support routine removal*, 23 December 2011, http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON137935 (accessed 17 May 2012).

60 House of Commons Health Committee, *PIP Breast implants and regulation of cosmetic interventions*, Sixteenth Report of Session 2010-12, 21 March 2012, p. 8.

61 Dame Sally Davies, United Kingdom Chief Medical Officer, *Letter to medical practitioners regarding PIP implants update*, 15 March 2012, p. 2, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_133075.pdf (accessed 21 May 2012).

62 Scientific Committee on Emerging and Newly Identified Health Risks, The Safety of PIP Silicone Breast Implants, 1 February 2012, http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf (accessed 14 May 2012).

63 House of Commons Health Committee, *PIP Breast implants and regulation of cosmetic interventions*, Sixteenth Report of Session 2010-12, 21 March 2012, p. 3.

In Australia, the TGA continues to monitor evidence relating to PIP breast implants and issue regular alerts with updated advice.

2.58 On 15 March 2012, the UK Chief Medical Officer (CMO), Dame Sally Davies wrote to general practitioners to highlight information which the MHRA became aware of in relation to PIP implants. This advice was in addition to correspondence sent to medical practitioners on 6 and 27 January 2012. The UK CMO encouraged practitioners to check their records and identify patients who received PIP implants, however confirmed advice that no routine removal of PIP implants as a precautionary measure was necessary.[64] This correspondence identified that some private providers were "falling short" in their responses to women coming to them with PIP breast implants (similar to experiences shared by some Australian women which are detailed in chapter 4). Dame Davis encouraged practitioners in the UK NHS to provide "all necessary reassurance and support for patients of private clinics who, for whatever reason, come to the NHS for help."[65]

2.59 In response to questions Dr Fleming explained that PIP silicone implants were not approved for use by the Food and Drug Administration (FDA) in the United States:

> You have to understand that the FDA had not approved any silicone implants between 1992 and 2006. At this point in time it has only approved three brands—Mentor, Allegan, Silimed—because the FDA requires specific long-term pre-marketing approval studies for any brand of implant before it approves that particular brand. To my knowledge PIP never underwent those tests in the US for its silicone implants.[66]

Chronology of events in relation to PIP breast implants

2.60 DoHA provided the committee with a chronology of events leading up to the device recall in 2010. This chronology reflects the TGA pre assessment process, including the onsite audit of the facility in France and the MDEC decision. This chronology is at Appendix 3.

2.61 Actions taken by the Australian Government, including the TGA, following the recall of PIP breast implants in Australia is explored further in Chapter 3.

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64 Dame Sally Davies, United Kingdom Chief Medical Officer, *Letter to medical practitioners regarding PIP implants update*, 15 March 2012, pp. 1-2, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_133075.pdf (accessed 21 May 2012).

65 Dame Sally Davies, United Kingdom Chief Medical Officer, *Letter to medical practitioners regarding PIP implants update*, 15 March 2012, p. 2, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_133075.pdf (accessed 21 May 2012).

66 Dr Daniel Fleming, Australasian College of Cosmetic Surgery, *Committee Hansard* , 9 May 2012, p.23

Chapter 3

Recall of PIP breast implants – TGA monitoring and withdrawal of medical devices

Actions undertaken for the Australian recall of PIP breast implants

3.1 Breast implants manufactured by PIP of France were recalled on 6 April 2010. The committee received evidence that, in relation to PIP breast implants, the recall was performed:

> ...as a voluntary recall by Medical Vision Australia in accordance with the procedures set out in the URPTG [Uniform Recall Procedure for Therapeutic Goods].[1]

3.2 Upon receiving advice from the French regulator, AFSSAPS[2] on 31 March 2010 through a National Competent Authority Report (NCAR), the TGA worked with Medical Vision Australia to recall this device from the market.[3] The submission from the DoHA explained the interaction between the regulator and the sponsor between 31 March and 6 April 2010 as follows:

> Later on the same day (31 March 2010), the TGA was contacted by a regulatory consultant acting for Medical Vision Australia. The consultant confirmed the AFSSAPS report of 31 March 2010.
>
> On 1 April 2010, in accordance with standard procedures as set out in the URPTG, the TGA wrote to Medical Vision Australia requesting confirmation that they had imported and distributed PIP implants in Australia and details of that distribution.
>
> On 3 April 2010 the TGA received confirmation via the sponsor's agent that Medical Vision Australia had already ceased importation and supply of PIP implants, had contacted medical practitioners to whom they had supplied stock requesting that the stock be returned, and had advised implanting surgeons to not implant any unused PIP implants.
>
> On 6 April 2010, a notice was posted on the TGA website advising that Medical Vision Australia (following consultation with the TGA) was undertaking the recall of all non-implanted silicone gel breast implants manufactured by PIP. The notice advised that the product was being recalled following concerns expressed by AFSSAPS that there may be an increased incidence of ruptures with this product that it was urgently

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1 Department of Health and Ageing, *Submission 30*, p. 29.

2 *Agence Française de Securité Sanitaire des Produits de Santé* (AFSSAPS), now known as National Security Agency of Medicines and Health Products (ANSM).

3 Department of Health and Ageing, *Submission 30*, p. 28.

> investigating the product and reports of its failure, and that further information would be provided on the TGA website. The notice also advised any consumer who was concerned about their implant to contact their treating breast implant physician for advice and follow up.[4]

3.3 The TGA issued the recall alert to consumers on their website on 6 April 2010. This alert included the following advice:

> Medical Visions Australia Pty Ltd following consultation with the Therapeutic Goods Administration is undertaking the recall of all non implanted silicone gel breast implants manufactured by Poly Implant Prothèse (PIP). The recall applies to all models of this type of implant.
>
> The product is being recalled following concerns by the French medical device regulatory authority (AFSSAPS) that there may be an increased incidence of ruptures with this product. The TGA is urgently investigating the product and reports of its failure. The TGA will provide further information on this website.
>
> Consumers with these silicone gel implants who have concerns should contact their treating breast implant physician for advice and follow-up.[5]

3.4 Following this formal recall by Medical Vision Australia, the TGA advised the committee the following actions were undertaken:

> ...the TGA sent a copy of the recall notice to the Australasian College of Cosmetic Surgery (ACCS) and the Australian Society of Plastic Surgeons (ASPS). Reference to the TGA alert was posted to their respective websites on 7 April 2010.
>
> On 7 April 2010, the TGA requested Medical Vision Australia to send a "Product Notification" to all surgeons who may have purchased the product. The wording of the formal letter and the product notification were agreed by the TGA and were despatched by Medical Vision Australia on 8 April 2010.[6]

3.5 The TGA explained to the committee that their powers are limited in relation to requiring consumers to have implants removed. As explained in DoHA's submission to the committee:

> ...when an implantable medical device is recalled, TGA's regulatory powers do not extend to requiring patients or recipients of such devices to have them surgically removed. Rather, where relevant, the TGA provides general advice to doctors and patients about the appropriate monitoring of such

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4 Department of Health and Ageing, *Submission 30*, p. 29.

5 Therapeutic Goods Administration, *Silicone gel breast implants manufactured by Poly Implant Prothese of France*, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-100406.htm (accessed 22 May 2012).

6 Department of Health and Ageing, *Submission 30*, p. 29.

> devices so that clinical management can be individualised to the circumstances of any patient who has such a device.[7]

3.6 The TGA cancelled PIP breast implants from the ARTG on 14 April 2010 at the request of Medical Vision Australia.[8]

Government action after the recall of PIP breast implants

Response time from the Government regarding the device recall

3.7 Over the course of the inquiry, concerns were raised with the committee about the length of time taken between the recall in April 2010 and the public response by the TGA in 2012 when media reports aired regarding this issue. As one submitter reflected:

> ...I have questioned why I hadn't been informed of the problem long before Sixty Minutes went to air. I was told by my surgeon that they had computer problems and had not been able to contact every one of their patients and that others had complained of the same. I find this a very poor explanation from all involved when my contact details have always been the same and two years have passed since the medical industry were informed of the product recall.[9]

3.8 As indicated in Chapter 2, the TGA did issue an alert for consumers about the product recall on 6 April 2010. Given the evidence received it is clear that the alert was not effective in reaching consumers.

3.9 The committee received evidence that the TGA does not have the authority to record patient information and contact them directly.[10] As such, it appears the most common form of communication from the TGA to consumers is via their website. The TGA has provided updated advice and information since April 2010, however there is an increase in frequency of these updates from December 2011.[11]

3.10 The TGA issued four updates throughout the year in 2010, and two in 2011 on PIP breast implants. In 2011, the first update was on 27 January and the second update was on 27 December.[12]

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7 Department of Health and Ageing, *Submission 30*, p. 1.

8 Department of Health and Ageing, *Submission 30*, p. 30.

9 Name withheld, *Submission 23*, p. 3.

10 Dr Brian Richards, Therapeutic Goods Administration, *Committee Hansard*, 9 May 2012, p. 35.

11 Therapeutic Goods Administration, *Poly Implant Prothese (PIP) breast implants*, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip.htm (accessed 22 May 2012).

12 Therapeutic Goods Administration, *Poly Implant Prothese (PIP) breast implants*, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip.htm (accessed 22 May 2012).

3.11 The TGA explained to the Committee that their level of engagement and follow up with French authorities within this timeframe was frequent:

> Between April 2010 and January 2011, the TGA had on a number of occasions sought additional advice from the French authorities regarding the results of their testing. It is the usual practice internationally that regulators share results of testing that are done. So, generally, if we have done testing we share that with all other interested regulators. We tried to get information on the actual findings. The French said, 'We're concerned about our rupture rate.' We said, 'What is your rupture rate? We are concerned about the tensile strength. Can you show us the results?' We were unable to get those results. In December 2011, the French government announced a policy change based on no new information that was available to the TGA that it would recommend the non-urgent precautionary removal of these implants based on some of these additional findings. We again sought information from the French authorities about those findings. It was not forthcoming, and so we did some further testing. Because we could not get the results of the rabbit irritation tests, we repeated those in a laboratory in Australia and we repeated them also in the same laboratory in France that had done them for the French authorities but could not tell us what the results were because that was commercial-in-confidence between the lab and the French authorities.[13]

3.12 The seriousness of PIP breast implant issues prompted the policy shift by the French authorities in early December 2011, following a report in France of the death a woman from anaplastic large cell lymphoma (ALCL), a rare form of cancer of the immune system. Following issuing information about this possible link early in December, this was later withdrawn. The French Health Ministry then released a press statement on 23 December 2011indicating there is "no increased risk of cancer in women who have PIP implants compared to other implants".[14]

3.13 The committee sought clarification from the French regulator regarding this correction; however at the time of publication of this report no response has been received.

3.14 The committee heard from several witnesses that a link between cancer and PIP implants and is not supported by clinical evidence. The Chief Medical Officer, Professor Baggoley reflected in his report on PIP breast implants:

> There is no evidence that the risk of ALCL in the breast for PIP breast implants is greater than for all silicone gel filled breast implants. No cases

13 Dr Brian Richards, Therapeutic Goods Administration, *Committee Hansard*, 9 May 2012, p. 33.

14 Press release of French Minister for Labour, employment and Health, 23 December 2011, http://www.ansm.sante.fr/var/ansm_site/storage/original/application/41d18730821fc09793fc9b848f6e090b.pdf (accessed 25 May 2012).

> of ALCL in the breast in women with PIP breast implants have been reported in Australia.[15]

3.15 Following the developments in France in December 2011, the TGA commenced frequent updates for consumers and medical practitioners on their website in January 2012. A hotline service for individuals concerned about PIP implants was set up in January 2012 and this is discussed further in Chapter 4.

3.16 The Consumers Health Forum Australia (CHFA) stated in their submission to the committee that the TGA acted with "reasonable timeliness to respond and provide information to consumers and health professionals about safety risks and treatment options"[16] and they particularly valued the measured advice provided by the Government and the:

> Publication of regular updates as further evidence emerged on risks associated with the implants
>
> Publication of information specific to the Australian context, including information on the number of PIP implants used in Australia and the number of rupture reports for these implants received by the TGA, the TGA's activities in testing the implants, the availability of these implants in Australia, and the absence of any reports of Anaplastic Large Cell Lymphoma in Australian women who had received PIP implants
>
> Provision of specific, separate information for consumers and health professionals
>
> Inclusion of information on reporting adverse events in some communications about PIP implants.[17]

3.17 However, the CHFA also stated the communication with the public could have been improved by the TGA publishing what information is "unknown" in order to be more transparent.[18] This was explained further at the hearing by Ms Karen Carey from the CHFA:

> When consumers think that performance is substandard, quite often it is because of an unrealistic expectation, and that unrealistic expectation can only be dealt with through information. An opportunity missed in this situation was to demonstrate that the TGA, out of all the governments in the world, actually took the most active position; however, if you are a consumer, have that implant in and need to know if you need to have the operation now, your expectations were not met.
>
> ...

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15 Department of Health and Ageing, *Poly Implant Prothese Breast Implants, Report of the Chief Medical Officer*, April 2012, p.5.

16 Consumers Health Forum Australia, *Submission 17*, p. 4.

17 Consumers Health Forum Australia, *Submission 17*, p. 4.

18 Consumers Health Forum Australia, *Submission 17*, p. 4.

> Had the TGA been more active, mainstream and honest about what information it had and did not have, I think those expectations would have been moderated.[19]

Committee View

3.18 The committee acknowledges the recent frequency of information provided by the Therapeutic Goods Administration on their website through safety alerts, background and updated advice. However, the committee is concerned about the time lag between the initial device recall in April 2010 and when the TGA commenced issuing this regular advice late in 2011.

3.19 The committee is also concerned about the TGA's focus on their website as the primary form of communication. While this is certainly appropriate for providing updates to individuals who are already engaged in an issue, relying on this to reach individuals who are not yet aware that they should be monitoring the website is clearly ineffective. The TGA needs to implement a comprehensive alert strategy for all future recalls so that affected individuals are aware of the situation and know to visit the website for further information. This strategy should utilise all options available through federal and state government communication portals to maximise the chances of the alerts reaching those affected. The committee is also of the view that when a health issue of considerable public concern occurs, Ministers and the top levels of federal and state governments have a role in providing leadership and coordination to ensure that information is disseminated quickly and effectively.

3.20 The committee is of the view that frequent advice on PIP breast implants could have been issued from April 2010 onwards. This advice could have been strengthened by including information regarding the interaction between the TGA and French authorities as well as updates on other information the TGA was seeking and tests that were being performed. The committee strongly encourages the TGA to consider this approach on device recalls in the future.

Recommendation 5

3.21 The committee recommends that the Therapeutic Goods Administration include in their updates on PIP breast implants, and as part of any future recalls on other devices or medications, details of the type of evidence they are pursuing in order to further inform the Australian public.

Engagement with international regulators

3.22 The committee received evidence about the TGA taking a lead role in convening international regulators to encourage information sharing regarding PIP breast implants. The TGA stated it had increased its "efforts to obtain as much information as possible from its international regulatory counterparts in the UK, the

19 Ms Karen Carey, Consumers Health Forum Australia, *Committee Hansard*, 9 May 2012, p. 4.

European Commission, the USA, Canada, Brazil, Japan, Switzerland and Singapore regarding PIP implants"[20] and convened an international laboratory testing group to share information on testing results on PIP breast implants.[21]

3.23 This engagement with international regulators included the TGA convening a teleconference with all major regulators on 11 January 2012 to promote information sharing. Although invited, the French regulator did not participate in this meeting.[22]

3.24 The committee heard from the Department that despite several efforts to obtain information from the French regulator, the Department only received the results from the AFSSAPS chemical, mechanical and biological testing on 7 March 2012. This information was obtained following request through the diplomatic post on 11 January 2012.[23]

3.25 At the hearing, the TGA acting National Manager, Dr Richards explained that:

> ...the European Commission has asked that scientific expert committee to reconvene and update that report and has invited the head of TGA's laboratories to participate in that committee in recognition of the leadership the TGA has shown internationally in the provision of scientific evidence.[24]

Committee view

3.26 The committee commends the TGA for its engagement with international regulators to date.

Recommendation 6

3.27 The committee recommends that the TGA publish updates and details of the discussions that have taken place with international regulators.

Establishment of advisory panels

3.28 The Australian Government convened two specialist advisory committees to support improved information and advice on PIP breast implants:

- The TGA convened an expert advisory panel to review the evidence in relation to the safety of PIP breast implants. This panel comprised clinical,

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20 Department of Health and Ageing, *Submission 30*, p. 36.

21 Therapeutic Goods Administration, *PIP breast implants – An updated Australian Perspective*, 23 March 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120323.htm (accessed 22 May 2012).

22 Department of Health and Ageing, *Submission 30*, p. 34.

23 Department of Health and Ageing, *Submission 30*, p. 35.

24 Dr Brian Richards, Therapeutic Goods Administration, Department of Health and Ageing, *Committee Hansard*, 9 May 2012, p. 36.

scientific and epidemiological experts from TGA statutory medicine and medical device safety committees, along with additional surgical experts from the Royal Australasian College of Surgeons, the Australian Society of Plastic Surgeons and the Australasian College of Cosmetic Surgeons.[25]

- The CMO established a Clinical Advisory Committee on 9 January 2012 to provide regular and frequent advice on clinical measures, risks and benefits, and communication strategies in response to health concerns related to PIP breast implants. The committee includes senior representatives of relevant clinical and consumer groups.[26]

3.29 Representatives from the Australian Society of Plastic Surgeons (ASPS) and the Australasian College of Cosmetic Surgeons (ACCS) were on both advisory panels. During the inquiry, the committee received evidence from several submitters regarding the potential conflict of interest in having medical professionals that used PIP breast implants in their surgeries advising the Australian Government issues regarding this medical device. An example of these concerns is expressed below:

> I also find the fact that they are using Dr Fleming as one of their main advisors on the issue very concerning as he is apparently one of the largest PIP implanters, if not the largest, in the whole country.[27]

3.30 Dr Daniel Fleming, representative from the ACCS, acknowledged the perceived conflict of interest and advised the committee:

> Any surgeon who has implanted PIP breast implants could have, or could be perceived to have a conflict of interest in giving advice about them.
>
> ...
>
> In fact I am neither biased for or against PIP and Medical Vision Australia in the advice I have given to the TGA and CMO Committees. The minutes of the meetings show that all of the advice I have given has been evidenced based or given in order to get more evidence.
>
> ...
>
> Nevertheless, the possibility of conflict of interest, or perceived conflict of interest does exist and has been addressed. My experience using PIP implants and my dealings with Medical Vision Australia were disclosed in writing by me to the chairmen of the committees.[28]

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25 Therapeutic Goods Administration, *PIP breast implants – An updated Australian Perspective*, 23 March 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120323.htm (accessed 22 May 2012).

26 Department of Health and Ageing, *Poly Implant Prothese Breast Implants, Report of the Chief Medical Officer*, April 2012, p.8.

27 Name withheld, *Submission 48*, p. 2.

28 Dr Daniel Fleming, *Response to Adverse comments made in submissions Nos 7, 46, 47 and 48*, received 8 May 2012, pp. 4-5.

3.31 The committee also received evidence from CHFA that having expertise on advisory panels are key to accurate information and this is appropriate if conflicts of interests are managed appropriately. As Ms Carey from the CHFA explained:

> ...it is really important to have the surgeons who have actually been implanting so they know about the device and to have the radiologists who can give advice about what tests are appropriate. So I would like to be able to say that sometimes conflicts of interest are necessary. On that committee all of the measures to manage those conflicts were in place and were exercised extremely well by the chair. I think everybody knew who had conflicts. When you have all of the stakeholders there, even though some of those stakeholders have conflicts, the debate on the committee allows the effects of those conflicts to be minimised.[29]

Type of TGA testing of PIP breast implants after the recall

3.32 The TGA requested PIP breast implants from the sponsor when the device was recalled on 6 April 2010 and requested further samples on 6 May 2010.[30] The TGA advised the committee that they were the first regulator to publish the outcomes of testing conducted on PIP breast implants on 2 July 2010 and that the French regulator announced their testing outcomes on 28 September 2010.[31] Outcomes from the initial tests conducted by the TGA was that:

> ...the PIP breast implants supplied in Australia conform to the relevant international standards for this type of product including those for gel cytotoxicity and shell strength.[32]

3.33 The TGA test results were supplied to the UK regulator, MHRA and the French regulator, AFSSAPS.[33]

3.34 Concerns with this initial testing were raised with the committee by several submitters stating this outcome was based on limited testing. One submitter explained that testing on non-implanted devices is limited as the TGA had tested samples that were not:

> ...subjected to the same heat, conditions or environment as which they would have been in the human body...To my research these three products, if kept at a cooler temperature are of a high viscosity thus meaning in the

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29 Ms Karen Carey, Consumers Health Forum Australia, *Committee Hansard*, 9 May 2012, p. 3.

30 Department of Health and Ageing, *Submission 30*, p. 30.

31 Department of Health and Ageing, *Submission 30*, p. 30.

32 Therapeutic Goods Administration, *Silicone breast implants manufactured by Poly Implants Prothese (PIP) of France – an update*, 2 July 2010, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-100702.htm (accessed 22 May 2012).

33 Department of Health and Ageing, *Submission 30*, p. 32.

> human body at temperature of 36.6 degrees Celsius, the viscosity of these products is severely compromised...[34]

3.35 The frustration about the TGA testing was evident in the information provided to the committee. Ms Telford, an Australian woman who had received PIP breast implants, stated:

> I am sick of hearing the TGA telling us that there is no evidence and they need to be tested, and then them saying that they tested the outer shell. I would like to know if they have actually tested a wide range of these implants that have been explanted from woman. [T]ested the silicone, the shell, test what happens when the industrial grade silicone contained in them are put inside a warm, wet environment and see what happens.[35]

3.36 Dr Richards provided evidence to the committee that the TGA tests of the viscosity of the gel have been "done in accordance with the international standard, and, of the samples tested by the TGA, all of the gels tested met the international standard for viscosity that applies to this type of device".[36]

3.37 The TGA continued to test PIP breast implants and in its submission to the committee, the Department of Health and Ageing indicated the following advice provided and action taken regarding this testing:

> On 1 October 2010, the TGA reaffirmed (by way of a statement on its website) its earlier (2 July 2010) advice that testing indicated PIP implants met relevant safety and quality requirements and that patients with concerns should consult their implanting physician.
>
> This advice was provided to the relevant specialist colleges in Australia (ASPS and ACCS) who had posted similar advice for patients on their websites in April and July 2010. On 12 October 2010, Medical Vision advised the TGA that, in accordance with the TGA's normal requirements, all recalled stock, which had not been provided to the TGA for testing, had been destroyed. On 7 February 2011 the TGA held a teleconference with members of the ASPS to update them on PIP implants.[37]

3.38 The CMO also provided the following explanation in his report on PIP breast implants:

> The TGA testing plan is using the broadest cross-section of samples of PIP breast implants available to the TGA, and includes both PIP1 and PIP 2 formulations of the filler gel. To date, samples of the product with an expiry date before 2011 have not been available to the TGA.

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34 Name withheld, *Submission 7*, p. 3.

35 Ms Suellen Telford, *Submission 39*, p. 1.

36 Dr Brian Richards, Therapeutic Goods Administration, Department of Health and Ageing, *Committee Hansard*, 9 May 2012, p. 33.

37 Department of Health and Ageing, *Submission 30*, p. 30.

> The TGA has tested 19 different batches (29 samples) of PIP breast implants available in Australia plus batches of other brands of breast implant for comparison. The TGA has obtained a further five batches (23 samples) of PIP breast implants from overseas for the on-going testing program.
>
> The TGA is investigating explanted PIP breast implants to complement testing being carried out on unused sterile PIP breast implants and to provide further evidence that will assist with determining the overall quality and safety of the product.[38]

3.39 The legal firm Tindall Gask Bently (TGB) however indicated that the testing was misdirected and focussed on ruptures rather than the silicone that was contained in the implants. Mr Tim White from TGB stated:

> ...it is clear that one of the primary concerns from the French authorities related to the use of unauthorised gel that had been utilised in the PIP implants. By contrast, the majority of the statements from the TGA have concentrated not on the use of unauthorised silicone but rather on the rupture rates of the PIP implants.[39]

3.40 The TGA issued advice regarding the concerns raised by the French regulator, AFSSAPS, and the results from TGA testing, on their website and issued the following advice in their update on 23 March 2012:

> The French regulatory authority, AFSSAPS, has reported that the authorised and unauthorised silicone gels have different ingredients which can result in differences in the physical and chemical properties of the gel. In particular, AFSSAPS noted that some batches of unauthorised gels contained higher amounts of small silicone molecules (called low molecular weight siloxanes) than the authorised gel. The results of the TGA testing for these small silicone molecules confirms the results obtained by the French authorities, but the presence of these chemicals (which are widely used in cosmetics) is not considered a health risk.[40]

3.41 The committee also received evidence from the CHFA that the need to conduct tests on explanted PIP breast implants is vital to provide accurate advice:

> I think in this instance there was a delay for the TGA to get the ex-planted devices in order to examine them. Examining items off the shelf can tell you about whether or not they conform with the specifications for the device, but getting an ex-planted device can tell you something really

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38 Department of Health and Ageing, *Poly Implant Prothese Breast Implants, Report of the Chief Medical Officer,* April 2012, p. 11.

39 Mr Tim White, Tindall Gask Bentley, answers to questions on notice, 9 May 2012 (received 17 May 2012).

40 Therapeutic Goods Administration, *PIP breast implants – An updated Australian Perspective*, 23 March 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120323.htm (accessed 22 May 2012).

> different. It can tell you whether the problem device conforms to those specifications, but it can also tell you whether the act of implanting that device into somebody changes the performance of the device. It is absolutely crucial, and I think the TGA need to be more active and faster in obtaining ex-planted devices.[41]

3.42 The committee also received evidence from Associate Professor Cooter of the Australian Society of Plastic Surgeons that surgeons usually sent explanted, faulty devices back to the manufacturer through the supplier, who would then be responsible for alerting the TGA.[42] This situation raised a significant issue in relation to a potential conflict of interest, where the party with the greatest financial stake (the manufacturer) is responsible for reporting faults with their own product. It also meant that the TGA may not have ready access to explanted devices for testing. Associate Professor also advised the committee that this issue of how surgeons should communicate their clinical explants information to the TGA has since been clarified[43] but did not expand on the nature of this clarification.

Committee view

3.43 The committee notes that in relation to PIP breast implants, the Therapeutic Goods Administration is continuing its testing on removed implants and is gathering data through following up adverse events reports. The committee believes the TGA needs to undertake appropriate testing, particularly on explanted devices, and publicly release these results as a priority. Advice issued by the TGA on test results should be supported by the Chief Medical Officer.

Recommendation 7

3.44 The committee recommends that the TGA review its processes to ensure that faulty explanted devices are available to the TGA for independent testing.

Data collection and record keeping for PIP breast implants

Data collection – adverse event monitoring

3.45 Under the Australian Regulatory Guidelines for Medical Devices, manufacturers and sponsors must inform the TGA of all reportable adverse events, within the appropriate timeframes. They must also ensure timely and appropriate

41 Ms Karen Carey, Consumers Health Forum Australia, *Committee Hansard*, 9 May 2012, p. 2.

42 Associate Professor Rodney Cooter, Australian Society of Plastic Surgeons, Committee Hansard, 9 May 2012, p. 9.

43 Associate Professor Rodney Cooter, Australian Society of Plastic Surgeons, *Committee Hansard*, 9 May 2012, p. 9.

action is taken. However, the TGA also encourages the reporting of adverse events by users of devices to monitor the performance of medical devices in Australia.[44]

3.46 As at 18 May 2012, the TGA had received 284 reports of confirmed ruptures and 56 reports of unconfirmed ruptures of PIP breast implants.[45] These reports were provided by surgeons, the supplier and patients. A report is confirmed when there is sufficient information to uniquely identify the patient, the implant used and that an X-Ray or other diagnostic image showed that the implant was ruptured or the implant was found to be ruptured when it was removed. An 'unconfirmed' report is where the TGA has sought additional information but has not received "sufficient information to uniquely identify the rupture".[46]

3.47 The TGA issued advice on 4 January 2012 that, based on the TGA's report data, the rupture rates of PIP breast implants were 0.4% and "well within the expected rupture rate for silicone breast implants".[47] The committee received evidence that this figure may have been misleading. The Australasian College of Cosmetic Surgery submission stated:

> In its 4 January 2012 web update, the TGA reported that it had received reports of ruptures of PIP implants equivalent to 0.4%. Although true, this was likely to mislead patients and give them false reassurance as the true rupture rate could not be deduced from the rates spontaneously reported to the TGA. This was bound to be a very significant under-estimate.[48]

3.48 One submitter was critical of this evidence base:

> The first indication I had of this was when the TGA initially reported very low rupture rates of the PIP breast implants based on incomplete and insufficient data from a voluntary reporting system. Yet the TGA used these inaccurate rates as 'evidence' that PIP breast implant rupture rates were similar to rupture rates of other breast implants.[49]

3.49 The Department of Health and Ageing explained in their submission to the committee that when the device was recalled, the TGA:

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44 Therapeutic Goods Administration, *Australian Regulatory Guidelines for Medical Devices*, Section 22, Post-market vigilance and monitoring requirements, May 2011, p. 304.

45 Therapeutic Goods Administration, PIP breast implants – TGA update, 18 May 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120518.htm (accessed 22 May 2012).

46 Therapeutic Goods Administration, PIP breast implants – TGA update, 18 May 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120518.htm (accessed 22 May 2012).

47 Therapeutic Goods Administration, *Poly Implant Prothese breast implants – An Australian Perspective*, 4 January 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-120104.htm (accessed 23 May 2012)

48 Australasian College of Cosmetic Surgery, *Submission 24*, p. 5.

49 Name withheld, *Submission 36*, p. 3.

> ...reviewed data it held in relation to ruptures of other brands of silicone gel implants. These data indicated that the number of ruptures of PIP implants, as reported to the TGA, did not exceed those that would be expected based on published studies concerning implants generally.
>
> Based on the information available to the TGA in the period immediately after the recall of PIP implants, the TGA considered that the initial reports from AFSSAPS of increased rupture rates of PIP gel implants were not reflective of the Australian situation.
>
> ...
>
> While the number of reported ruptures of PIP implants was subject to the same spontaneous, voluntary reporting by users that applied to other brands of silicone breast implants, TGA considered it reasonable to compare the prevalence of reported ruptures with that reported for other brands. However, once TGA stimulated the reporting of ruptures of PIP ruptures by writing to surgeons in January 2012 asking for all such ruptures to be reported, such comparisons ceased to be valid.

3.50 It is noted by DoHA in their submission that there are limitations to this data. Notably, the voluntary basis of reporting to the TGA, and other regulators, does not provide an accurate measure of actual adverse events as "there will always be under-reporting".[50] However, the committee notes the excellent performance of the National Joint Replacement Registry, which collects information on approximately 99 percent of relevant procedures in Australia[51] and that information is provided to the Registry on a voluntary basis by hospitals and medical practitioners. The committee is of the view that, with the appropriate systems in place, under-reporting does not have to be accepted as unavoidable.

3.51 Several submitters advised the committee they had reported an adverse event to the TGA regarding their PIP breast implants, however indicated that they had limited follow up from the TGA. As one woman explained :

> I submitted an ‘adverse event to a medical device’ form to the TGA in January 2012 yet, except for a standard email acknowledgement of receipt, I was not asked for further details until April 2012, when I was sent a letter requesting that the TGA contact my treating doctors for further information of my symptoms. This delay is unacceptable, particularly when the TGA were advised in the ‘adverse event to a medical device’ form that I was so ill from the PIP breast implants, I had been hospitalised.[52]

3.52 The Australian Medical Association (AMA) stated in their submission that those implantable devices "are likely to always have a failure rate" and the TGA's role in post-market assessments such as adverse event monitoring and timely responses to

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50 Department of Health and Ageing, *Submission 30*, p. 31 footnote 26.

51 Senate Community Affairs References Committee, Inquiry into The regulatory standards for the approval of medical devices in Australia, *Committee Hansard,27 September 2011*, p. 18-19.

52 Name withheld, *Submission 36*, p. 3.

device recalls would be strengthened by the introduction of implantable device registries.[53]

Committee view

3.53 The committee accepts that the TGA is now endeavouring to share information as it becomes available, and has taken steps to ensure their advice about the PIP breast implants is based on the current evidence it has available to it.

Recommendation 8

3.54 The committee recommends that the TGA's advice about PIP breast implants include the limitations of the evidence and data to ensure that consumers and medical professionals alike are in receipt of as much information as possible that will enable them to make informed decisions about any future treatment.

Recording keeping – the need for an opt-out breast implant registry

3.55 The committee received evidence from witnesses which raised concerns about the current record keeping practices regarding breast implants. Australia has a breast implant registry; however the current arrangements only generate limited data. The organisation currently responsible for maintaining the current breast implant registry, the Australian Society of Plastic Surgeons (ASPS) explained that the current Breast Implant Registry (BIR) in Australia has provided limited information because of its voluntary nature and low capture rates.[54] The current BIR is an opt-in arrangement and records are kept only when a patient volunteers to be part of this registry. The submission from ASPS explained:

> Not only was the registry's 'opt-in' design at fault but each patient was levied a fee to be included in the BIR thereby compounding the disincentives to participate.[55]

3.56 The ASPS further explained that the BIR has a low capture and of the approximate 13 000 PIP breast implants sold in Australia, the current BIR captured less than 4% of these.[56] It could be argued that if this database was a comprehensive registry of patients that had received PIP breast implants, it could have been drawn on to advise consumers about the product recall.

3.57 Several submitters raised their concerns with the committee about the lack of record keeping and limited notification of the recall. Many women were not contacted

53 Australian Medical Association, *Submission 2*, pp. 1-2.

54 Australian Society of Plastic Surgeons, *Submission 18*, p. 5.

55 Australian Society of Plastic Surgeons, *Submission 18*, p. 2.

56 Australian Society of Plastic Surgeons, *Submission 18*, p. 2.

and advised about the recall due to poor record keeping practices by surgeons, or due to absence of a centralised database. As one submitter stated in her submission:

> ...they have failed us by not having adequate record keeping requirements in place, neither in the local surgeries or at a mandatory centralised reporting agency so that if this does happen, individuals affected can be informed as matter of course and make their own judgements with appropriate medical advice as to the course of action from there.[57]

3.58 The value of clinical registries, particularly in light of the PIP breast implant recall notification of recall and adverse event monitoring, is widely accepted by stakeholders. The CMO provided evidence to the committee regarding the value of registers in relation to identifying patients that have medical devices.

> The value of registers as safety and quality items that can assist, at the very minimum, to identify patients who have implantable medical devices is understood.
>
> ...
>
> The best way of communicating with patients who have devices is not of a general or indirect nature; it would be able to go to them directly and say, 'We understand you have this device. There is now an issue. Please now go and contact your doctor.' It is very straightforward.[58]

3.59 The AMA shared this view and stated in their submission to the committee that clinical registries:

> ...allow medical practitioners and the TGA to respond appropriately when there is a clear failure of a device that is beyond that of like products. For example, a breast implant registry could have provided early evidence of the failure rate of PIP breast implants compared to other breast implants.
>
> Clinical registries allow medical practitioners to identify problems early, respond appropriately in a coordinated manner and support clinical decisions about which devices are delivering the best patient outcomes in particular clinical circumstances.[59]

3.60 The CHFA also provided evidence to the committee in support of a device registry, stating that it should be based on an opt-out arrangement.

> The international experience and Australian experience shows that an opt-on register simply does not get user reliability of data and therefore the data that you have is so biased as to be pretty useless. So if you are going to have a register it has to be an opt-off.[60]

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57 Name withheld, *Submission 23*, pp. 3-4.

58 Professor Chris Baggoley, Chief Medical Officer, Department of Health and Ageing, *Committee Hansard*, 9 May 2012, p. 36.

59 Australian Medical Association, *Submission 2*, p. 1.

60 Ms Karen Carey, Consumers Health Forum Australia, *Committee Hansard*, 9 May 2012, p. 5.

3.61 DoHA indicated that the opt-out approach is the preferred model and explained:

> The Australian Commission on Safety and Quality in Health Care (ACSQHC) report *Operating Principles and Technical Standards for Australian Clinical Quality Registries* (2008), identified two methods by which consent can be obtained to participate in a clinical quality register:
>
> 1. Asking individuals to register their willingness to be included (opt in); or
> 2. Presuming that an individual will be willing to be included on a register unless they lodge an objection (opt off or opt out).
>
> The ACQSHC found that 'it has been repeatedly demonstrated … that requiring specific permission in advance from potential research participants (opt in) will lead to the collection of a relatively small fraction of eligible cases and the resulting data will have no credibility for quality improvement'.
>
> The ACQSHC report recommended that the opt out consent should be a standard approach taken upon the establishment of new registers.[61]

3.62 Internationally, the value of registries for collecting data was recently reflected in the European Commission Scientific Committee on Emerging and Newly Identified Health Risks report, 'The Safety of PIP Silicone Breast Implants' released on 1 February 2012, This report recommended "a reliable database on silicone breast implants be established."[62]

3.63 The ASPS has reviewed the design and capability of the current BIR and compared this with the successful National Joint Replacement Registry (NJRR) monitored by the Australian Orthopaedic Association (AOA). The NJRR was explored in detail in the committee's 2011 report on the regulation of medical devices.[63] The NJRR design is an opt-out arrangement in which the patient automatically goes on to the registry and their data is captured, unless they officially object to this occurring.[64]

3.64 The committee is aware that the ASPS and the Monash University has collaborated in developing a proposal for a new Breast Device Registry (BDR), with the proposal including the TGA to provide expert input on the BDR development.[65]

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61 Department of Health and Ageing, response to a question taken on notice, 9 May 2012, received 23 May 2012.

62 Department of Health and Ageing, *Submission 30*, p. 39.

63 Senate Community Affairs References Committee, *The regulatory standards of medical devices in Australia*, November 2011, p. 35.

64 Australian Society of Plastic Surgeons, *Submission 18*, p. 5.

65 Monash University, School of Public Health and Preventative Medicine, *Submission 42*, pp. 1-2.

This redesign BDR which is an opt-out arrangement is at the pilot stage and is being trialled at three independent hospitals.[66]

Committee view

3.65 In light of the PIP breast implants recall, the committee believes there is a need for a thorough collection of data regarding breast implants and other medical devices. The committee is of the view that an opt-out breast implants registry would provide more accurate data regarding what type of implants patients received, when and by what surgeon, that could be drawn on should a similar device recall occur in the future. The committee also thinks that other types of medical devices would benefit from similar registries.

Recommendation 9

3.66 The committee recommends that, in light of the Poly Implant Prothese breast implant recall, the Department of Health and Ageing establish an opt-out Breast Implant Registry as a priority. The design of such a registry should be based on the National Joint Replacement Registry.

Medicare subsidy for MRI

3.67 In order to evaluate whether breast implants have ruptured and may need removal, an MRI scan is required. As Associate Professor Cooter from the ASPS explained:

> [A] MRI is highly accurate in identifying ruptures with high sensitivity and specificity. The imaging of choice for "standard" international practice for assessment of breast implant integrity is MRI.[67]

3.68 The Australian Government announced on 10 March 2012, that from 12 March 2012, patients with PIP breast implants will have access to Medicare benefits for one MRI scan to evaluate the integrity of their implants. This rebate is available for 12 months until 12 March 2013.[68]

3.69 These Medicare rebates apply to the new PIP MRI items and the schedule fee for the PIP MRI services has been set at $500 per item. The committee received evidence at its hearing that women who have an MRI will be covered for $426 out of the approximate cost of $500.[69] However, it remains at the provider's discretion whether or not to bulk bill. DoHA issued the following advice regarding this discretion:

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66 Australian Society of Plastic Surgeons, *Submission 18*, p. 6.

67 Australian Society of Plastic Surgeons, *Submission 18*, p. 6.

68 Department of Health and Ageing, *Submission 30*, p. 6 and pp. 45-46.

69 Dr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 9 May 2012, p. 36.

> There are bulk billing incentives for diagnostic imaging services, including these new MRI services. Medical practitioners, including radiologists, are free to set their own value on the services they provide. While the Government is responsible for setting the schedule fee on which Medicare benefits are based, there is nothing to prevent radiologists or any other medical practitioner setting fees that exceed those in the schedule. In these circumstances, you may be required to pay the gap between the fee charged and the Medicare rebate.[70]

3.70 The committee also notes evidence provided by DoHA in relation to what these Medicare arrangements do not cover:

> Medicare arrangements do not cover the cost of prosthetics, which in this case is the breast implant. The cost of these may be subsidised by private health insurance, depending on the terms of the policy. PIP implants were listed on the Prostheses List in August 2006, and were removed in August 2010 at the request of the sponsor and hence have not been subsidised by private health insurance since then. However, other breast prostheses remain on the Prostheses List and, subject to the patient's policy, will be subsidised by private health insurers when the surgery is medically necessary or where the surgery is a service for which Medicare benefits are payable. Hence, women who are undergoing medically necessary implant removal and replacement can expect that private health insurance benefits will be available.[71]

3.71 The importance of MRI scans is two-fold. The scans provide patients with an accurate assessment of the integrity of their implants and the results of these scans may also feed into data regarding rupture rates. As the ACCS stated in their submission:

> ...the true rupture rate of PIP implants is not yet known. This needs to be deduced from the results of the MRI scans currently being performed on large numbers of women with PIP implants. Patients can then be informed of the rupture rate and how it compares to the known rupture rate of other brands of breast implants. This information will allow women to make informed decisions about whether or not they wish to remove, replace or continue to monitor their PIP implants.[72]

3.72 The committee notes that there are investigations being undertaken on how best to audit the results of the MRIs being performed around Australia in order to obtain a more accurate indication of the rupture rate of PIP Implants.[73]

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70 Department of Health and Ageing, Medicare-Eligible MRI service for Poly Implant Protheses (PIP) breast implants, 5 May 2012, http://www.health.gov.au/internet/main/publishing.nsf/Content/di-mri-pip**,** (accessed 22 May 2012).

71 Department of Health and Ageing, *Submission 30*, p. 46.

72 Australasian College of Cosmetic Surgery, *Submission 24*, p. 2.

73 Australasian College of Cosmetic Surgery, *Submission 24*, p. 3.

3.73 On evidence received from individual women with PIP breast implants, the committee understands the Medicare rebates for MRI scans are also welcomed, however the 12 month period in which the Medicare rebate is available may not be sufficient. Associate Professor Cooter, President of the ASPS, provided evidence to the committee that ideal practice would include regular MRI scanning of implants to assess whether a rupture has occurred.

> **Senator XENOPHON:** There was an announcement several months ago by the government to fund MRI scans, which you say are the gold standard for determining whether there is a leak or a rupture. It is a one-off scan until 12 March next year. Is a one-off scan sufficient or do you think it would be prudent to offer that rebate or that assistance beyond a once-off and that it should be done on an annual basis for the next two or three years? What is a precautionary approach in respect of the number of MRI scans to determine whether there is a problem with these implants?
>
> **Associate Prof. Cooter:** At least every second year would be ideal practice in my view. It comes back, however, to the use-by date of implants. There is some mounting view that a 10-year time frame should be put on this. Given that it is now over two years since the last one went in, up to four MRIs would cover everyone...[74]

Committee view

3.74 The committee acknowledges the Australian Government's announcement regarding Medicare items covering an MRI scan, and notes this announcement came almost two years after the product recall. The committee is of the view that the one-off nature of these scans and the 12 month time limit on these rebates is too limited. The committee therefore strongly encourages the Australian Government to extend these rebates in accordance with the current medical advice.

Recommendation 10

3.75 The committee recommends that the Australian Government extend the Medicare rebates for MRIs in accordance with the current medical advice.

Locations of MRI machines with a breast coil

3.76 In addition to the frequency of MRI scans, the issue of the location of appropriate MRI machines (i.e. machines with a breast coil) to conduct the scan to accurately evaluate the integrity of the breast implants was raised with the committee. This is explored further in Chapter 4 of this report.

Establishment of National breast implant hotline

74 Associate Professor Rodney Cooter, Australian Society of Plastic Surgeons, *Committee Hansard*, 9 May 2012, p. 10.

3.77 The Australian Government also announced on 7 January 2012 the national hotline for Australian patients concerned about their PIP breast implants to contact and seek additional information and support. This national line is available 24 hours a day across Australia.[75] DoHA stated in their submission to the committee that up until midnight 13 April 2012, the line had received 3,756 calls.[76]

3.78 The committee received evidence about this hotline which indicated that the calls are answered by registered nurses.[77] Many submitters to this inquiry have raised concerns regarding the level of information and support they received after contacting this hotline. These concerns have included the feeling that the registered nurses were reading from an "information sheet and had no real insight into the problem"[78] and that that hotline constantly referred women back to the TGA website or advised them to seek information from the surgeon.[79]

3.79 At the inquiry's hearing, the committee also received evidence regarding the follow-up function this hotline was undertaking in relation to providing additional information to women that had contacted the hotline. In particular, DoHA had 10 registered nurses that were completing call-backs to women who had contacted the hotline and indicated they want more information as it came to light.

> In total 2,230 original callers will receive at least one attempt at call-back during this period if a primary contact is not made. As at 12:30 today there have been 128 outbound calls made to patients. Of these, 107 have been successful attempts and, of these successful calls, 48 calls were longer than 30 seconds. The remainder of these will have a second attempt made if possible within the initial period. The feedback from the nurses who are doing the calls is that the calls have been very much welcomed by the recipient and people were grateful to have received that feedback. A number of recipients have said they do not have the time to listen to the full script. Obviously it is a question of whether people have the time to listen, but, as I said, this was thought about quite carefully in terms of whether this would be more or less anxiety producing. But, given that people had indicated interest and had provided their details to enable us to contact them, that is why we decided we would proceed in this way...[80]

3.80 While the committee accepts that not all women will have the same experience with contacting this hotline, and some may find the information helpful, many submitters to this inquiry have indicated they found this hotline did not equip

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75 Department of Health and Ageing, *Submission 30*, p. 6.

76 Department of Health and Ageing, *Submission 30*, p. 2.

77 Department of Health and Ageing, *Submission 30*, p. 6.

78 Name withheld, *Submission 7*, p. 2; Name withheld, *Submission 16*, p. 2.

79 Name withheld, *Submission 35*, p. 2; Name withheld, *Submission 36*, p. 4.

80 Ms Jane Halton PSM, Secretary of Department of Health and Ageing, *Committee Hansard*, 9 May 2012, p. 38.

them with additional information about the PIP breast implants and that they did not feel supported through this process.

3.81 The impact of the PIP breast implants issue on Australian patients is explored further in Chapter 4 of this report.

Committee view

3.82 The committee supports the establishment of the national hotline for PIP breast implants. The committee is concerned however that the evidence provided by individual women that the hotline did not provide the support they required. Broader reform and implementation of recommendations

3.83 In addition to the TGA's handling of the PIP breast implants recall, the committee received evidence regarding the need for increased transparency in relations to all medical devices. The CHFA particularly expressed their concerns that recommendations made from the Health Technology Assessment in Australia (HTA Review) regarding transparency were not yet implemented.

3.84 The HTA was undertaken in 2009 and recommendations arising from this review are in various stages of implementation.[81] However, particular recommendations that are relevant to the PIP breast implants issue, particularly post-market surveillance have not yet been responded to by the Australian government; two years after these recommendations were made. As the CHFA submission explains, these recommendations are 13, 14 and 15 of the HTA Review:

> Recommendation 13 called for the TGA to take steps to increase the rate of reporting of adverse events, including by health service providers and consumers, in order to improve the contribution of post-market surveillance to patient safety. The reporting of adverse events has repeatedly been identified by consumers as a necessity. Many health consumers would not know where to begin if they wanted to report an issue with a device, and health professionals have also identified concerns with current adverse event reporting processes. Consumers have also identified the importance of providing formal feedback to all stakeholders involved in the reporting of adverse events, to increase confidence that action has been taken and encourage future reporting of adverse events.
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> ....
>
> Recommendation 14 called for the Department of Health and Ageing to explore options for consideration by Government to facilitate the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions for devices and procedures, in order to improve the contribution of post-market surveillance to the sustainability of the health system and the longer-term regulatory efficiency of HTA processes. This recommendation was strongly welcomed by consumers.

81 Consumers Health Forum Australia, *Submission 17*, p. 7.

> Recommendation 15 called for the establishment of register for high-risk implantable devices and/or procedures. The recommendation followed the successful implementation of the National Joint Replacement Registry. Consumers have seen the benefits of the registry model, and would welcome the establishment of additional registries, with appropriate stakeholder consultation and involvement, in conjunction with other strategies to enhance adverse event reporting and action.[82]

3.85 The committee's 2011 report into the regulatory standards for medical devices also discussed the HTA Review and the need to implement these recommendations to strengthen monitoring and surveillance of devices in Australia.

Committee view

3.86 The committee notes that recommendations 13, 14 and 15 of the HTA Review are subject to further consideration by the Australian government. The Australian government is yet to respond to the committee's 2011 report that recommended the Department of Health and Ageing implement recommendations 13, 14 and 15 of the HTA Review recommendations in a timely manner. This point is reiterated in the context of the PIP breast implants recall and should be done as a matter of urgency.

Recommendation 11

3.87 The committee recommends that the Department of Health and Ageing implement recommendations 13, 14 and 15 of the HTA Review recommendations as soon as possible. The committee notes this recommendation was also made in its 2011 report on regulation of medical devices (recommendation 7).

82 Consumers Health Forum Australia, *Submission 17*, pp. 7-8.

Chapter 4

Personal impact of PIP breast implants on Australian patients

Key issues

4.1 The committee has concerns generally about the adequacy of the advice given to women considering breast implant surgery. It is important that patients have a full awareness of the risks of all breast implants. There is a real need for full advice to be provided prior to surgery about these risks, how long the implants will last, and the post surgical medical support that will be available.

4.2 The committee received evidence from many women who have had PIP breast implants for a variety of reasons ranging from cosmetic through to reconstructive purposes. Regardless of the reason for receiving PIP breast implants, the following areas of concern were common:

- A general lack of awareness by women that they were receiving PIP breast implants;
- Ongoing health issues since receiving PIP breast implants;
- Confusion and distress as a result of the information made available to the public (i.e. official technical advice issued by the TGA and media messaging);
- Lack of support from surgeons who conducted the implant surgery; and
- Inability to access MRI facilities in some areas.

4.3 This chapter explores these key areas and draws on evidence to highlight issues that were raised by submitters to this inquiry. It also sets out the committee's views and recommendations, where relevant, in each area.

Lack of awareness about PIP breast implants

4.4 A consistent theme of evidence provided to the committee was the lack of awareness by consumers that they had received PIP breast implants in the first place, followed by a lack of awareness by consumers that there was an issue with PIP breast implants in 2010.

4.5 Some submitters told the committee that they were not provided information about the implants and the manufacturer when they were considering breast implants, and that this denied them the opportunity to undertake research to further inform their choices. As one submitter advised, she had:

> ...met with a number of cosmetic and plastic surgeons throughout Perth to discuss the surgical correction of my asymmetry. As a close friend had undergone breast augmentation with surgeon A, I decided to proceed with his services. I underwent surgery on 17 April 2007, when surgeon A

> inserted PIP devices into my left and right breasts. I was not given a choice of implant manufacturer.[1]
>
> And
>
> ...I wasn't even told what he was using. I did not even receive a card with my implant information on it.[2]

4.6 Many submitters provided evidence indicating they found out about issues with PIP breast implants through the media in 2011/12, and then had to check their personal medical files to determine whether they had implants manufactured by PIP:

> After watching the 60 minutes program on 11th March 2012, I became concerned that I may have these PIP implants. After an extensive search of my house and old files I located my breast implant card and was devastated to learn that I had PIP implants. I was even more upset to learn that in April of 2010 the implants had been recalled, and yet I had heard nothing from my surgeon...[3]

4.7 As one submitter reflected in her submission, she had to contact the surgeon herself to determine what type of implants she had received:

> After seeing several news stories regarding PIPs and their scrutiny in the media, initially, I wasn't concerned, as I had received no contact from surgeon to inform me that these were the implants that I had. I wasn't aware at the time that I was a recipient of PIPs. After several more stories were frequenting local news I decided to email my surgeon for confirmation of the brand of my implants. To my shock I was informed that I had PIPs and should see a doctor and schedule a removal...[4]

4.8 Other submitters were aware the TGA had advised surgeons to contact patients about this issue, however reflected that no one had contacted them, despite the device being recalled in 2010.

> I am aware that they were recalled in April 2010. I am aware it was suggested that surgeons and clinics should contact their patients. They did not.[5]

4.9 Legal firm Tindall Gask Bentley provided evidence to the committee that a lack of communication from surgeons to women with PIP breast implants was a critical issue. As Mr White advised the committee at its public hearing:

> The TGA initially indicated that they wrote to the sponsor of the implants requesting that the sponsor write to the doctors that had used these

1 Name withheld, *Submission 32*, p. 1.

2 Name withheld, *Submission 47*, p. 1.

3 Name withheld, *Submission 35*, p. 1.

4 Ms Nikki Janeway, *Submission 19*, p. 1.

5 Name withheld, *Submission 26*, p. 1.

> implants. That was the initial position that the TGA advised in 2010. Subsequently, in one of the statements by the TGA—I think it was 23 March 2010—they said that they wrote to the doctors direct in January 2012. What I am hearing from a lot of women is that they are still being contacted up until recently by doctors, and this is the first occasion that they are hearing from doctors that they have PIP implants. It is now well over two years since the withdrawal of them, and women are telling me that they are only just being contacted by doctors to advise them that they have these implants. My point is that there is a massive breakdown in communication here.[6]

4.10 The TGA provided evidence to the committee that the responsibility for contacting surgeons and patients does not fall within their remit. In addition to explaining that the TGA is not responsible for regulating medical practice, the acting National Manager of the TGA stated:

> ...sponsors are required to keep records of people to whom those devices have been supplied so that in the event of a recall those people can be contacted, and that is the sponsor's responsibility.[7]

4.11 The TGA did however acknowledged that they understood that there was a lack of awareness among consumers about this issue and, in the evidence provided to the committee, indicated that the TGA did take action to encourage surgeons to contact their patients.

> **Dr Richards**...Because we could not get the results and we could not wait for the results, we thought we had better make sure the surgeons contact their patients. It is a professional responsibility that the surgeons have; it is a duty of care that they have. We provided the surgeons with the additional information. So the TGA medical officers came in on a weekend in early January [2012] and tried to call all the surgeons, and surprisingly got a lot of answering machines on a Sunday. They came in the next day and continued to contact them, and we sent registered letters. We got a list from the sponsor of all the surgeons and we sent registered mail to the surgeons to ensure that the surgeons received the information and were encouraged to contact their patients. We can lead horses to water, Senator—
>
> **Senator MOORE:** That was the first time the TGA had direct communication with the surgeons?
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> **Dr Richards:** Individual surgeons, because prior to that we took the view that that was the responsibility of the sponsor, and the sponsor had done that. We were getting reports from patients that they had not been contacted, so we took additional steps to encourage that to occur.[8]

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6 Mr Tim White, Tindall Gask Bentley, *Committee Hansard*, 9 May 2012, p. 16.

7 Dr Brian Richards, Therapeutic Goods Administration, Department of Health and Ageing, *Committee Hansard*, 9 May 2012, p. 29.

8 Dr Brian Richards, Therapeutic Goods Administration, Department of Health and Ageing *Committee Hansard*, 9 May 2012, p. 34.

Committee view

4.12 The committee is concerned that consumers receiving implantable devices have been provided with limited information about the device itself before surgery. The committee considers it a fundamental duty of medical practitioners to provide patients as much information as possible to allow them to make informed decisions.

4.13 Further, the committee is concerned with the limited follow-up from some surgeons to their patients regarding the PIP breast implants recall. Better data collection practices in the future may alleviate some issues identified with this process. The committee strongly believes that surgeons have a responsibility to proactively engage with their current and former patients over issues and concerns with implanted medical devices.

4.14 The committee also notes that similar issues were raised during this committee's inquiry into medical devices, which would appear to point to serious problems with the current system. The committee strongly advises the TGA, through the CMO, to consider providing medical practitioners with guidelines stating the TGA's expectations of them in these situations.

Recommendation 11

4.15 The committee strongly recommends that professional bodies, particularly the ASPS and ACCS, ensure through formal advice that surgeons are aware of their responsibilities to ensure that they provide an ongoing advisory role to their patients even after medical treatment has concluded.

Ongoing health issues

4.16 Although evidence about the health issues that individual patients encountered differed, the committee did receive common health complaints from women who had PIP breast implants. An example of the health issues are listed below in a submission made by Ms Jodie Blake:

> Breast pain, shoulder blade pain, neck pain, arm pain,
>
> Joint muscle pain, ovary pain, Chest pain.
>
> Short term memory loss.
>
> Swelling, fluid retention, Inflammation
>
> Breathing issues/shortness of breath
>
> Excessive hair loss, dry hair and skin problems, rashes allergies, sensitive to heat and cold.
>
> Low blood pressure, low blood sugar, dizziness/seeing stars vision issues, sensitive to light and sound, ringing in ears.
>
> Anxiety depression, hormone issues, dead limbs in sleep. Chronic fatigue.
>
> Rupture related: swollen enlarged breast, lumpy breast. Burning sensation. Excessive stretching which in turn has disfigured my breast.

> Recurring chronic abdominal pain and bowel problems, which I was hospitalised for requiring intravenous antibiotics to clear infection and anti-reflux medication and morphine for the pain.[9]

4.17 In addition to the health issues identified above, many women described experiencing soreness and tingling in limbs,[10] eye concerns,[11] autoimmune symptoms[12] and complications with lymph nodes containing silica.[13]

4.18 Many submitters spoke of the personal impact these issues have had on different aspects of their lives in addition to the health issues, such as:

- Inability to work on a full time basis due to health issues;[14]
- Adverse impact on engaging with their children effectively;[15]
- Financial impact through not being able to work and out of pocket expenses for surgeries;[16] and
- Significant anxiety and mental stress.[17]

4.19 The CMO, Professor Baggoley, noted the level of the consumer anxiety and distress in his report on PIP breast implants:

> Consumers have provided reports to the TGA on their experience with PIP breast implants. These reports are on local breast implant complications such as rupture and contractures, and anxiety and distress. A number of the consumer reports also described the consumer experiencing systemic symptom/s, such as fatigue, general malaise, hair loss and headaches, which are reported to be associated with their implant. The TGA is seeking consent from these individuals to contact their treating doctor to gain further information on the nature of their symptoms, and the results of any investigations.
>
> Systemic or general symptoms, such as fatigue and headache, may be experienced as part of many different health conditions. It is important that women experiencing these symptoms visit their medical practitioner so that

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9 Ms Jodie Blake, *Submission 33*, p.1.

10 Name withheld, *Submission 32*, p. 2.

11 Name withheld, *Submission 31*, p. 1.

12 Name withheld, *Submission 36*, p. 2.

13 Name withheld, *Submission 13*, p. 1; Name withheld, *Submission 32*, p.2; and Name withheld, *Submission 35*, p. 2.

14 Name withheld, *Submission 25*, p. 1; Name withheld, *Submission 36*, p. 1; and Name withheld, *Submission 18*, p. 1.

15 Ms Suellen Telford, *Submission 34*, p. 1; and Name withheld, *Submission 33*, p. 2.

16 Ms Nikki Janeway, *Submission 19*, p. 2; Name withheld, *Submission 12*, p. 1; Name withheld, *Submission 27*, p. 2; and Name withheld, *Submission 36*, p. 2.

17 Name withheld, *Submission 36*, p. 2; and Name withheld, *Submission 35*, p. 1.

> a personalised review can be carried out to exclude other underlying conditions.[18]

Committee view

4.20 The committee acknowledges the common health issues and adverse experiences of Australian women with PIP breast implants, particularly the emotional and financial stress this situation has caused.

4.21 The committee is encouraged by the TGA's steps in contacting individual treating doctors about symptoms, however would suggest more can be done in terms of acknowledging that it is ultimately the responsibility of the surgeon. Professional bodies, such as the Australian Society of Plastic Surgeons and the Australasian College of Cosmetic Surgery should be contacting their members and issuing formal advice about being cognisant of the personal distress these situations create and maintaining the highest standard of medical practice.

Breastfeeding mothers with PIP implants

4.22 A key concern expressed to the committee from women was the issue of breastfeeding while having PIP breast implants and the potential health impact this has had on their children. As one submitter explained:

> I have been left with industrial grade silicon and other chemicals inside of me, potentially endangering my child and myself.[19]

> And

> We don't know the long term effects that these implants may or may not have on our health. I hope every day that by breastfeeding my daughter unaware for 4months and three weeks that there will be no side effects to her, or long term health problems. Again I live with the guilt and the unknown. There is no definite proof over the long term effects or not on my daughter. I hope I am worrying for nothing but I just do not know. Had I known earlier then this could have at least been fixed.[20]

4.23 One submitter spoke of the health issues her child experienced since birth which may be attributed to breastfeeding with ruptured PIP breast implants:

> My ultrasound report was both implants ruptured with right hand side silicone in lymph nodes. Left one was leaking. I went into panic and shock. My baby was under 10 weeks old and I immediately stopped breastfeeding as I couldn't bare even the thought of feeding him through potentially toxic and unknown substances in my breast. He already had enough health problems

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18 Department of Health and Ageing, *Poly Implant Prothese Breast Implants: Report of the Chief Medical Officer*, April 2012, p. 17.

19 Name withheld, *Submission 32*, p. 2.

20 Name withheld, *Submission 26*, p. 2.

....

> My recent baby was born with fluid on his lungs, enlarged lymph nodes and cyst on his adrenal gland. I had a tougher pregnancy with him with a lot of pain on my right side ie pelvis, kidney, abdominal and headaches. He was born at 36.5wks. When he was around 5 wks old I was rushed to emergency in an ambulance again with unexplained right side pain.[21]

4.24 When questioned about the potential risk of breastfeeding with these implants, Dr Daniel Fleming from the Australasian College of Cosmetic Surgeons provided the following explanation:

> The silicone molecules are too large to get into the milk and there is more silicone in supermarket milk than there is in the breast milk of women with silicone breast implants.[22]

4.25 The UK Breastfeeding network has issued advice stating that although there have been no studies regarding the passage of gel contained in PIP breast implants, in general:

> Silicone by nature is extremely inert and is unlikely to be absorbed in the GI tract by a nursing infant although good studies are lacking. Silicone is a ubiquitous substance, found in all foods, liquids, etc.[23]

4.26 The TGA has also issued the following advice regarding health impact on babies from mothers with PIP breast implants breastfeeding:

> No toxic chemicals have been found in PIP breast implants (whether intact or ruptured) that are likely to affect the production of breast milk (lactation) in a woman with either ruptured or intact breast implants, or have any effect on the health of breast-fed babies.[24]

4.27 The Chief Medical Officers (CMO) report on PIP breast implants which was published on 7 May 2012[25] was silent on the issue of breastfeeding.

Committee view

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21 Name withheld, *Submission 13*, p. 1.

22 Dr Daniel Fleming, *Committee Hansard*, 9 May 2012, p. 27.

23 The Breastfeeding Network (UK), *Silicone Breast Implants and Breastfeeding*, http://www.breastfeedingnetwork.org.uk/pdfs/dibm/Silcone_Implants_and_Breastfeeding_January_2012.pdf (accessed 18 May 2012).

24 Therapeutic Goods Administration, *Consumers Questions and Answers*, 27 April 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120107.htm (accessed 18 May 2012).

25 Department of Health and Ageing, answer to question taken on notice, 9 May 2012, received 23 May 2012.

4.28 The Committee understands the deep concern felt by mothers concerning the effect ruptured implants could have on their children through breastfeeding. The committee notes the advice provided by the Therapeutic Goods Administration about breastfeeding children with PIP breast implants, however also noted the limited nature of evidence regarding the impact breastfeeding while having ruptured PIP breast implants.

Recommendation 12

4.29 The committee recommends that the clinical advisory committee established by the Chief Medical Officer should develop advice, based on current evidence regarding breastfeeding and PIP breast implants, as soon as possible, and that this information be included in future Chief Medical Officer reports on this issue.

Confusion with public messages

4.30 The committee heard from many submitters that part of their level of anxiety about the PIP breast implants resulted from contradictory public messages issued by the Australian Government and media reports.

4.31 The contradictory messages resulted from the TGA and CMO publicly advising that testing found no evidence that the risks involved with the use of PIP breast implants are any greater than those for any other brand of silicone gel-filled breast implants and recommended 'no routine removal of implants'[26] whereas the media reports broadcast by current affairs programs, *60 Minutes* (Channel Nine) and *Sunday* (Channel Seven) on 11 March 2012 stated women were living with "toxic time bombs".[27]

4.32 An example of this confusion with messaging in the media as opposed to what the TGA was recommending was highlighted by Ms Telford who stated she:

> ...was absolutely mortified and worried after reading all of the reports and media stories. I was also extremely confused, as reports from the TGA were conflicting with other things I was reading. Here we had the TGA saying they are fine, no cause for alarm and there's no evidence suggesting they are poisonous or that they rupture any easier or faster than other types of implants.
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> ...

26 Therapeutic Goods Administration, PIP breast implants – TGA update, 18 May 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120518.htm (accessed 20 May 2012);

27 Channel Nine Sixty Minutes, *Toxic Time Bombs*, 11 March 2012, http://sixtyminutes.ninemsn.com.au/article.aspx?id=8431882 (accessed 8 May 2012); Channel Seven, Sunday Night, Exploding PIP breast implants, 11 March 2012, http://au.news.yahoo.com/sunday-night/transcripts/article/-/13143657/exploding-pip-breast-implants/ (accessed 8 May 2012).

> These things are known to be made with none medical grade silicone! I am sick of hearing the TGA telling us that there is no evidence and they need to be tested...[28]

4.33 This contradictory public messaging contributed to Australian patients' anxiety with this issue. Professor Rodney Cooter from the Australian Society of Plastic Surgeons stated there was:

> ...unresolved anxiety out there and while that exists it is clear that patients would prefer to have the implants out. There is still a lot of doubt. The science that has been done is very robust, but there are still a lot of unanswered questions that, hopefully, will not be answered in a negative fashion later.[29]

4.34 As noted earlier, many submitters have stated they became aware of issues with PIP breast implants through the media and not from the TGA or their surgeons. While the committee accepts that not all individuals were adversely affected by becoming aware of this issue through media reports, and notes some women were grateful they were made aware of the issues through the media,[30] many submitters stated that their anxiety increased as a result of the coverage:

> All the while being sick with worry and not knowing what it was that I had implanted. News headlines reading "Ticking time bombs" and adding to a very stressful situation.[31]

> The Sixty Minutes program came as a shock to me on 11/03/2012. I had missed the media attention prior to this surrounding PIP breast implants. Of course I went and checked my file at home and was just dismayed to find that this was what I had in my body and no-one had bothered to inform me.[32]

> And

> After seeing information about PIP's on the television on the 11th of March 2012 I called the agency I went through for my surgery to find out if I had these implants, never expecting that I actually would. When they confirmed I did have the PIP's I was devastated and became an emotional wreck! I vomited and cried on and off for a couple of days and I couldn't sleep, I was so distressed about what I had in my body.[33]

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28 Ms Suellen Telford, *Submission 39*, p. 1.

29 Professor Rodney Cooter, Australian Society of Plastic Surgeons, *Committee Hansard*, 9 May 2012, p. 11.

30 Name withheld, *Submission 35*, p. 3.

31 Name withheld, *Submission 16*, p. 2.

32 Name withheld, *Submission 23*, p. 3.

33 Name withheld, *Submission 48*, p. 1.

4.35 Some submitters indicated that it was a combination of media coverage and lack of information from the TGA that contributed to their anxiety about PIP breast implants. As one submitter explained:

> News headlines reading “Ticking time bombs” have made it impossible not to panic about the risks to my health and the TGA’s information and advice helpline provided me with very little information and no comfort.[34]

4.36 The committee heard from the Consumers Health Forum Australia (CHFA) that media reports can exacerbate public concerns, particularly when there is an apparent lack of public information on the issue:

> We know there were some very vulnerable women—for example, women who were pregnant—and, when the scare stories went into the mainstream media like *60 Minutes*, there were women turning up to their GPs, asking if they should have terminations of their pregnancies... These were very vulnerable women, and misinformation like that which happened in the mainstream media really occurs when there is an information vacuum. Had the TGA been more active, mainstream and honest about what information it had and did not have, I think those expectations would have been moderated.[35]

4.37 DoHA advised the committee that there was a 'spike' in consumers' calls to the Breast Implants information hotline following media reports airing in March which may be a reflection of the anxiety generated from the coverage.[36]

4.38 The Australasian College of Cosmetic Surgery (ACCS) however indicated that the TGA's communication strategy did "not keep pace with its world leading testing and analysis work"[37] however also stated that the media reports had let Australian women down.

> The reliance largely on web-based information for patients and the lack of a more proactive communication strategy has created a vacuum which has been filled partially with inaccurate information. The result has been to undermine the public’s confidence in the TGA, which has further harmed women already understandably concerned about their health. Members of the College are seeing the consequences of this in consultations with patients every day.[38]

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34 Name withheld, *Submission 34*, p. 1.

35 Ms Karen Carey, Consumers Health Forum, *Committee Hansard*, 9 May 2012, p. 4.

36 Ms Jane Halton, Secretary, Department of Health and Ageing, *Committee Hansard*, 9 May 2012, p. 34.

37 Australasian College of Cosmetic Surgeons, *Submission 24*, p. 5.

38 Australasian College of Cosmetic Surgeons, *Submission 24*, p. 5.

4.39 Dr Fleming, in his capacity representing the ACCS at the public hearing, reiterated this point to the committee, stating the media coverage was 'sensationalistic' and undermined the public confidence in the TGA:

> ...do not underestimate the effect that this undermining of confidence in the TGA has had on patients, to the extent that I have had patients who have been considering aborting wanted pregnancies for fear of damage to their unborn children from PIP implants—and there is absolutely no medical reason or evidence behind that at all. They have simply been terrorised by sensationalistic media reporting, which has not been matched by a sufficiently robust communication strategy from either the TGA or the government.[39]

4.40 The CHFA indicated that the TGA had actively taken steps of alerting the Australian public to the issues with the PIP breast implants and that they welcomed the "move towards increased transparency and improved communication from the TGA".[40]

4.41 The committee received evidence that the TGA has responded in a "timely, appropriate and evidence based manner to concerns"[41] with PIP breast implants, however communication about the issues and information sharing could always be done more effectively.[42] The individual women who provided evidence to the committee however did not often view this messaging in the same light, often questioning the rationale that lead to the recommendation that immediate removal was not necessary:

> If the product is safe enough to be left in our bodies in the TGA's opinion, why have they stopped the sale of the device for new procedures? The regulatory bodies of other advanced Western societies such as the UK, France, Germany and the USA have announced that the product is not safe.[43]

4.42 The TGA has issued 33 alerts, updates and information (including consumer questions and answers) on their website since April 2010.[44] The committee heard from the TGA that although their role is not to regulate medical practice, they did

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39 Dr Daniel Fleming, Australasian College of Cosmetic Surgeons, *Committee Hansard*, 9 May 2012, p. 24.

40 Consumers Health Forum Australia, *Submission 17*, p. 3.

41 Australasian College of Cosmetic Surgery, *Submission 24*, p. 1.

42 Consumers Health Forum Australia, *Submission 17*, p. 5.

43 Name withheld, *Submission 34*, p. 1.

44 Example of TGA alert, *PIP breast implants – TGA Update*, 18 May 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120518.htm (accessed 20 May 2012).

encourage doctors to contact their patients on this issue as they do not have to power to direct surgeons to contact individuals.[45] Dr Richards explained to the committee:

> ...advice from the TGA to consumers, to patients, was to contact their doctor.
>
> ...
>
> The TGA has no role in regulating medical practice and does not record, nor has it the authority to record, details of individual patients to whom these devices are supplied.[46]

4.43 The communication provided by the TGA appears comprehensive; however this is only effective if consumers know where to access this information. When this point was raised with the TGA, Dr Richards advised the committee that "this recall was published in the media as well".[47] While this may be the case, the evidence provided to the committee showed that the TGA's communication strategies are not always effective in raising awareness with affected individuals.

Committee view

4.44 The committee notes the TGA does not have a role in maintaining individuals information and communicating with them directly about medical devices, however also notes the efforts the TGA has undertaken in providing as much information as possible to consumers via their website and engagement with surgeons directly.

4.45 Based on the evidence received, the committee considers that media reports on PIP breast implants contributed to Australian patients' anxiety.

4.46 The committee encourages the TGA to continue to issue regular alerts regarding PIP breast implants, and include in these updates information about what the TGA is currently investigating further. The committee suggests the CMO issue frequent media releases regarding the PIP breast implants situation, providing the most current advice, a summary of the facts and what further testing is being undertaken to facilitate accurate media coverage on this issue.

Lack of support from surgeons

4.47 In addition to the lack of notification from surgeons about the issues with PIP breast implants, the committee also heard evidence regarding a lack of support from some surgeons and, in some instances, inappropriate responses from surgeons when patients tried to seek further information about their implants. One woman shared with the committee her experience of contacting the surgery to seek more information only to be told the surgery did not use PIP implants.

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45 Dr Brian Richards, Therapeutic Goods Administration, *Committee Hansard*, 9 May 2012, p. 35.

46 Dr Brian Richards, Therapeutic Goods Administration, *Committee Hansard*, 9 May 2012, p. 35.

47 Dr Brian Richards, Therapeutic Goods Administration, *Committee Hansard*, 9 May 2012, p. 35.

> When I called my surgeon to ask them about my implants, as I had a small card stating that I indeed had PIP implants, they denied ever using them at their clinic. It was after much arguing with them that they agreed that I did in fact have these implants in my body as I had the Identification card in my hand.[48]

4.48 Others submitters spoke of contacting their surgeons and being made to feel as if they were overreacting.

> They made me feel as though I had done something wrong and that I was wasting their time with my phone call. When I got off the phone I could not stop crying, I did not call them because I was angry, I called them for advice and support...[49]

> And

> They told me I was being stupid and irrational and there was no cause for concern, while shooing me out the door they gave me an information sheet regarding the bankruptcy and concerns of the PIP implants.[50]

4.49 Some patients actively sought information from both government information sites as well as from their surgeons. The evidence received reflected frustration when women were directed back to their medical practitioner. Submitters explained that there seemed to be no one taking ownership of the issue:

> I was disappointed to have to hear about the PIP implants issue through the media and not to be contacted by my doctor personally to be advised. I become aware of it in December and of course was extremely concerned. I immediately contacted my surgeon to be advised [their] records detailed I had PIP implants. I was emailed the government link and advised the media was over reacting, and if I was concerned to contact my local GP.[51]

> And

> ...I question that the TGA, the government and the surgeons themselves would not feel it is fit to inform people as a mandatory course of action when something like this happens. I have also been shocked by the surgery's "nothing to do with us" attitude about the faulty goods supplied.[52]

4.50 The committee heard evidence from Dr Fleming about what the process is for surgeons when these concerns are raised with them:

> The first thing is that the patients must have access to the doctors; they must not be fobbed off. They need to be seen for a consultation or, if they live in a far-distant place, they need to have a rapid telephone consultation with the

48 Ms Jodie Blake, *Submission 33*, p. 1.

49 Name withheld, *Submission 35*, pp. 1-2;

50 Name withheld, *Submission 7*, p. 2.

51 Name withheld, *Submission 35*, p. 1.

52 Name withheld, *Submission 23*, p.3.

> doctor. In the first instance, having had the specific conversation with the patient, we would direct them to the video series. There is information there which is factual, understandable and evidence based. Our experience has been that if patients watch the video series their anxiety levels are substantially abated. Nobody is saying there is not a potential problem with PIP implants. We would then recommend the patient have an MRI scan—that is why the Medicare rebate is so important—to see whether the implant is ruptured.[53]

4.51 Both the plastic surgeons and cosmetic surgery bodies, the ASPS and ACCS respectively, have codes of practice for their members that set out guidelines for ethical practice and achieving the highest quality of patient care. Both codes refer to members having to undertake their medical practice in a client-centred manner. In regards to adverse events or complications, the ASPS code specifies the following:

> If the patient suffers an adverse event, or has an outcome that is less favourable than expected, members must provide the patient with an open and honest explanation of what has happened. There should be no attempt to cover up any complication or medical error.[54]

4.52 The ASPS code states that any person may bring a complaint against an ASPS member and that complaints must be made in writing and anonymous complaints will not be accepted.[55]

4.53 The ACCS code of practice reflects their members must "practice with integrity and honour, in the best interests of their patients, and with the patient's safety and quality of care being paramount."[56] This code also sets out that members need to provide "full and adequate" post-operative care, and sets out a detailed complaints process for consumers should the care not be appropriate. This process also stipulates complaints must be in writing.[57]

Committee view

4.54 Based on the evidence received regarding PIP breast implants, the committee is very concerned that some medical practitioners have not appropriately responded to patients when approached to provide information and support in light of issues with PIP breast implants. The committee views medical practitioners simply referring patients to a national information line as being an unacceptable response.

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53 Dr Daniel Fleming, Australasian College of Cosmetic Surgery, *Committee Hansard*, 9 May 2012, p. 25.

54 Australian Society of Plastic Surgeons, *Code of Practice 2011*, p. 10.

55 Australian Society of Plastic Surgeons, *Code of Practice 2011*, p. 13.

56 Australasian College of Cosmetic Surgery, *ACCS Consumer/Patient Code of Practice*, p. 4.

57 Australasian College of Cosmetic Surgery, *ACCS Consumer/Patient Code of Practice*, p. 14.

4.55 The committee encourages women who have felt mistreated by their medical practitioners to lodge complaints as per the processes outlined in the professional codes of practice.

4.56 The committee also encourages the Chief Medical Officer to write to medical practitioners that have been known to use PIP breast implants across Australia reminding them of their obligations under their professional codes of practice and to provide accurate information to women with PIP breast implants.

4.57 The committee is also of the view that it would be useful for the TGA to raise awareness among both the public and medical professionals about the provision of appropriate information relating to medical devices. The TGA, through the CMO, should also consider whether it is relevant to require medical practitioners to provide comprehensive written information to patients about the device they have been implanted with, and whether the TGA or other relevant body should impress on patients the importance of having this information in case of recall. The committee considers an increased emphasis on consumer education in health could have resulted in better outcomes for affected women in this instance. Consumers that are educated and aware of the services and treatments available to them, as well as their potential implications are more likely to make fully informed decisions and to recognise any issues before they are otherwise alerted.

Inability to access MRI facilities

4.58 In order to accurately evaluate the integrity of PIP breast implants, an MRI scan needs to be undertaken and the MRI machine requires a breast coil to undertake this evaluation.

4.59 The committee understands that not all Australian women have access to the necessary MRI machines with the breast coil to assess whether their implants have ruptured and require removal. When asked if these machines with breast coils were easily accessible all across Australia, Mr Bartlett from the Department of Health and Ageing advised the committee that:

> They are reasonably accessible all across Australia. I think it is fair to say that MRIs are not distributed right across the country. You find considerably more in metropolitan areas than you do in regional.
>
> **CHAIR:** What about northern Australia?
>
> **Mr Bartlett:** I think there is an MRI machine in Darwin.
>
> Senator **MOORE:** With a breast coil?
>
> **Mr Bartlett:** I could not tell you that for sure, I would have to check the map as well.[58]

58 Mr Richard Bartlett, Department of Health and Ageing, *Committee Hansard*, 9 May 2012, p. 37.

4.60 According to the list of diagnostic imaging practices that provide breast MRI service there are a number of MRI machines with this breast coil throughout Australia in both regional and metropolitan areas. However, at the time of taking evidence for this inquiry, there were no breast coil facilities available in the Northern Territory which means patients in northern Australia cannot access these facilities.[59] The Department of Health and Ageing advised the committee:

> The Northern Territory has one Medicare-eligible MRI unit located at Royal Darwin Hospital. This unit has recently procured a breast coil and will be accepting PIP patients from 5 June 2012.[60]

Committee comment

4.61 The committee believes readily accessible MRI facilities throughout Australia are critical. It is noted that current MRI breast coil machines are spread fairly widely across Australia, however the committee was disappointed that patients in the Northern Territory did not have access to breast coils in order to assess whether a rupture has occurred when the product was recalled. The committee is pleased that this facility will now be available to affected women in the NT in June 2012.

59 Department of Health and Ageing, List of Diagnostic Imaging Practices that Provide Breast *MRI services*, http://www.health.gov.au/internet/main/publishing.nsf/Content/1FC8BB90FA205A1BCA2579C600081471/$File/Table%20of%20Eligible%20PIP%20MRI's%2027%20April%2012.pdf (accessed 21 May 2012).

60 Department of Health and Ageing, answer to question taken on notice, 9 May 2012, received 23 May 2012.

Chapter 5

Summary of key issues

5.1 The scope of this inquiry was narrow in that the terms of reference focussed particularly on the TGA's role in managing the PIP breast implants recall in Australia. The committee received useful evidence over the course of the inquiry, however the data it received is limited in terms of 'unknown' information, such as how PIP breast implants compare with other silicone implants, and what the level of risk is from PIP implants.

5.2 Although the scope of this inquiry was limited, the PIP breast implants situation has raised some key issues regarding the TGA handling of medical device recalls. These include:

- The critical need for the TGA to issue regular updates to consumers, medical practitioners and suppliers regarding device recalls, and the importance of including what information they know and what information they are developing, including what evidence is being gathered through further testing or follow up with international regulators.
- The importance of monitoring and following up conditions that are placed on sponsors when a medical device is included in the ARTG, not just when an issue is identified.
- The need for comprehensive and accurate data collection when patients receive implants so this can be drawn on in the event of a device recall.
- Post market surveillance is critical for monitoring the effectiveness of medical devices, and the role that everyone plays in this process is not always clear.
- Where consumers have raised issues, such as breastfeeding with implants, this needs to be addressed in formal advice from the Australian Government.

5.3 During this inquiry, the committee did not receive any evidence regarding general safety issues with silicone breast implants. It is unclear whether the issues raised during this inquiry are specific to PIP breast implants, or whether breast implants in general can lead to similar outcomes. This chapter outlines key areas which remain unclear to the committee based on the current information.

Comparative rupture rates of breast implants

5.4 The committee received evidence that all devices have risks and implantable devices are likely to have a failure rate.[1] What remains unclear is whether risks identified with PIP breast implants are the same as all other silicone breast implants. The Australian government advice on PIP breast implants remains as follows:

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1 Australian Medical Association, *Submission 2*, p. 1.

> Testing undertaken by TGA to date has not found evidence that the risks involved with the use of PIP breast implants are any greater than those for any other brand of silicone gel-filled breast implants.[2]

5.5 Following the recall, the TGA reviewed its data regarding the number of reports of rupture of PIP breast implants as well as other adverse events associated with this device:

> From 2002 to April 2010 TGA had received 22 reports relating to rupture of PIP implants. At 4 January 2012 the number of reports relating to rupture was 37.[3]

5.6 As at the 25 May 2012, the TGA had confirmed reports of PIP breast implants was ruptures was 287.[4] This is a significant increase in reported ruptures; however the TGA update does not provide further explanation regarding this increase since 2010.

5.7 Some submitters referred to data that highlighted higher rupture rates of PIP breast implants which seemed to fuel patient anxiety in light of the TGA advice stating risks with these implants were the same as other silicone implants. As one submitter explained:

> I was advised that an Australian Plastic Surgeon..., was also experiencing a 20% rupture rate from his PIP patients. So I was aware that there was a real problem with the PIP breast implants including an unacceptable rupture rate and many women suffering distressing symptoms (with or without rupture).[5]

5.8 This reported rupture rate was made by Dr Timothy Cooper, and in response to this report, Dr Richards from the TGA explained:

> The evidence is that most of these women had a rupture on one side and an intact implant on the other. That is in fact a rupture rate of the device of around 10 per cent. That is how rupture rates are usually quoted in the international literature and the FDA reviews. Dr Cooper reported an experience of 20 per cent of his patients having had a rupture, which is around the same as saying a 10 per cent rupture rate.

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2 Therapeutic Goods Administration, *PIP breast implants – TGA update*, 25 May 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120525.htm (accessed 28 May 2012).

3 Department of Health and Ageing, *Submission 30*, p. 31.

4 Therapeutic Goods Administration, *PIP breast implants – TGA update*, 25 May 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120525.htm (accessed 28 May 2012).

5 Name withheld, *Submission 36*, p. 3.

> Rupture is a known complication of any type of breast implant, whether it is saline or silicone, whether it is PIP or any other brand. Ruptures are a common event.[6]

5.9 At this inquiry's hearing, Dr Fleming of Australasian College of Cosmetic Surgery that, told the committee the rupture rates of PIP breast implants are not yet known and MRI scanning will be critical to determining the true rupture rates of these implants:

> We have a huge number of people out there who have had MRI scans. Not only that; if they have a rupture on the MRI scan they will be having surgery which will confirm or deny the accuracy of the MRI scan. We know what rupture rates are from MRI scans and from the FDA studies of Allergan and Mentor implants. We know, for example, Mentor implants have a rupture rate of 13.6 per cent by 10 years after implantation. I believe—and it is just based on anecdote, on what I have seen and from talking to my colleagues since we have had these MRIs available to us—that there is an increased rupture rate with PIP implants and I believe that there is an early spike.[7]

5.10 The TGA continues to test PIP breast implants and the TGA expert panel, at its meeting of 17 May 2012, noted data from the subsidised MRIs over the next year will assist in ascertaining the rupture rates of PIP implants.[8] This expert panel also noted:

> ...the importance of clinician engagement in any epidemiological studies designed to investigate rupture rates further and encouraged implanting surgeons to actively participate in any such study.[9]

5.11 The fact that rupture rates for PIP implants is not known was also reiterated by the Department at the hearing:

> The evidence in relation to the actual rupture rate for PIP implants is still not conclusive. No-one really knows...
>
> We understand that a number of surgeons and radiologists are collaborating to try and collect better data now that more women are having access to MRI scans. So in 2010, when these devices were recalled, there was no suggestion that they were likely to have an increased rupture rate compared

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6 Dr Brian Richards, Therapeutic Goods Administration, *Committee Hansard*, 9 May 2012, pp. 30-31.

7 Dr Daniel Fleming, Australasian College of Cosmetic Surgery, *Committee Hansard*, 9 May 2012, p. 24.

8 Therapeutic Goods Administration, *PIP breast implants – TGA update*, 25 May 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120525.htm (accessed 28 May 2012).

9 Therapeutic Goods Administration, *PIP breast implants – TGA update*, 25 May 2012, http://www.tga.gov.au/safety/alerts-device-breast-implants-pip-120525.htm (accessed 28 May 2012).

> to other modern breast implants... But, as 2012 has evolved and more and more women who, frequently, have no symptoms are having MRI scans and discovering ruptures, we are gradually getting better data, but we do not have a definitive rupture rate.[10]

Committee view

5.12 The committee is of the view that given the true rupture rate of PIP breast implants is not yet known, and that only further data collection and studies will determine this, then this should be reflected in the official advice issued by the TGA.

Recommendation 13

5.13 The committee recommends that the TGA include in their advice that it is unclear whether PIP breast implants rupture more than other silicone breast implants and that further testing and investigation of PIP breast implants will continue to inform this advice.

Manufacturing quality control for PIP breast implants

5.14 It also remains unclear to the committee whether the critical concern with PIP breast implants is the manufacturing quality control. As Dr Fleming advised the committee, the 'spike' in an increased rupture rate may be attributed to practices undertaken in developing these implants:

> What I do not know is whether or not that is due to poor manufacturing practices or poor quality control rather than something intrinsically weak in the implant because unapproved gels were used.[11]

5.15 The French regulator advised in recalling the device that the manufacturer had replaced 'unauthorised silicone gel' for the silicone gel which had been approved for use.[12] In response the TGA tested un-implanted PIP breast implants during April, May and June 2010 to assess the risk of this device, particularly in regard to risk of rupture and the gel toxicity:

> Testing involved samples from eight batches of product covering a range of sizes and dates of manufacture and included both smooth and textured shells. Samples were tested with respect to their physical and mechanical properties (resistance to rupture) as well as for cytotoxicity (that is, propensity to cause damage to cells). The shell and gel of implants were found not to be cytotoxic and tensile tests on the shell material and the shell seams and seals showed that the implants met the requirements of the applicable international standards.

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10 Dr Brian Richards, Therapeutic Goods Administration, *Committee Hansard*, 9 May 2012, p. 31.

11 Dr Daniel Fleming, Australasian College of Cosmetic Surgery, *Committee Hansard*, 9 May 2012, p. 24.

12 Department of Health and Ageing, *Submission 30*, p. 32.

5.16 In January to April 2012, the TGA also undertook a review of the 2003 onsite audit of the French manufacturer PIP and the findings remain:

> ...that the documentation reviewed by the TGA auditors contains no irregularities that would have signalled the intention of PIP to use unauthorised silicone (filler) in the implant. The specification for the silicone implant material reviewed by the auditors was consistent with the material submitted and approved by the TGA.[13]

5.17 It is still unknown whether the unauthorised silicone used by the PIP manufacturer is dangerous and will cause adverse health implications for patients. The committee heard evidence stating silicone in itself is not toxic and there is not much difference between 'industrial' and 'medical grade' silicone.[14] However, this is little comfort to Australian patients that may have implants made of unauthorised silicone with the chance of the implants rupturing and this spreading in the body.

5.18 The TGA continues to test implants throughout 2012 and there continues to be no "specific safety concern for PIP breast implants" identified from mechanical, toxicology or chemical tests carried out.

Committee view

5.19 The committee notes that there is limited evidence regarding whether poor manufacturing has contributed to the current situation with PIP breast implants. Further, it is unclear whether implants with unauthorised gel have been used in the Australian market which only testing of implants that have been removed will determine. The committee strongly urges the TGA to undertake testing of explanted PIP implants as a matter of priority to inform official advice about PIP manufacturing quality.

Conclusion

5.20 There is no denying the PIP situation has generated concern and distress amongst Australian patients. Australian women have been adversely affected through this process as many have indicated health concerns, particularly anxiety which in itself is an illness.

5.21 Given the situation, information should be as accessible as possible, for both consumers and medical practitioners so they can support their patients in advice they provide. Issues regarding clear communication and processes for accessing information and reporting problems with medical devices are not new and have been raised before with the committee.

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13 Department of Health and Ageing, *Submission 30*, p. 35.

14 Dr Daniel Fleming, Australasian College of Cosmetic Surgery, *Committee Hansard*, 9 May 2012, p. 25.

5.22 While consumer input is invaluable to the monitoring of the performance of medical devices, consumers often do not know how to navigate and interact with complex regulatory systems so information needs to be tailored, comprehensive and easy to find in order to be effective.

5.23 There are multiple players in the medical system that all play important but distinct roles. Patients navigating this complicated system, particularly in distressing situations, do not need to encounter responses that simply refer them on to other professionals or to be told that there is nothing anyone can do. The PIP breast implant situation highlighted shortfalls at many levels, and all those involved need to adopt a considerate and informative response to women with PIP breast implants.

Senator Rachel Siewert

Chair

Additional comments by Government Senators

1.1 An issue highlighted by both this inquiry and the inquiry into medical devices is the need for greater clarity of the role of the TGA and the role of the Chief Medical Officer (CMO) in high risk implantable medical device recalls.

1.2 While the TGA, through the recall process, has responsibility for informing sponsors that the medical device is no longer on the ARTG and therefore unable to be used in Australia, it is less clear who, if anyone, has responsibility for providing general clinical advice to the population of patients who continue to have their high risk medical devices implanted.

1.3 Nothing can, nor should, replace the clinical advice provided directly to individual patients by their treating health professional; however it is clear from evidence that there was an expectation from consumers that either the TGA or the CMO would provide general clinical advice.

1.4 In the case of the PIP recall the convening of an expert clinical group (albeit two years after the recall) by the CMO to develop such general advice and monitor any change in evidence emerging from the work of the TGA, would appear to be an appropriate model.

1.5 Government Senators suggest that the more routine use of such a model in the case of high risk medical device recalls be explored by DoHA and the CMO and that a clear set of protocols be developed.

Senator Claire Moore **Senator Carol Brown**

Additional comments by Senator Xenophon

The human consequences of regulatory failure

Nick Xenophon, Independent Senator for South Australia

1.1 I would like to acknowledge the many witnesses who provided information to the committee of their own personal experiences with the PIP breast implant devices. This evidence was vital to the committee's understanding of the impact this recall has had on people who were implanted with these devices, and I thank these courageous individuals for their testimonies.

1.2 Many of the issues raised in this inquiry in relation to the Therapeutic Goods Administration were also raised in the previous inquiry into medical devices, undertaken by this committee. I am very concerned that there is a common thread of serious problems in relation to approval and post-market monitoring of devices, and communication of information to the public. While I acknowledge that the TGA has been much more forthcoming in this case in comparison to the withdrawal of the De Puy hip devices, I am concerned that evidence was provided to the committee which still demonstrates significant systematic failures in the TGA's systems.

1.3 It is very unfortunate that Medical Vision Australia refused to appear before the committee, or to provide information in any way. Engagement with the committee process would have shown a willingness on the part of MVA to be involved in discussing the failures of regulatory systems in Australia and overseas, and how they can be addressed. I also believe MVA's participation would have been meaningful for the individuals who have been affected by these implants.

1.4 I am also concerned about MVA's refusal to participate in the inquiry in light of the company's restructure last year. According to records from ASIC, in December 2011 the company appeared to separate its cosmetic arm from its other operations, forming two separate companies (Medical Vision Australia Cardiology & Thoracic Pty Ltd, and Medical Vision Australia Plastic & Cosmetic Pty Ltd)[1]. It would have been very useful for MVA to state on the record the reasons for this split, and the impact this split may have on individuals seeking legal redress, including whether it

[1] Australian Securities and Investments Commission, *ASIC Historical Company Extracts*, 24 January 2012 (attachment 1)

would make it more difficult for victims of the product MVA sponsored to seek compensation.

1.5 It is also important to note that the lack of a properly operating breast implant device registry added to the difficulties faced by the TGA and other bodies in collecting information on the PIP device. The new 'opt-out' registry discussed by Associate Professor Rodney Cooter, President of the Australian Society of Plastic Surgeons[2], should be strongly and immediately supported by the Government, as the previous inquiry into medical devices demonstrated the importance of a comprehensive, properly operating registry.

1.6 The arrangements in relation to the Special Access Scheme and informed consent are very concerning, and indeed appear woeful. While it evident that such a scheme should be in place to assist seriously ill patients who require specialist products, it is hard to see how the SAS would be relevant for breast implant devices, when there are already many approved devices to choose from. I support the committee's recommendation in this matter.

1.7 The TGA's lack of follow-up in relation to the provision of annual reports by sponsors of Class III medical devices, as required by the standard condition placed on sponsors when devices are listed on the Australian Register of Therapeutic Goods, is unacceptable. While I acknowledge that a follow-up system was established in 2011 and is now in place, it is vital that the TGA collect and analyse all missing information to ensure that there is no risk to Australian health consumers. This example also points to a lax attitude towards post-market monitoring within the TGA, which was also apparent during the previous inquiry into medical devices. While I note that the TGA has acknowledged this and is taking steps to create a more positive, pro-active stance, it does raise the question of how many problems we will be facing in the future because action was not taken in the past. I strongly endorse the committee's recommendation regarding this issue.

1.8 I note the committee's comments in relation to the fact that either the TGA or the sponsor of a device can take action in response to issues with a device. In response to the committee's report on the inquiry into medical devices, I raised concerns about the use of 'voluntary withdrawals' as opposed to recalls. It hints at a potentially

[2] Professor Rodney Cooter, Australian Society of Plastic Surgeons, *Committee Hansard,* 9 May 2012, p. 8

conflicted relationship between the TGA and the sponsor. The Hon. Dr Michael Armitage, of the Australian Health Insurance Association, provided evidence to that committee in relation to the importance of recalls as a type of sanction for companies[3]. A voluntary withdrawal obviously does not have the same impact.

Additional Recommendation: That an independent review of the TGA's processes relating to device withdrawals and recalls be conducted within the next 12 months, with a view to strengthening the TGA's position as an independent regulator

1.9 The previous committee inquiry also made several recommendations in relation to adverse event reporting, as noted in the committee's report. The Government has yet to respond to these recommendations. It is my position that the PIP breast implant device recall, and the issues surrounding it, emphasise the urgent need for reform in this area.

1.10 It is extremely concerning that evidence provided to the committee showed serious flaws in the TGA's original approval of the PIP devices. Presumably the processes relating to the clinical evaluator and the Medical Devices Evaluation Committee (as it was at the time) exist so that devices are only listed when the appropriate conditions and safeguards are in place. It is incomprehensible that the TGA would not follow the recommendations made by its own advisory committee (MDEC) in relation to comprehensive annual reports from the sponsor. It seems very unlikely that this expert committee, specifically set up to provide "independent medical and scientific advice to the Minister and the Therapeutic Goods Administration (TGA) on the safety, quality and performance of medical devices supplied in Australia including issues relating to premarket conformity assessment and post market monitoring"[4] would make these recommendations without reason. I believe the committee ought to have gone further and emphasised that this recommendation was not followed seems to indicate a 'low risk' attitude towards breast implant devices which is unacceptable given their Class III rating.

1.11 The fact that the approval for the device rested on the "arguments for essential similarity"[5] when there was limited clinical data is also very concerning.

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[3] The Hon. Dr Michael Armitage, AHIA, Community Affairs References Committee Hansard, 27 September 2011, p 4

[4] Therapeutic Goods Administration website: http://www.tga.gov.au/archive/committees-mdec.htm, retrieved 29 May 2012

[5] Department of Health and Ageing, *Submission 30*, p. 25

Recommendation 4 from the committee's previous inquiry into medical devices was a specific response to very real concerns that an increased number of very similar devices on the market do not necessarily equal better health outcomes[6]. In fact, thanks to the comprehensive data collected by the National Joint Replacement Registry, we know that many of the hip and knee prosthetic devices approved for use in Australia perform "worse, or no better than, those that are currently available"[7]. This fact refutes the very idea that a device should be approved on the grounds that it is 'essentially similar' to another device.

1.12 These circumstances raise particular concerns, especially when compared to the example of the Food and Drug Administration (FDA) in the US for a similar time period. As addressed in the committee's report, Dr Daniel Fleming of the Australasian College of Cosmetic Surgery provided evidence that, between 1992 and 2006, the FDA did not approve any silicone implants, and currently has only approved three brands. According to Dr Fleming, this is due to the FDA's requirement in relation to long-term pre-market approval studies[8].

1.13 It is also important to note that it is on the public record that surgeons were notifying the TGA of problems with these implants. In particular, Dr Tim Cooper, a plastic surgeon from Western Australia, stated on the ABC's *Background Briefing* program that he had written to the TGA with his concerns about the high failure rate of the device[9]. He was informed by the TGA that no further action would be taken at that time, and that they would continue to monitor the situation[10]. This was clearly an unsatisfactory response. Dr Cooper, and others like him, should be applauded for their efforts to encourage action on the part of the TGA in relation to these devices.

1.14 The committee also received evidence that some individuals with PIP implants were not contacted by their surgeons and, as a result, these individuals only became aware of problems with their devices through the media. This is totally unacceptable but, unfortunately, is consistent with evidence provided to the previous

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[6] Community Affairs References Committee, *Report on the regulatory standards for the approval of medical devices in Australia*, p. 99

[7] Ibid, p. 100

[8] Dr Feming, *Committee Hansard*, 9 May 2012, p. 23

[9] *Background Briefing*, 5 February 2012, online: http://www.abc.net.au/radionational/programs/backgroundbriefing/pip-implants/3804660#, retrieved 31 May 2012

[10] Ibid

inquiry on medical devices[11]. I support the committee's recommendation in relation to this, as well as the committee's advice that the TGA provide medical practitioners with written guidelines to outline their responsibilities in these situations.

1.15 I also support the committee's comments in relation to the TGA's reliance on their website as the primary form of communication with the public. An average health consumer cannot be expected to constantly check the website just in case the device they have been implanted with has been recalled. While I encourage the TGA's efforts to provide information and updates through their website, it is clear that a more comprehensive alert system is needed, particularly given the fact that surgeons do not (or cannot) always make contact with their patients to pass on information.

1.16 The issue of the type of information provided by the TGA also needs to be addressed. I commend the TGA for their increased efforts at transparency and public awareness, especially compared to their activities in relation to the De Puy hip devices. However, it is important that the TGA also provides the public with details of what further information they are seeking, what further testing they are undertaking, and so on. This will help to reassure health consumers that the TGA takes these types of issues seriously, and is acting accordingly. I support the committee's recommendation in relation to this.

1.17 One example of the TGA's poor communication is the response to a question on notice I received from the TGA in relation to the gel contained in PIP implants available in Australia. I asked whether the gel in the implants was in fact the same gel that was originally approved, and the TGA's response was that the gel "conform[ed] to the relevant international standards for this type of product" and that the samples tested had "superior physical properties to the approved gel"[12]. In response to another question on notice as part of this inquiry, the TGA finally provided a more satisfactory answer, which explained the issues with testing and detailed the TGA's methods and knowledge[13]. While I acknowledge the TGA may not have had as much information when it answered my original question in October 2010, an open and straightforward answer about what the TGA knew so far and what they were intending to find out would have been welcomed. This type of open communication is also much more

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[11] Community Affairs References Committee, *Report on the regulatory standards for the approval of medical devices in Australia*, p. 76

[12] Therapeutic Goods Administration, answer to question on notice, Budget Estimates June 2010, received 11 October 2010 (attachment 2)

[13] Therapeutic Goods Administration, answer to question on notice, received 23 May 2012

helpful to health consumers, as opposed to answers that appear to be constructed specifically to hide something, even if this is not the intention. I strongly agree with evidence provided by Ms Karen Carey of the Consumers Health Forum, who stated:

> *"Had the TGA been more active, mainstream and honest about what information it had and did not have, I think those expectations [of health consumers] would have been moderated."*[14]

1.18 The TGA's delay in finding examples of explanted PIP devices to examine is also concerning. The current testing regime, where devices can be tested by the TGA, the manufacturer or other parties, appears to disadvantage the TGA as it may not have had the opportunity to examine an explanted device before a recall or withdrawal. If this system had operated more effectively, the TGA would have been able to carry out tests on explanted devices already in their possession, rather than facing a delay while devices were procured.

1.19 I strongly support the committee's comments in relation to DOHA's assertion that "there will always be under-reporting" in relation to medical devices[15]. As the committee asserts, the National Joint Replacement Registry, operated by the Australian Orthopaedic Association, has an excellent history of data collection. Evidence from the NJRR was instrumental in the committee's previous inquiry into medical devices, and this registry should be considered as the benchmark in Australia. I also support the committee's recommendation in relation to this, although I believe it would be appropriate to aim for comprehensive registries for all implantable medical devices in Australia.

Additional Recommendation: That an independent inquiry be undertaken into the feasibility of establishing comprehensive registries for all implantable medical devices in Australia

1.20 I endorse the committee's comments in relation to the TGA's national hotline. While such a service could have been invaluable, the committee received evidence from heath consumers that the hotline did not provide them with the information and support they needed. The TGA should conduct an internal review into the operation of the hotline so that such a service can be offered more effectively in the future.

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[14] Ms Karen Carey, Consumers Health Forum, *Committee Hansard*, 9 May 2012, p. 4

[15] Department of Health and Ageing, *Submission*, p.31 footnote 26

Additional Recommendation: That the TGA conduct or commission a review into the operation of its National Hotline, with a view to improving the service in the future

1.21 I share the committee's concerns about the lack of Government action in implementing recommendations 13, 14 and 15 from the Review of the Health Technology Assessment, and I strongly support the committee's recommendation in relation to this. The PIP implant recall, coupled with the issues raised in this committee's previous inquiry into medical devices, point at serious flaws in the system. Recommendations 13, 14 and 15 of the HTA would go some way towards ensuring that Australian health consumers do not face another serious failure on the part of the regulator.

1.22 It is also concerning that some evidence provided to the committee seemed to indicate a 'commoditisation' of healthcare in relation to cosmetic surgery. Professor Rod Cooter, President of the Australian Society of Plastic Surgeons, stated that many of the PIP implants were inserted by cosmetic surgeons, who are unlikely to be credentialled at major public hospitals. According to Professor Cooter, this then creates problems if "things go wrong", as patients end up in the public system and are taken on as patients by specialist surgeons who are credentialled to work in public hospitals[16]. On the other hand, Dr Daniel Fleming of the Australasian College of Cosmetic Surgery pointed out that as there is no specialty of cosmetic surgery, qualifications in this area are not given the same weight as qualifications in plastic surgery or other specialties[17]. Many health consumers would not be aware of these factors and, given the increase in popularity of cosmetic surgery procedures, it would be appropriate for guidelines or regulations to be developed in relation to disclosure to patients. This would ensure that patients knew exactly what type of care their practitioner could provide and where this care would take place, and prevent the establishment of 'one stop shops' for cosmetic surgery procedures.

Additional Recommendation: That the Department, in conjunction with relevant industry groups, establish regulations for patient disclosure relating to the specific qualifications of and services provided by their surgeon

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[16] Prof. Rod Cooter, Australian Society of Plastic Surgeons, *Committee Hansard*, 9 May 2012, p. 7

[17] Dr Daniel Fleming, Australasian College of Cosmetic Surgery, *Committee Hansard*,, 9 May 2012, p. 21

1.23 The issue of compulsory insurance for sponsors of medical devices was also raised during the hearing, with the TGA stating that there is currently no requirement for sponsors to have medical indemnity insurance[18]. However, the representatives of the Consumers Health Forum pointed out that in the past, the Government has become the default insurer for adverse events, and that requiring medical indemnity insurance would have a double benefit as insurers would also seek to limit risks[19]. Given the fact that in this case, the manufacturer of the device is bankrupt and the sponsor has restructured its company (although I note that MVA declined to provide evidence in relation to the reasons behind their restructure), compulsory insurance would have given individuals implanted with PIP devices some peace of mind.

Additional Recommendation: That all sponsors or manufacturers of medical devices listed on the ARTG be required to hold medical indemnity insurance

1.24 It is clear that there are many similarities between this case and the matters raised during the previous inquiry into medical devices. In both cases, serious systemic flaws have been highlighted and recommendations have been made to address these. It is very disappointing that the Government has not yet responded to the previous inquiry or taken steps towards implementing recommendations 13, 14 and 15 of the HTA, which has been recommended in both inquiries.

1.25 Australian health consumers have been let down once again by systemic failures on the part of the regulator. Evidence provided to the committee illustrated, once again, serious flaws in the approval and post-market monitoring processes for medical devices. Individual submitters also expressed their anger and disappointment at the TGA's level of communication with them and the public as a whole, and this matter needs to be addressed as a matter of urgency.

1.26 These two examples (PIP breast implants and De Puy hip prostheses) have illustrated the serious problems, and with it the untold pain and suffering for thousands of Australians, which could well have been avoided. While the TGA and DOHA can make changes for the future processing and monitoring of medical devices, we do not know what harm will still be caused by these past and current bad

[18] Dr Brian Richards, Therapeutic Goods Administration, *Committee Hansard*, 9 May 2012, p. 30

[19] Ms Karen Carey, Consumers Health Forum, *Committee Hansard*, 9 May 2012, p. 3

practices. Ultimately, Australians should not have to pay for the regulator's failures with their own health.

Additional Recommendation: That the Government implement the recommendations of this inquiry and the previous inquiry into medical devices as a matter of urgency

NICK XENOPHON
Independent Senator for South Australia

Senator Xenophon additional comments- attachments

Attachment 1: Australian Securities and Investments Commission, *ASIC Historical Company Extracts*, 24 January 2012

Attachment 2: Therapeutic Goods Administration, answer to question on notice, Budget Estimates June 2010, received 11 October 2010

ASIC Current and Historical Extract as at Date: 24 Jan 2012 Time: 12:47:20

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The Information Division of the Australian Securities & Investments Commission is certified under the Australian Quality Standard AS 3901 (International Standard ISO 9001).

084 706 338 MEDICAL VISION AUSTRALIA PTY LTD **Document No**

ACN (Australian Company Number): 084 706 338
Registered in: South Australia
Previous State Number:
Registration Date: 12/10/1998
Next Review Date: 12/10/2012
Company bound by:
Australian Business Number: 87 084 706 338

Current Organisation Details

Name : MEDICAL VISION AUSTRALIA PTY LTD 014127807
Name Start: 12/10/1998
Status : Registered
Type : AUSTRALIAN PROPRIETARY COMPANY
Class : LIMITED BY SHARES
Subclass : PROPRIETARY COMPANY

Registered Office

RINALDI & CO 100 GREENHILL ROAD UNLEY SA 5061 014127830
Start Date: 21/10/1998

Previous Registered Office

5 TH LEVEL 76 WAYMOUTH STREET ADELAIDE SA 5000 014127807
Start Date: 12/10/1998 Cease Date: 20/10/1998

Principal Place of Business

99 KING WILLIAM STREET KENT TOWN SA 5067 1E6948521
Start Date: 29/10/2010

Previous Principal Place of Business

35 NORTH TERRACE HACKNEY SA 5069 1E0608225
Start Date: 19/01/2005 Cease Date: 28/10/2010

UNIT 6 174 PAYNEHAM ROAD EVANDALE SA 5069 014127830
Start Date: 12/10/1998 Cease Date: 18/01/2005

LEVEL 5 76 WAYMOUTH STREET ADELAIDE SA 5000 014127807

Start Date: 12/10/1998 Cease Date: 12/10/1998

Directors

ZDENKO RACIC 017082126
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 12/10/1998

Previous Directors

ROSIE RACIC 017082126
6 KENT ROAD HIGHBURY SA 5089
Born: 05/07/1962 - CALABRIA ITALY
Appointment Date: 12/10/1998 Cease Date: 05/04/2004

DAVID GARRY 014127807
LOT 12 WILHELM ROAD LITTLEHAMPTON SA 5250
Born: 14/06/1950 - UNITED KINGDOM
Appointment Date: 12/10/1998 Cease Date: 12/10/1998

Secretary

ZDENKO RACIC 0E9752685
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 05/04/2004

Previous Secretary

ROSIE RACIC 017082126
6 KENT ROAD HIGHBURY SA 5089
Born: 05/07/1962 - CALABRIA ITALY
Appointment Date: 12/10/1998 Cease Date: 05/04/2004

DAVID GARRY 014127807
LOT 12 WILHELM ROAD LITTLEHAMPTON SA 5250
Born: 14/06/1950 - UNITED KINGDOM
Appointment Date: 12/10/1998 Cease Date: 12/10/1998

Share Structure

Note: For each class of shares issued by a proprietary company, ASIC records the details of the top twenty members of the class (based on shareholdings). The details of any other members holding the same number of shares as the twentieth ranked member will also be recorded by ASIC on the database. Where available, historical records show that a member has ceased to be ranked amongst the top twenty members. This may, but does not necessarily mean, that they have ceased to be a member of the company.

Class: ORD 1E0853745
ORDINARY SHARES
Number of Shares/Interests Issued : 10
Total Amount (if any) Paid / Taken to be Paid: 200008.00
Total Amount Due and Payable : 0.00

Members

Class : ORD No. Held: 2 1E0853745
Beneficially Held: NO Paid : FULLY
** JOINT MEMBER **
GIOVANNI POLITO
4 BIRKENHEAD COURT PARA HILLS SA 5096

GABRIELLA POLITO
4 BIRKENHEAD COURT PARA HILLS SA 5096

Class : ORD No. Held: 4 1E0853745
Beneficially Held: YES Paid : FULLY
ROSALBA RACIC
6 KENT ROAD HIGHBURY SA 5089

Class : ORD No. Held: 4 1E0853745
Beneficially Held: YES Paid : FULLY
ZDENKO RACIC
6 KENT ROAD HIGHBURY SA 5089

Charges Registered and Related Documents Received

Note: A charge is some form of security given over the property/assets of the company. In order to obtain details of the 'amount secured by a charge', 'the property charged', the property released from a charge or the documents relating to a satisfaction, assignment or change in details, it is necessary to obtain a 'CHARGES EXTRACT'.

ASIC Charge Number : 689418 Status : Registered
Date and time Registered : 31/03/1999 15:41:00 Fixed/floating : Both Fixed & Floating
Date Created : 19/03/1999
Chargee/Trustee : 004 044 937 NATIONAL AUSTRALIA BANK LIMITED
Documents Received

Form Type	Description	Date Lodged	Proc'd	No. Pages	Document No
309	NOTIFICATION OF DETAILS OF A CHARGE	31/03/1999	YES	41	014900995

Note: This extract may not contain all charges for corporations registered prior to 1991 and it may be advisable to also search the State or territoty records held by the ASIC.

Documents Received (except those listed already under Charges)

Form Type	Date Received	Date Processed	No. Pages	Effective Date	
484	02/11/2010	02/11/2010	2	29/10/2010	1E6948521
484C	Change to Company Details Change of Principal Place Of Business (Address)				
484	19/04/2005	19/04/2005	3	13/04/2005	1E0853745
484	Change to Company Details				
484O	Changes to Share Structure				
484G	Notification of Share Issue				
484N	Changes to (Members) Share Holdings				
484	25/01/2005	25/01/2005	2	19/01/2005	1E0608225
484C	Change to Company Details Change of Principal Place Of Business (Address)				
484	08/04/2004	08/04/2004	2		0E9752685
484E	Change to Company Details Appointment or Cessation of A Company Officeholder				
316	31/01/2003	06/03/2003	3	20/11/2002	0E8531086
316L	Annual Return Annual Return - Proprietary Company				(AR 2002)
304	12/12/2001	18/12/2001	2	11/12/2001	017082126
304C	Notification of Change of Name or Address of Officeholder				
316	12/12/2001	08/01/2002	3	10/12/2001	08470633L
316L	Annual Return Annual Return - Proprietary Company				(AR 2001)

316 31/01/2001 12/02/2001 3 10/01/2001 08470633K
316L Annual Return Annual Return - Proprietary Company (AR 2000)

316 31/01/2000 22/02/2000 3 18/01/2000 08470633J
316L Annual Return Annual Return - Proprietary Company (AR 1999)

316 26/03/1999 26/03/1999 3 25/03/1999 08470633I
316L Annual Return Annual Return - Proprietary Company (AR 1998)

304 15/10/1998 16/10/1998 1 12/10/1998 014127869
304A Notification of Change to Officeholders of Australian Company

207 14/10/1998 15/10/1998 1 12/10/1998 014127833
207 Notification of Share Issue

370 14/10/1998 15/10/1998 2 14/10/1998 014127832
370 Notice of Retirement or Resignation By Director or Secretary

284 14/10/1998 15/10/1998 1 12/10/1998 014127831
284A Notification of Share Cancellation Redeemable Preference Shares

203 14/10/1998 15/10/1998 1 12/10/1998 014127830
203 Notification Of
203A Change of Address
203G Change of Address - Principal Place of Business

201 12/10/1998 12/10/1998 2 12/10/1998 014127807
201C Application For Registration as a Proprietary Company

Note: Where no Date Processed is shown, the document in question has not been processed. In these instances care should be taken in using information that may be updated by the document when it is processed. Where the Date Processed is shown but there is a zero under No. Pages, the document has been processed but a copy is not yet available.

Annual Returns

Year	Return Due Date	Extended Due Date	AGM Due Date	Extended AGM Date	AGM Held Date	O/Stand
1998	31/01/1999	30/04/1999				N
1999	31/01/2000					N
2000	31/01/2001					N
2001	31/01/2002					N
2002	31/01/2003					N

Note: Where the expression "Unknown" is shown, the precise date may be available from records taken over on 1 january 1991 and held by the ASIC in paper or microfiche.

Contact Address for ASIC use only

Section 146A of the *Corporations Act 2001* states:
'A contact address is the address to which communications and notices are sent from ASIC to the company.'

G 100 GREENHILL ROAD UNLEY SA 5061
Start Date: 28/06/2003

*** End of Extract ***

ASIC Current and Historical Extract as at Date: 24 Jan 2012 Time: 12:45:08

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154 907 310 MEDICAL VISION AUSTRALIA HOLDINGS PTY LTD **Document No**

ACN (Australian Company Number): 154 907 310
Registered in: South Australia
Previous State Number:
Registration Date: 22/12/2011
Next Review Date: 22/12/2012
Company bound by:

Current Organisation Details

Name : MEDICAL VISION AUSTRALIA HOLDINGS PTY LTD 027298911
Name Start: 22/12/2011
Status : Registered
Type : AUSTRALIAN PROPRIETARY COMPANY
Class : LIMITED BY SHARES
Subclass : PROPRIETARY COMPANY

Registered Office

RINALDI & CO 100 GREENHILL ROAD UNLEY SA 5061 027298911
Start Date: 22/12/2011

Principal Place of Business

99 KING WILLIAM STREET KENT TOWN SA 5067 027298911
Start Date: 22/12/2011

Directors

ZDENKO RACIC 027298911
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 22/12/2011

Secretary

ZDENKO RACIC 027298911
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 22/12/2011

Share Structure

Note: For each class of shares issued by a proprietary company, ASIC records the details of the top twenty members of the class (based on shareholdings). The details of any other members holding the same number of shares as the twentieth ranked member will also be recorded by ASIC on the database. Where available, historical records show that a member has ceased to be ranked amongst the top twenty members. This may, but does not necessarily mean, that they have ceased to be a member of the company.

Class: ORD 027298911
ORDINARY SHARES
Number of Shares/Interests Issued : 100
Total Amount (if any) Paid / Taken to be Paid: 100.00
Total Amount Due and Payable : 0.00

Members

Class : ORD No. Held: 80 027298911
Beneficially Held: NO Paid : FULLY
054 945 621 Z & R RACIC PTY. LTD.
6 KENT ROAD HIGHBURY SA 5089

Class : ORD No. Held: 20 027298911
Beneficially Held: NO Paid : FULLY
** JOINT MEMBER **
GIOVANNI POLITO
4 BIRKENHEAD COURT PARA HILLS SA 5096

GABRIELLA POLITO
4 BIRKENHEAD COURT PARA HILLS SA 5096

Documents Received

Form Type	Date Received	Date Processed	No. Pages	Effective Date	
201	22/12/2011	22/12/2011	9	22/12/2011	027298911
201C Application For Registration as a Proprietary Company					

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ASIC Current and Historical Extract as at Date: 24 Jan 2012 Time: 12:43:33

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154 921 829 MEDICAL VISION AUSTRALIA CARDIOLOGY & THORACIC PTY LTD Document No

ACN (Australian Company Number): 154 921 829
Registered in: South Australia
Previous State Number:
Registration Date: 23/12/2011
Next Review Date: 23/12/2012
Company bound by:

Current Organisation Details

Name : MEDICAL VISION AUSTRALIA CARDIOLOGY & THORACIC PTY LTD 027298923
Name Start: 23/12/2011
Status : Registered
Type : AUSTRALIAN PROPRIETARY COMPANY
Class : LIMITED BY SHARES
Subclass : PROPRIETARY COMPANY

Registered Office

RINALDI & CO 100 GREENHILL ROAD UNLEY SA 5061 027298923
Start Date: 23/12/2011

Principal Place of Business

99 KING WILLIAM STREET KENT TOWN SA 5067 027298923
Start Date: 23/12/2011

Directors

ZDENKO RACIC 027298923
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 23/12/2011

Secretary

ZDENKO RACIC 027298923
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 23/12/2011

Share Structure

Note: For each class of shares issued by a proprietary company, ASIC records the details of the top twenty members of the class (based on shareholdings). The details of any other members holding the same number of shares as the twentieth ranked member will also be recorded by ASIC on the database. Where available, historical records show that a member has ceased to be ranked amongst the top twenty members. This may, but does not necessarily mean, that they have ceased to be a member of the company.

Class: ORD 027298923
ORDINARY SHARES
Number of Shares/Interests Issued : 100
Total Amount (if any) Paid / Taken to be Paid: 100.00
Total Amount Due and Payable : 0.00

Members

Class : ORD No. Held: 100 027298923
Beneficially Held: NO Paid : FULLY
154 907 310 MEDICAL VISION AUSTRALIA HOLDINGS PTY LTD
99 KING WILLIAM STREET KENT TOWN SA 5067

Documents Received

Form Type	Date Received	Date Processed	No. Pages	Effective Date	
201	23/12/2011	23/12/2011	8	23/12/2011	027298923
201C Application For Registration as a Proprietary Company					

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154 921 892 MEDICAL VISION AUSTRALIA PLASTIC & COSMETIC PTY LTD **Document No**

ACN (Australian Company Number): 154 921 892
Registered in: South Australia
Previous State Number:
Registration Date: 23/12/2011
Next Review Date: 23/12/2012
Company bound by:

Current Organisation Details

Name : MEDICAL VISION AUSTRALIA PLASTIC & COSMETIC PTY LTD 027298921
Name Start: 23/12/2011
Status : Registered
Type : AUSTRALIAN PROPRIETARY COMPANY
Class : LIMITED BY SHARES
Subclass : PROPRIETARY COMPANY

Registered Office

RINALDI & CO 100 GREENHILL ROAD UNLEY SA 5061 027298921
Start Date: 23/12/2011

Principal Place of Business

99 KING WILLIAM STREET KENT TOWN SA 5067 027298921
Start Date: 23/12/2011

Directors

ZDENKO RACIC 027298921
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 23/12/2011

Secretary

ZDENKO RACIC 027298921
6 KENT ROAD HIGHBURY SA 5089
Born: 18/04/1956 - POZESA CROATIA
Appointment Date: 23/12/2011

Share Structure

Note: For each class of shares issued by a proprietary company, ASIC records the details of the top twenty members of the class (based on shareholdings). The details of any other members holding the same number of shares as the twentieth ranked member will also be recorded by ASIC on the database. Where available, historical records show that a member has ceased to be ranked amongst the top twenty members. This may, but does not necessarily mean, that they have ceased to be a member of the company.

Class: ORD 027298921
ORDINARY SHARES
Number of Shares/Interests Issued : 100
Total Amount (if any) Paid / Taken to be Paid: 100.00
Total Amount Due and Payable : 0.00

Members

Class : ORD No. Held: 100 027298921
Beneficially Held: NO Paid : FULLY
154 907 310 MEDICAL VISION AUSTRALIA HOLDINGS PTY LTD
99 KING WILLIAM STREET KENT TOWN SA 5067

Documents Received

Form Type	Date Received	Date Processed	No. Pages	Effective Date	
201	23/12/2011	23/12/2011	8	23/12/2011	027298921
201C Application For Registration as a Proprietary Company					

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*** End of Extract ***

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2010-2011, 2 and 3 June 2010

Question: E10-109

OUTCOME 1: Population Health

Topic: BREAST IMPLANT RECALL

Hansard Page: CA 87

Senator Xenophon asked:

Can the TGA provide advice on whether the gel that was initially approved for use in PIP breast implants was the same gel found in independent testing by the TGA?

Answer:

Both the TGA and French regulatory authorities have been undertaking product sample testing to ensure the implants meet quality and safety requirements. TGA's test results to date indicate that the PIP breast implants supplied in Australia conform to the relevant international standards for this type of product including gel cytotoxicity and shell strength.

The TGA undertook further tests on the gel contained within the implant. The approved gel and the gel in the PIP implants were polysiloxane-based materials. The samples tested by TGA contained a gel that had superior physical properties to the approved gel. Specifically, if the shell were to rupture the viscosity of the gel was such that it would be less likely to leak when compared to the originally approved gel material.

The French Authorities are currently testing samples of gel that were taken during their audit. They have agreed to release those results to the TGA and other regulatory agencies as soon as they are available.

Appendix 1

Submissions received by the committee

1	Stryker Australia
2	Australian Medical Association
3	Confidential
4	Confidential
5	Confidential
6	Confidential
7	Name Withheld
8	Confidential
9	Confidential
10	Confidential
11	Confidential
12	Name Withheld
13	Name Withheld
14	Private Healthcare Australia
15	Medical Technology Association of Australia
16	Name Withheld
17	Consumers Health Forum Australia
18	Australian Society of Plastic Surgeons Inc
19	Ms Nikki Janeway
20	Confidential
21	Confidential
22	Ms Tammy Perrett

23 Name Withheld

24 Australasian College of Cosmetic Surgery

25 Name Withheld

26 Name Withheld

27 Name Withheld

28 Name Withheld

29 Ms Jessica van Woensel

30 Department of Health and Ageing Attachment 1

31 Name Withheld

32 Name Withheld

33 Ms Jodie Blake

34 Name Withheld

35 Name Withheld

36 Name Withheld

37 Name Withheld Attachment 1 Attachment 2 Attachment 3 Attachment 4

38 Ms Julie Patterson

39 Ms Suellen Telford

40 Confidential

41 Ms Rhonda Bailey Attachment 1 Attachment 2 Attachment 3

42 Monash University, School of Public Health and Preventive Medicine

43 Department of Industry, Innovation, Science, Research and Tertiary Education

44 National Heart Foundation Australia Attachment 1 Attachment 2

45 Medical Error Action Group

46 Name Withheld

47 Name Withheld

48 Name Withheld

49 Name Withheld

50 Device Technologies

Additional Information Received

1 Response to adverse comment raised in submissions #7, #46, #47 and #48 from Dr Daniel Fleming, received 8 May 2012

Answers to Questions on Notice

1 Answers to Questions on Notice from Tindall Gask Bentley, received 17 May 2012

2 Answers to Questions on Notice from Australian Society of Plastic Surgeons, received 18 May 2012

3 Answers to Questions on Notice from Department of Health and Ageing, received 23 May 2012

4 Answers to Questions on Notice from the Australian College of Cosmetic Surgery, received 22 May 2012

5 Answers to Questions on Notice from the Therapeutic Goods Administration, received 29 May 2012

Appendix 2

Public hearings

Wednesday, 9 May 2012 – Parliament House

Witnesses:

Australasian College of Cosmetic Surgery

Dr Daniel Fleming

Australian Society of Plastic Surgeons

Associate Professor Rodney Cooter, President

Consumers Health Forum of Australia

Ms Carol Bennet, Chief Executive Officer

Ms Karen Carey, Board Director

Department of Health and Ageing

Professor Chris Baggoley, Commonwealth Medical Officer

Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division

Ms Jane Halton, Secretary

Mrs Samantha Palmer, First Assistant Secretary, People Capability and Communication

Department of Human Services

Ms Vicki Beath, General Manager, Health Programs Division

Mr Doug Fawns, National Manager, Medicare and Veterans' Affairs Processing Branch

Therapeutic Goods Administration

Dr Brian Richards, National Manager

Tindall Gask Bentley

Mr Timothy White, Solicitor

APPENDIX 3

Chronology of regulatory, communication and other activities undertaken regarding PIP implants

Date	Event
13 September 1999	First application and approval for a PIP silicone gel implant for individual patient use under the Special Access Scheme (SAS).
22 September 1998	Precise Medical Supplies lodged application to register three types of breast implant manufactured by Poly Implant Prothèse (PIP): implants pre-filled with a polysaccharide solution; implants pre-filled with a silicone gel; and implants pre-filled with saline. Applications to register the polysaccharide-filled and silicone-filled implants were not pursued due to lack of data from PIP to support registration. The application for registration was supported by European Commission (EC) certification for each implant type issued by TÜV Rheinland in October 1997. Manufacturer was PIP at 337 Avenue de Bruxelles, La Seyne Cedex, France. EC certification was based on assessment for Class IIb products.
15 March 2000	PIP saline prefilled implants, sponsored by Precise Medical Supplies, registered on ARTG.
4 October 2002	New medical devices framework introduced in Australia - implantable mammary prostheses are classified as Class III medical devices.
16 October 2002	Transfer of sponsorship of all PIP-manufactured products from Precise Medical Products to Medical Vision Australia.
31 October 2002	First adverse event report for PIP silicone gel implant (arising from SAS use). Rupture of implant 2 years post-implantation.
14 November 2002	Medical Vision Australia applied to include PIP silicone gel implants on the ARTG. However, the application was not made under the provisions of the new regulatory framework and was not supported by the correct level of conformity assessment certification.
14 April 2003	Application for conformity assessment lodged by Medical Vision Australia for silicone gel breast implants manufactured by PIP.
28 May 2003	TGA accepted application for conformity assessment and notifies applicant.
28 May 2003	Evaluation of application for conformity assessment commences. Application referred within the TGA for the following evaluations of data provided in the dossier: a) microbiological assessment b) biocompatibility and biological safety assessment c) materials and manufacturing assessment d) clinical assessment.

Date	Event
May 2003	Arrangements for onsite audit of the PIP manufacturing facility commenced.
17-19 November 2003	TGA audit of PIP facilities at 337 Ave de Bruxelles, La Seyne Sur Mer, France.
15 December 2003	Manufacturer provided additional information relating to non-conformities identified during the audit.
March 2004	PIP obtained an EC Conformity Assessment Certificate (covering the necessary scope for PIP implants) from the European Notified Body, TÜV Rheinland.
23 August 2004	All non-conformities identified at the TGA onsite audit resolved and the TGA audit report closed out.
3 September 2004	Application considered by Medical Devices Evaluation Committee (MDEC) following referral by the TGA. The MDEC resolution was no objection to the inclusion of these implants on the ARTG subject to the provision of comprehensive annual post-market reports to the TGA for a period of 7 years from the date of inclusion.
18 October 2004	TGA issued Conformity Assessment Certificates (CAC) to PIP for the manufacture of a range of silicone gel-filled breast implants. CAC valid for five years.
3 November 2004	Application by the sponsor Medical Vision Australia for ARTG inclusion of the PIP implants covered by the TGA Conformity Assessment Certificate.
30 November 2004	PIP Implants included on ARTG (nine ARTG entries) for the sponsor Medical Vision Australia.
4 July 2006	First SAS approval for titanium dioxide coated silicone gel breast implants.
10 November 2006	First patient enrolled in a clinical trial sponsored by Medical Vision Australia using PIP titanium dioxide coated silicone gel breast implants.
4 June 2007	TGA acknowledged clinical trial notification for clinical trial using the PIP titanium dioxide coated implants.
31 August 2009	TGA contacted Medical Vision Australia regarding impending expiry of TGA CAC for PIP implants (expiry on 18 October 2009).
25 September 2009	Medical Vision Australia submitted an application to vary the manufacturer's evidence used to support their ARTG entries for PIP gel-filled implants. Variation was requested because the manufacturer was changing from TGA certification (due to expire on 18/10/2009) to European (CE) certification. CE certification was issued by EU Notified Body, TÜV Rheinland, and included Design Exam certification.
30 September 2009	TGA accepted the variation to the manufacturer's evidence with result that PIP implants were included in the ARTG on the basis of CE certification.
18 October 2009	PIP's TGA Conformity Assessment Certificate expired after 5 years.

Date	Event
31 March 2010	TGA notified by Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) of its decision to recall and suspend the marketing of silicone breast implants manufactured by PIP because it had "registered" an increase in reports regarding implant rupture and local complications and had discovered that the company had used an unauthorised silicone gel in the products.
31 March 2010	TGA contacted by Medical Vision Australia regarding the French recall of PIP implants.
1 April 2010	TGA wrote to Medical Vision Australia requesting details of the distribution of PIP implants in Australia.
2 April 2010	AFSSAPS advised the TGA that further information would be very difficult to obtain because PIP officially went into receivership on 30 March 2010 and was "currently dissolved".
3 April 2010	Medical Vision Australia advises TGA that it had ceased importation and supply of PIP implants, and had contacted medical practitioners requesting that the stock be returned and not used.
3 April 2010	TGA request sent to UK Medicines and Healthcare products Regulatory Authority (MHRA) asking for any further information on the reasons for the PIP recall in France.
6 April 2010	Request for information from MHRA for implant rupture rates. Request information from AFSSAPS for implant rupture rates that led to recall action. Medical Vision Australia confirmed that all importation and distribution of PIP products had been halted. It also advised that it will advise all implanting surgeons to stop any further operations and return stock to the sponsor. Note: the 7 customers known to have stock were contacted by email and phone. All customers acknowledged the email.
6 April 2010	Notice posted on the TGA website advising that Medical Vision Australia was undertaking the recall of all non-implanted silicone gel breast implants manufactured by PIP. A copy of the recall notice to customers, the web statement and notification to colleges is attached
6 April 2010	TGA sent a copy of the recall notice to the Australasian College of Cosmetic Surgery (ACCS) and the Australian Society of Plastic Surgeons (ASPS).
6 April 2010	TGA requested information about implant ruptures from AFSSAPS.
7 April 2010	TGA requested Medical Vision Australia to send a "Product Notification" to all surgeons who may have purchased PIP implants.
7 April 2010	Medical Vision Australia advised all surgeons who have implanted PIP implants sourced from that company about the recall.
7 April 2010	Response from MHRA with general outline of the issues as understood. MHRA advice that rupture rate for PIP implants in UK was "not unusual".

Date	Event
8 April 2010	State and territory health departments notified of recall of PIP implants
8 April 2010	"Product Notification" sent to surgeons by Medical Vision Australia advising that all unused PIP implants were being recalled due to concerns about their failure rate and that at this time, no action is required other than the normal follow-up procedures for patients implanted with this product.
13 April 2010	TGA follow up with AFSSAPS regarding email request of 6 April 2010, concerning rate of breast implant rupture.
14 April 2010	PIP implants cancelled from ARTG.
29 April 2010	AFSSAPS advised the TGA that, while true rates of rupture were not available, it had observed a relative increase in the rate of rupture of PIP implants over the period 2007 to 2009 and it was this apparent increase that led to the discovery of gel substitution and subsequent recall.
April – May – June 2010	TGA performed laboratory testing of samples of PIP implants.
19 May 2010	TGA website updated with information for consumers stating it was continuing its investigation into issues relating to overseas reports of increased rupture rates of PIP implants and that the TGA was awaiting the results of tests being conducted internationally on the implants.
10 June 2010	TGA requested AFSSAPS to provide information on the unauthorised gel composition used by PIP and their test results.
11 June 2010	Outline of tests to be performed provided by AFSSAPS. No formulation details provided for unapproved gel other than "the silicone included in PIP implants are issued from known European industrial suppliers".
12 June 2010	TGA requested AFSSAPS to provide production records to match with lots supplied in Australia.
22 June 2010	AFSSAPS unable to provide information on production records but advised that they believed that implants of the types with "MX and Asymmetric references produced after 2006" would have had the approved gel.
29 June 2010	Email from AFSSAPS indicating that test results "have been delayed".
2 July 2010	TGA website updated with laboratory test results indicating that PIP implants supplied in Australia conform to the relevant international standards for gel cytotoxicity and shell strength.
28 July 2010	Email from AFSSAPS providing information when test results would be available, and seeking information about the laboratory testing performed by the TGA.
4 September 2010	AFSSAPS email advising that they had seized implants and raw materials from PIP.
20 September 2010	Request from MHRA to share the results of the TGA's laboratory testing.
28 September 2010	AFSSAPS provided advice about their test results and a copy of the accompanying press statement.

Date	Event
29 September 2010	TGA provided advice to MHRA regarding the TGA laboratory test results.
30 September 2010	TGA requested additional information from AFSSAPS regarding their test results.
30 September 2010	MHRA requested permission to use information provided by TGA.
1 October 2010	TGA received advice from MHRA about its web statement.
1 October 2010	TGA website updated to reference AFSSAPS and MHRA websites for additional information and confirming TGA test results. TGA sent notification of update to TGA's website to the Australian Society of Plastic Surgeons and the Australasian College of Cosmetic Surgeons.
5 October 2010	TGA requested information from MHRA about their awareness of any testing being undertaken in other countries.
12 October 2010	Medical Vision Australia advises the TGA that all recalled stock, which had not been provided to the TGA for testing, had been destroyed.
12 October 2010	Request from AFSSAPS for information regarding batches of breast implants tested by TGA.
22 October 2010	TGA responded to AFSSAPS with requested test information.
25 October 2010	Request from AFSSAPS for further clarification of TGA's test results.
25 November 2010	Recall was closed on TGA database following confirmation from Medical Vision Australia that all returned product had been destroyed.
27 January 2011	TGA coordinated simultaneous release of web statement with FDA in the USA regarding the issue of lymphoma associated with breast implants. TGA continued to consult the FDA on this issue.
7 February 2011	TGA held teleconference with Australian Society of Plastic Surgeons to discuss enhancing the breast implant registry and providing an update regarding PIP and also regarding ALCL.
7 December 2011	TGA received information from AFSSAPS about a case of ALCL associated with a PIP implant and confirming its previous advice to patients. AFSSAPS requested specific information about breast implants and cases of ALCL in Australia
21 December 2011	TGA provided advice to AFSSAPS in response to their questions about breast implants and reported cases of ALCL in Australia.
21 December 2011	AFSSAPS advised the TGA that in France, media coverage states health authorities were considering recommending removal of PIP implants from 30,000 women in France.
21 December 2011	TGA web statement posted regarding media coverage in France linking PIP with ALCL.

Date	Event
22 December 2011	Updated web statement from MHRA regarding consultations with other European agencies and TGA. MHRA stated that there is no evidence of any increase in incidence of cancer associated with PIP breast implants and no evidence of any disproportionate rupture rates other than in France.
23 December 2011	Announcement by the French Minister of Health recommending that women in France have their PIP implants removed although there is no urgency to do this. Recommendation was due to the increased rupture rate not to do with any association with cancer.
3 January 2012	TGA contacted ASPS, ACCS and RACS and members of TGA's statutory expert advisory committees regarding PIP breast implants and establishment of an expert advisory panel.
3 January 2012	TGA contacted all state and territory CHOs regarding PIP implants and requested data from their jurisdictions.
3 January 2012	TGA contacted regulatory authorities in Switzerland, Canada, Singapore, USA, Brazil, European Commission and Japan seeking further information on PIP available in their jurisdictions.
3 January 2012	TGA contacted Private Health Insurance Administration Council seeking information on private health insurance data on PIP implants.
4 January 2012	First meeting of TGA expert advisory panel.
4 January 2012	TGA website updated with media release and "PIP implants – the Australian perspective".
4 January 2012	TGA contacted NSW Clinical Excellence Commission requesting PIP implant information.
4 January 2012	TGA sent letter to all current sponsors of breast implants requesting information about ruptures, other complaints and number of implants supplied.
6 January 2012	TGA requested ASPS, ACCS and RACS to instruct their members to assemble lists of their patients who have received a PIP implant.
6 January 2012	Telephone discussion with the offices of state and territory CHOs regarding any use of PIP implants in their jurisdictions.
6 January 2012	TGA sent further requests for information to regulatory authorities in Switzerland, USA, Japan, France, Singapore, Canada and EC.
7 January 2012	Breast Implant Information Line established at 6am.
7 January 2012	Media release by the Gillard Government announcing new hotline for women concerned about their breast implants.
7 January 2012	Further request from TGA To AFSSAPS and MHRA regarding testing requirements/results.
7 January 2012	TGA web statements on PIP implant Questions and Answers.

Date	Event
7 January 2012	TGA began contacting surgeons who were supplied with PIP implants.
7 January 2012	TGA contacted sponsors who may have supplied PIP implants under SAS.
8 January 2012	TGA discussed with ASPS and ACCS the information being conveyed to their members by the TGA.
9 January 2012	DoHA Chief Medical Officer convened a Clinical Advisory Committee to provide him with regular and frequent advice related to PIP breast implants.
9 January 2012	TGA requested from European Commission copies of TÜV Rheinland audit reports. Referred to AFSSAPS.
9 January 2012	TGA requested information from AFSSAPS on audits of breast implant manufacturers.
9 January 2012	TGA received response from AFSSAPS to regarding audit reports.
9 January 2012	TGA received response from AFSSAPS in response to email of 7 January 2012 requesting information regarding testing.
9 January 2012	TGA contacted Australian Commission on Safety and Quality in Health Care requesting data on PIP implants.
9 January 2012	TGA contacted CHOs of each state and territory advising them of the surgeons in their state who had used PIP implants.
10 January 2012	TGA sent registered letters to surgeons who may have supplied PIP implants. Letters also sent to ASPS and ACCS as part of mail out.
10 January 2012	TGA contacted Chair of Advisory Committee on Safety of Medicines to request advice on possible study designs that could be used to detect rupture rate of PIP compared to other prostheses.
10 January 2012	Letter to ASPS, ACCS and RACS requesting further data on PIP implants for analysis by TGA and to also request data from the Breast Implant Registry.
10 January 2012	TGA convened teleconference with state and territory CHOs.
11 January 2012	Communication with French Government seeking clarification of allegations of fraudulent activity by manufacturers of PIP implants.
11 January 2012	TGA convened teleconference of overseas regulators.
12 January 2012	TGA website updated with information regarding the TGA's testing of PIP implants, and an update to Questions and Answers.
12 January 2012	TGA contacted Medical Vision Australia requesting additional information regarding supply of PIP implants under SAS.
12 January 2012	TGA website updated to reflect changes to Questions and Answers on DoHA website and provide the latest results of laboratory testing.

Date	Event
12 January 2012	Email to AFSSAPS requesting information about breast implant samples and the introduction of the gel.
13 January 2012	TGA requested advice from the MHRA and the European Commission on European wide plans to ensure the safety of breast implants currently on the market.
13 January 2012	A summary of TGA's Laboratory testing results circulated to overseas regulators.
13 January 2012	Communication from French Government noting advice from the French Authorities has not been received regarding allegations of fraudulent activities by manufacturers of PIP implants, and seeking information on Australian implant rupture rates.
13 January 2012	Email from AFSSAPS in response email 12 January 2012, regarding tests carried out on PIP implants.
13 January 2012	Email to AFSSAPS requesting sample of implant containing each type of gel.
16 January 2012	Teleconference with state and territory CHOs to discuss available prostheses implant and removal data that could potentially be used to assess rupture rates.
17 January 2012	TGA sent letter to ASPS, ACCS and RACS requesting they send further information to their members in case some PIP implanting surgeons could not be contacted from the TGA mail-out on 10 January 2012.
19 January 2012	TGA convened International Laboratory Testing Panel for PIP breast implants to confer about laboratory testing for the scientific analysis of the quality and safety of PIP implants: this panel includes Australia, Brazil, the Czech Republic, European Commission, Germany, Ireland, UK and the Netherlands.
20 January 2012	Second meeting (teleconference) of TGA's expert advisory panel on PIP implants.
20 January 2012	TGA website updated
20 January 2012	Response from AFSSAPS to email of 13 Jan 2012 re providing samples of gel for testing.
27 January 2012	TGA website updated.
30 January 2012	Communication from French Government regarding the use of a different silicone gel and the outcome of criminal proceedings against PIP founder.
1 February 2012	AFSSAPS advised TGA of detailed reports (in French) of work undertaken by AFSSAPS.
3 February 2012	Communication with French Government responding to request for information on the number of cases of implant rupture rates in Australia, and seeking advice from AFSSAPS to assist Australian testing program.

Date	Event
3 February 2012	TGA website updated.
7 February 2012	Intra-dermal irritation testing on PIP gel and shell commenced.
9 February 2012	TGA hosted second teleconference of International Laboratory Testing Panel for PIP breast implants.
10 February 2012	Communication with European governments (Czech Republic, French, German and Netherlands) regarding respective policy decisions on PIP implants.
10 February 2012	TGA website updated.
17 February 2012	TGA website updated.
20 February 2012	Communication from Czech Ministry of Health regarding policy decisions on PIP implants.
23 February 2012	Third teleconference of TGA's expert advisory panel on PIP implants.
24 February 2012	TGA website updated.
1 March 2012	Questionnaires sent to surgeons who have reported ruptures of PIP implants, with the aim of gathering detailed information about the rupture, the gel, the actual or potential issues of the rupture and the contra-lateral implant if there is one.
2 March 2012	TGA website updated.
7 March 2012	DoHA received detailed reports of the AFSSAPS chemical, mechanical and biological testing.
8 March 2012	TGA hosted 3rd meeting of the International Laboratory Testing Panel for PIP breast implants (ITPP).
9 March 2012	TGA website updated.
10 March 2012	Media release by the Minister for Health, the Hon Tanya Plibersek MP, announcing access to subsidised MRI scans for women with PIP breast implants from 12 March 2012.
10 March 2012	TGA website updated with advice on subsidised MRI scans.
12 March 2012	Breast Implant Information Line script updated with information regarding subsidised MRI scans for women with PIP breast implants.
13 March 2012	Fourth teleconference of TGA's expert advisory panel on PIP implants.
16 March 2012	TGA website updated.
23 March 2012	TGA website updated.
30 March 2012	TGA website updated.

Date	Event
2 April 2012	TGA website updated.
5 April 2012	TGA website updated.
13 April 2012	TGA website updated.

Key

- Unshaded rows indicate regulatory and communication activities undertaken by the TGA.
- Shaded rows indicate activity undertaken by DoHA and media releases from the Health Minister and Parliamentary Secretary for Health and Ageing.

Appendix 4

List of Recommendations made in the Senate Community Affairs References Committee report into *The Regulatory Standards for the Approval of Medical Devices in Australia*

Recommendation 1

5.16 The committee recommends that the Therapeutic Goods Administration make a list of the devices on the Australian Register of Therapeutic Goods publicly available.

Recommendation 2

5.17 The committee recommends that the Department of Health and Ageing fully implement Recommendation 8c of the Health Technology Assessment Review regarding the need for increased rigour of regulatory assessment of higher-risk medical devices.

Recommendation 3

5.18 The committee recommends that the level of assessment of Class III medical devices be increased.

Recommendation 4

5.19 The committee recommends that the Therapeutic Goods Administration investigate whether allowing an increasing number of medical devices onto the Australian market actually improves clinical outcomes; and whether a more judicious approach could improve pre-market assessment and post-market surveillance of higher risk medical devices, for the ultimate benefit of patients.

Recommendation 5

5.23 The committee recommends that the Therapeutic Goods Administration continue to consult widely with stakeholders, including consumer health organisations, on the amended proposals related to third party conformity assessment; and weigh carefully considerations of the advantages of streamlined international regulatory frameworks and patient safety.

Recommendation 6

5.28 The committee recommends that the Therapeutic Goods Administration continue its prudent approach to the regulation of reprocessed single-use medical devices, with due consideration for issues of informed patient consent and the

need for suitable mechanisms to enable tracing of remanufactured medical devices in the case of adverse events.

Recommendation 7

5.39 The committee recommends that the Department of Health and Ageing implements Recommendations 13, 14, and 15 of the Health Technology Assessment Review in a timely manner. These recommendations address the need for improved post-market surveillance by increasing the rate of reporting of adverse events, including by health service providers and consumers; facilitating the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions; and establishing further clinical registers for high risk implantable devices and procedures.

Recommendation 8

5.40 The committee recommends that the Therapeutic Goods Administration put in place mechanisms to educate and encourage doctors to report adverse incidents associated with the use of medical devices. The committee further recommends that the Department of Health and Ageing introduce mandatory reporting for health practitioners to the Therapeutic Goods Administration on relevant issues, in certain circumstances including problems with medical devices.

Recommendation 9

5.41 The committee recommends that the Government implements the Recommendations of the Therapeutic Goods Administration Transparency Review in a timely manner.

Recommendation 10

5.42 The committee recommends that the Therapeutic Goods Administration consider simultaneously allocating or aligning the great variety of codes used to identify medical devices, in order to facilitate more efficient regulation and more rapid identification of devices when problems occur.

Recommendation 11

5.43 The committee recommends that the Department of Health and Ageing consider a mechanism for flagging billing codes in order to identify devices subject to an alert or recall; as well as a consequent adjustment to benefits paid, based on industry feedback as to the performance of the device.

Recommendation 12

5.46 The committee recommends that the Therapeutic Goods Administration consider whether custom made dental devices are adequately regulated; and whether the approach used in the United Kingdom of requiring a statement of

manufacture to be provided to patients, and retained by the dental practitioner, has merit.

Recommendation 13

5.47 The committee recommends that the Therapeutic Good Administration carry out an investigation to ascertain whether importation of medical devices via the internet is adequately regulated.

Recommendation 14

5.52 The committee recommends that the Therapeutic Goods Administration, in consultation with the National Joint Replacement Registry, investigate ways in which information provided by the National Joint Replacement Registry can be used and responded to in a more timely way for the benefit of patients, and to inform future evidence based decision making on the listing of prostheses on the Australian Register of Therapeutic Goods.

Recommendation 15

5.57 The committee recommends that the Department of Health and Ageing prepare, as a matter of priority, a comprehensive communications strategy to inform medical practitioners, patients and the general public about the issues associated with De Puy hip and hip resurfacing devices as well as options for treatment, obtaining further information, and reporting adverse outcomes. The committee further recommends that such a strategy be implemented as a standard process for any future adverse event reporting.

Recommendation 16

5.58 The committee recommends that the Department of Health and Ageing, as a matter of urgency, consider the best way of establishing a process for monitoring the levels of cobalt, chromium, and other toxic metals; and any possible health effects, in all patients who have received metal-on-metal hip replacements.

Recommendation 17

5.59 The committee recommends that the Government consider the best mechanism for initiating and advancing research on the health effects of cobalt, chromium, and other toxic metals, on the human body. The committee also recommends that consideration be given to ensuring adequate funding for that research is made available.

Recommendation 18

5.64 The committee recommends that the Department of Health and Ageing undertake further work to address the issue of inducements paid by pharmaceutical companies and medical device manufacturers to doctors and

teaching hospitals, in line with the Physician Payment Sunshine provisions of the Patient Protection and Affordable Care Act of 2009 in the United States. The definition of inducements should include a commercial interest in a company or device; any cash payments or discounts offered to medical practitioners; and any other gifts provided to medical practitioners.