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]
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> And
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> ...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—
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> **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,
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> Joint muscle pain, ovary pain, Chest pain.
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> Short term memory loss.
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> Swelling, fluid retention, Inflammation
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> Breathing issues/shortness of breath
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> Excessive hair loss, dry hair and skin problems, rashes allergies, sensitive to heat and cold.
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> Low blood pressure, low blood sugar, dizziness/seeing stars vision issues, sensitive to light and sound, ringing in ears.
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> Anxiety depression, hormone issues, dead limbs in sleep. Chronic fatigue.
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> 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.
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> 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.
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> ...
>
> 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.