

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 1998⁴ 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](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

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 ARTG. 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

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 taken²²

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

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

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 figures³⁶ 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 Assessment³⁸ 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

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

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.

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, AFSSAPS⁵² 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

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

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, Allergan, 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.

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

