Chapter 3

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

Actions undertaken for the Australian recall of PIP breast implants

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Government action after the recall of PIP breast implants

Response time from the Government regarding the device recall

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Committee View

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

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

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

Recommendation 5

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

Engagement with international regulators

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

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

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

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

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

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

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

Committee view

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

Recommendation 6

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

Establishment of advisory panels

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Type of TGA testing of PIP breast implants after the recall

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Committee view

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

Recommendation 7

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

Data collection and record keeping for PIP breast implants

Data collection – adverse event monitoring

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

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

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

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

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

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

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

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

3.48 One submitter was critical of this evidence base:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Committee view

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

Recommendation 8

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Committee view

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

Recommendation 9

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

Medicare subsidy for MRI

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Committee view

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

Recommendation 10

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

Locations of MRI machines with a breast coil

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

Establishment of National breast implant hotline

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Committee view

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

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

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

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

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

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

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

Committee view

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

Recommendation 11

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

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