The Australasian College of Cosmetic Surgery

Raising Standards, Protecting Patients

20 April 2012

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Senate Community Affairs Committee Inquiry: The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants

The Australasian College of Cosmetic Surgery welcomes the opportunity to provide a submission to the Senate Community Affairs Committee Inquiry into the role of the Government and the TGA regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants.

The Australasian College of Cosmetic Surgery (ACCS) is a multi-disciplinary body of general surgeons, plastic and cosmetic surgeons, dermatologists, ear nose and throat surgeons, ophthalmologists, general practitioners and other doctors who specialise in cosmetic medicine and surgery. The goal of the ACCS is to ensure the safe provision of cosmetic surgery and cosmetic medical procedures to the Australian community through the supply of appropriately trained and certified medical practitioners. The College has made a full application to the Australian Medical Council to have Cosmetic Medical Practice recognised as a new Medical Specialty. That application may be viewed at: www.cosmeticmedicalpracticesubmission.info

The ACCS, along with other relevant organisations, has been working closely with the Therapeutic Goods Administration and the Commonwealth Chief Medical Officer to provide expert advice in response to concerns over the manufacture of prosthetic breast implants manufactured by French company Poly Implant Prothese, or PIP. The College's representative, Dr Daniel Fleming, sits on the TGA and CMO advisory panels formed to provide expert advice to the Government.

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Summary

The College believes the TGA has responded, and continues to respond, in a timely, appropriate and evidence based manner to the concerns raised about the manufacture of PIP implants. The College also believes the TGA has not communicated effectively with the public.

Based on the current evidence, the College agrees that there is no medical reason for recommending all women with PIP implants, who do not have a rupture or other complications, have them removed or replaced. The detailed reasons for this are explained in a video series the College has produced to allow patients to make informed decisions. These can be viewed at http://www.youtube.com/playlist?list=PL8F6BAEEF3FE97D60 and form part of this submission.

Importantly 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.

Reasoning

1. In March 2010, the French Authorities became aware that to make its breast implants PIP had been using silicone gel formulations which were different to those approved on its manufacturing license.

2. The French issued an international alert and the TGA immediately issued a recall of all un-implanted PIP breast implants.

3. At this point it was necessary to begin a testing program to address the safety and quality of the PIP implants.

4. The French regulator (AFSSAPS), the UK regulator (MHRA) and the TGA did this.

5. The most important test was to determine if the gel used by PIP was toxic to human cells. The TGA was the first to inform the public, on 2 July 2010, that the PIP implants tested had passed the relevant test for toxicity and also for shell strength. This was some months prior to AFSSAPS and the MHRA confirming their own toxicity tests were also negative.

6. AFSSAPS reported two tests were abnormal – one specific shell strength test (the tensile elongation test) was failed by one specific model of PIP

implant only. AFSSAPS also announced a positive result in the rabbit dermal irritation test. In this test, silicone is injected under the skin of rabbits and the presence and degree of any irritation is measured. This positive rabbit test indicated a possible irritant potential of PIP gel compared with other approved gels.

7. The French also confirmed that the relevant tests for any cancer inducing potential in the PIP gels were negative.

8. The TGA attempted to obtain further information from AFSSAPS regarding its abnormal tests in order to assess their significance, but AFSSAPS were unwilling or unable provide the details the TGA had requested.

9. AFSSAPS did not recommend the removal of all PIP implants until December 23, 2011, some 14 months after its testing results were released. The decision was not on the basis of any further testing. The recommendation was in fact that AFSSAPS “suggested” removal of intact PIP implants should be “proposed” to patients by their surgeons as a “preventative” measure.

10. The timing of this recommendation came 48 hours after a spokesperson for the French Health Ministry had announced to the press on 21 December 2011 that, "Today, we're in the process of evaluating these breast implants because of the apparent cancer risk." This was a serious error that caused panic among patients around the globe. The PIP implants had passed the same cancer tests that all implants are required to pass and there was no new credible evidence to the contrary. The French Health Minister corrected this error in the announcement 48 hours later stating that there was no increased cancer risk with PIP implants and suggesting that women should consider with their surgeons removing these implants as a precaution. The French positive rabbit test was cited as a justification for this recommendation. This made getting details of the test from AFSSAPS and assessing its validity even more important.

11. The TGA and the CMO convened expert advisory committees in January 2012 to assist in developing an appropriate response.

12. The College recommended that a Medicare rebate for MRIs for PIP patients be made available and a study be initiated to determine accurately the true rupture rate of PIP implants. The Minister for Health announced the Medicare rebate on 10 March 2012. A formal study has not been arranged, however. With the encouragement of the TGA, the College is investigating a study to audit the results of the MRIs being performed around Australia in order to obtain a more accurate indication of the rupture rate than will be provided by the raw data.

13. The TGA undertook further testing and made further attempts to obtain details of the French tests.

14. Belatedly, further details of the French testing were made available to the TGA. This has shown that the tensile elongation test was performed inappropriately rendering the result invalid. The TGA again repeated this test on more samples according to the ISO protocol and the PIP implants exceeded the standard.

15. It also became evident that the French rabbit irritation test had also not been performed in the same manner as in the ISO standard and the results had not been reported in the standardised way. The TGA repeated the test in Australia according to the standard and the result was negative. To be more confident, the TGA also sent the gel samples to France and commissioned the same French laboratory AFSSAPS had used to repeat the test again. It was also negative.

16. The TGA has in fact performed more tests and more extensive tests, on more samples of PIP implants than any other regulator in the world.

17. The TGA has instigated regular teleconferences with other regulators around the world to share information. Because of the more extensive testing done by the TGA other regulators are using the TGA's results to formulate their own policy responses.

18. The French regulator AFSSAPS has declined to join the teleconferences.

19. The TGA are continuing the testing program to ensure that nothing has been missed. The TGA and the CMO continue to meet with the expert advisory committees regularly.

20. The TGA's position is consistent with the current recommendations of the MHRA and the 2012 European Commission's extensive report on the PIP issue.

TGA communications

It is very important that women who are understandably worried about the health implications of their PIP implants have access to the information they need to make informed decisions about their health. It can be argued that the TGA's communication strategy has not kept pace with its world leading testing and analysis work. And since a regulator's job is to inform as much as it is to test and/ or approve, that is a serious concern.

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.

The College alerted the TGA to this and subsequent updates have been more circumspect when reporting figures. However, the College understands that Government policy prevents the TGA from either removing the misleading information from the 4 January 2012 update or even being able to add a note to the 4 January statement clarifying that the reported rate should not be relied upon. If this is the case, the College recommends that the policy be changed to allow corrective action to be taken.

The media has used this example to attack the TGA and in seeking to persuade the public, wrongly, that the TGA's handling of the PIP issue is incompetent in general.

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. Two examples of sensationalistic and irresponsible reporting have been highlighted by ABC Television's *Media Watch* program. The College encourages Committee members to view the program at:
http://www.abc.net.au/mediawatch/transcripts/s3464163.htm

It is regrettable that so many women have been so ill served by these media reports. The legitimate concern of women with PIP breast implants must be met with accurate information and sound, evidence-based advice, not sensationalistic reporting, which may cause them more harm. The College therefore produced a series of videos which does provide patients with this type of accurate, evidence based information in a straightforward way. Again, constrained by policy reasons, the TGA has not been able to provide a direct link to the videos but has been able to provide a link to another government website www.healthinsite.gov.au which has a link to the videos.

The need for a breast implant registry

This incident also points to the need for a reliable national breast implant registry. The current one, managed by the Australian Society of Plastic Surgeons (ASPS), has not been effective with only a small percentage of women who have breast implants in Australia, being included on it. There are a number of reasons for this; one of which is that ASPS only represents one group of surgeons who perform breast augmentation in Australia. Also, the College is aware that many ASPS members themselves have not used the registry.

In 2006, the then Minister for Health and Ageing made a declaration under section 124 of the *Health Insurance Act 1973* (concerned with promoting efficient quality assurance activities), to allow the collection and dissemination of breast implant information for safety and research purposes. The registry was also to make it more efficient to contact patients in the event of, for example, a device recall such as has occurred in the PIP case.

The current scheme does not meet the criteria articulated in the 2006 declaration nor can it so long as it remains in the control of one group. It is therefore not unanticipated that it has proved to be of little utility when it was needed most and certainly has not met the standard of an “efficient quality assurance” scheme envisaged under the 2006 Declaration.

To be effective and in the best interests of patients, such a registry must be managed independent of any society or organisation which may have or be perceived to have a vested interest. The key elements which should guide the establishment and running of any such registry are that it be:

1. Independently run by a trusted third party
2. Established with the agreement and input of all of the groups representing doctors who perform breast augmentation or reconstructive surgery.
3. Secure with patient privacy protected including non-identification of patient and doctor
4. Mandatory or Opt-out (rather than opt-in) for patients
5. Liability indemnification to prevent use of reported information being used against reporting doctors
6. Recognised the most important purpose is to facilitate the rapid identification and contact of patients if a concern about a specific device is discovered.

The last point is very important because if the registry seeks to have a wider purpose, for example tracking of complication rates of specific brands or specific surgeons, the reliability of the input data will be compromised and thus so will the primary purpose.

The College strongly recommends and would support the establishment of a breast registry that was anchored in these principles. The 1999 NSW report on cosmetic surgery, to which the College was a significant stakeholder and adviser, recommended that the TGA be given legislative authority to establish a mandatory device-tracking registry for current and future recipients of breast implants.

Although the College understands that the TGA is prohibited legislatively to manage such a scheme, the College is hopeful that a new breast registry currently under discussion and to be managed by Monash University will meet the requirements of an effective national registry.

In the meantime, myself, the College's executive and advisors are available to provide any assistance the Inquiry may require. Dr Daniel Fleming, the College's representative on the TGA and CMO expert advisory panels, is available to appear before your Committee.

Yours sincerely

Dr Colin Moore FRCS FRACS FACCS
President