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