

Breast implants – should we trust the TGA?

Can the government's health watchdog really be trusted to provide authoritative advice for Australian women on the safety of breast implants? The crisis in confidence about the implants comes at a time when faith in the calibre of government advice is lacking and the level of trust between the Therapeutic Goods Administration (TGA) and the public is shaky at best.

Reassurance from the Chief Medical Officer and government Ministers, as reported in weekend media, is also inadequate as it sings from the song sheet provided by the TGA. This advice, based primarily on Australian experience, is markedly out of step with countries like France, Germany and the Czech Republic which have recommended routine removal. Australian women deserve better.

It is clear that the TGA has not been performing to expectations. A recent investigation into the TGA over its transparency and accountability identified real concerns. Catherine King MP, the Federal Parliamentary Secretary for Health, took action in response to the level of disquiet across the health sector by commissioning a review chaired by Professor Dennis Pearce. The report was released last June and stated that while much had been done in recent years "the expectations of the public are not being met and there is more that the TGA can do".

Last month French health authorities advised 30,000 women to have their PIP implants removed because of an increased risk of rupture. However, the limited international focus for the TGA statement is based on statements from Britain where "testing by the UK regulator shows no evidence of cancer forming chemicals in the implants" – evidence that is consistent with Australian findings and is convenient for the TGA. There is a difference between risks of rupture and risks of cancer. Australian women expect much more balanced advice that the TGA has provided to date.

There are reasons why the government would be reluctant to provide similar advice as that provided in France. The costs to the health system of around five thousand such operations would be very significant at a time when all Australian governments are attempting to get the costs of hospital and health care under control. However, each time there is a recall of medical devices that have actually been used, as opposed to preventive action, there is a loss of community faith in our regulatory systems.

Currently, information being provided for Australian women comes from the six safety advisories that the TGA has issued since April 2010. Unfortunately, the TGA's response to the international concern over possible faulty *Poly Implant Prosthesis* (PIP) breast implants again falls short of meeting public expectations and will not give confidence to consumers. Indeed, the TGA response is somewhat myopic in its approach. The most recent TGA statement advises women that "there is currently no evidence of increased rupture rate for PIP implants in this country". What is this based on? In the same paragraph they state that there is "relatively limited available data". Yet there is evidence and a wealth of information available internationally that suggests otherwise.

This is not the first time that the TGA has been caught out mishandling health issues. The Public Health Association of Australia (PHAA) submitted to the Pearce Inquiry that the TGA had not been forthright or accurate in information that it provided regarding adverse reactions to the H1N1 influenza vaccine in children. In April and June of 2010 the TGA identified 16 cases of convulsions in

children under five years old as a reaction to Panvax. However, a subsequent independent review found that the number was more than double that identified by the TGA.

The TGA came under much more scathing criticism by the PHAA for failure to disclose critical information in a timely manner. In our submission to the Pearce Review in regard to vaccinations in children, the PHAA pointed out just how disingenuous the TGA could be. They sat on information about febrile convulsions in children for weeks but pointed the finger at other agencies about more minor delays.

In responding to the Pearce Review last month the government agreed to increase information about medical devices and make it easier for them to be recalled. However, this will have no impact on the use of PIP breast implants as the TGA recalled all implants that were waiting to be inserted into Australian women in April 2010.

The Federal government has taken action to improve community confidence in the TGA. However, the breast implant issue has emerged within weeks of its response to the Pearce review. The issue will provide a litmus test as to just how responsive the TGA has really become to community concerns.

The quandary is that these implants were judged as not safe enough to be implanted but are now judged to be safe enough to remain as implants. It should not be surprising that the International Society of Aesthetic Plastic Surgery advocates for the no-risk option. They support the French recommendation to remove PIP implants arguing "even without any clinical signs of rupture, these implants should be removed or exchanged immediately."

The evidence cited by the TGA to postpone action is twofold. Firstly, the PIP implants do not seem to be rupturing at the expected rate for all implants in Australia. According to acting Health Minister Nicola Roxon, there have been about 500,000 Australian implants inserted over the past decade. The general rupture rate over the same period has been around one in ten. The TGA argues the rate over the nine year period of PIP implants in Australia is much lower at around one in two hundred and fifty.

This extraordinary difference illustrates the problem with the TGA's approach.

This rate is only for ruptures reported to the TGA! The arrogance of this approach is incomprehensible. Why is the TGA focusing just on its own limited Australian data without referring to rupture rates from overseas?

Secondly, of the thirty seven ruptures that have been referred to in the TGA's own data there have been no reports of the rare cancer, anaplastic large cell lymphoma (ALCL), associated with PIP implants in Australia. What about those not on the TGA data base? There is also the argument "the gel from the PIP implant is non-toxic to the tissue around the implant even if the implant does rupture". The TGA has conceded the necessity to continue investigating the issue over coming months and will no doubt issue further advisories on its website. Once again there is a reluctance to look beyond Australian data. This does little to encourage confidence in the organisation – how long will it wait for enough Australian women to suffer an adverse event before acting?

How many Australian women will need to suffer before the TGA determines that it will have enough evidence to make similar recommendations to its European counterparts?

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