Australian Government Response

to

Senate Community Affairs References Committee

Report on The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothèse (PIP) breast implants

July 2013

Government response to recommendations

Recommendation 1
The committee recommends that there be rigorous systems put in place to ensure that medical practitioners provide consumers with all the information needed to allow them to give fully informed consent.

Response:

The Australian Government notes the recommendation, and undertakes to bring it to the notice of the Medical Board of Australia (MBA) for consideration.

Codes relating to the conduct of medical practitioners are the responsibility of the MBA. The MBA *Good Medical Practice: A Code of Conduct for Doctors in Australia* describes the ethical and professional standards that are expected to be met by all doctors registered to practise in Australia. It specifically covers informed consent (section 3.5).

Where a practitioner is believed to be acting outside the Code of Conduct, a notification can be made to Australian Health Practitioner Regulation Agency (AHPRA). The practitioner may then be subject to investigation or performance assessment by the Board so that appropriate action can be taken to protect the public.

Recommendation 2
The committee recommends that the TGA review all cases where sponsors have not met their obligations in relation to their listing on the Australian Register of Therapeutic Goods to ensure that these cases do not pose any health risk to the Australian public, and that important data has not been missed.

Response:

The Australian Government agrees with this recommendation, noting that in the context of the Report the recommendation refers specifically to high risk medical devices.

In 2010, the TGA implemented a process under which all annual reports required to be submitted by sponsors of Class III, Active Implantable Medical Devices and implantable Class IIb medical devices for the first three years of inclusion of the device on the Australian Register of Therapeutic Goods are audited and reviewed. All such reports have since this time been so audited and reviewed. Following the TGA's review of annual reports, appropriate regulatory action is taken where necessary.

Recommendation 3
The committee recommends that the Department of Health and Ageing include as part of their annual report process, information on the TGA's procedures for monitoring requirements placed on Class III medical devices.

Response:

The Australian Government agrees with the recommendation.

Since 2010, the TGA has had in place processes for monitoring requirements placed on the sponsors of high risk medical devices (see response to Recommendation 2). In accordance with this recommendation, the Department of Health and Ageing will seek to make information on these procedures available through its Annual Report.

Recommendation 4
The committee recommends that the TGA put in place measures to ensure that when recommendations made by the Advisory Committee on Medical Devices (formally the Medical Devices Evaluation Committee) are not followed, the delegate needs to set out specific and compelling reasons why the decision was taken.

Response:

The Australian Government agrees with the recommendation, and notes that the delegate is already required to document the specific reasons for their decision.

The Advisory Committee on Medical Devices (ACMD) is a statutory committee established under the Therapeutic Goods Regulations 1990 to advise and make recommendations to the Minister or Secretary about matters related to medical devices.

The ACMD may be asked for advice relevant to a decision to include a medical device on the Australian Register of Therapeutic Goods (ARTG). The delegate may take into account advice from the ACMD when making his or her decision. The Government agrees that the delegate should continue to document the specific reasons for that decision.

Recommendation 5
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.

Response:

The Australian Government agrees with the recommendation.

Consistent with the Australian Government's commitment to transparency, the TGA will adopt a strong focus on improving its communication and engagement with the community.

The Government will ensure that the TGA focuses on the information needs of the community and other stakeholders to ensure that the right information is presented in a way that meets the varying needs of all stakeholders.

The TGA website will be continuously improved and updated to ensure that it provides high quality information about its investigations into the safety of medical devices. In relevant cases this information will include the type of evidence being pursued.

In August 2012, the TGA made the Database of Adverse Event Notifications (DAEN) available to the public through its website[1]. DAEN provides information about adverse events to medicines that have been reported to the TGA since 1971. Further work will be

[1] The database is available at http://www.tga.gov.au/safety/daen.htm

undertaken to provide the public with access to Australian and New Zealand adverse drug and medical device incident data.

Recommendation 6
The committee recommends that the TGA publish updates and details of the discussions that have taken place with international regulators.

Response:

The Australian Government notes the recommendation and consistent with its response to Recommendation 5 will ensure that every effort is made to provide stakeholders with more information.

In particular circumstances, it may not be possible to disclose information about the content of discussions that have taken place with international regulators. The Australian Government and the TGA have signed agreements with several overseas regulatory agencies. These international agreements may include provisions detailing the circumstances under which confidential information and documentation exchanged under the agreement cannot be provided to third parties and therefore cannot be published.

Recommendation 7
The committee recommends that the TGA review its processes to ensure that faulty explanted devices are available to the TGA for independent testing.

Response:

The Australian Government notes the recommendation and agrees to review the relevant processes.

The TGA's Medical Device Incident Reporting and Investigation Scheme (IRIS) has in place a process to request return of faulty devices to the TGA for testing as part of the investigation into an incident when circumstances require. However, under current arrangements the TGA is not able to mandate that explanted devices be returned. The TGA will review the clarity and effectiveness of existing processes to facilitate obtaining samples of explanted medical devices that have been reported through IRIS when laboratory testing by the TGA is deemed to be appropriate and necessary to the investigation.

Recommendation 8
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.

Response:

The Australian Government agrees with the recommendation and will review the information on the TGA website in the light of this recommendation.

The Government will ensure that the TGA focuses on the information needs of the community and other stakeholders to ensure that the appropriate information is presented and that it includes a description of the limitations of the evidence and data provided.

Recommendation 9
The committee recommends that, in light of the Poly Implant Prothèse 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.

Response:

The Australian Government agrees with the recommendation.

As part of the 2013-14 Budget, the Government will provide seed funding of up to $5.1 million over two financial years to establish and maintain two clinical quality registers for breast implants and cardiac devices before they move to industry cost-recovery arrangements in 2015. The Government agrees that an opt-out approach will be adopted by the new breast implant register in line with the recommendation of the Australian Commission on Safety and Quality in Health Care on this matter.

The Government notes that the National Joint Replacement Registry is a successful registry that can provide a model for other registries subject to necessary adjustments for different devices and medical specialties as appropriate.

Recommendation 10
The committee recommends that the Australian Government extend the Medicare rebates for MRIs in accordance with the current medical advice.

Response:

The Australian Government agrees with the recommendation.

The PIP MRI initiative enables patients to access Medicare-eligible MRI scans to evaluate the integrity of the implants in all PIP patients and to detect implant rupture in patients who may have subsequently developed symptoms (whether or not they have previously had a normal imaging examination). The initiative has been extended for another 2 years from 11 March 2013 to 11 March 2015.

Recommendation 11a
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).

Response:

The Australian Government agrees with the recommendation.

In relation to Recommendation 13 of the HTA Review, the Government's response to Recommendation 8 of the Senate Inquiry into *The regulatory standards for the approval of medical devices in Australia* provides a response regarding the need to encourage greater reporting of adverse events from therapeutics (including medical devices).

In relation to Recommendation 14 of the HTA Review, the Government's response to Recommendation 7 of the Senate Inquiry into *The regulatory standards for the approval of medical devices in Australia* provides a response regarding the expanded use of post market surveillance data.

Recommendation 15 of the HTA Review is that registers for high risk implantable medical devices and/or procedures be established. This is addressed by the Budget measure outlined in the response to Recommendation 9 above.

Recommendation 11b
The committee strongly recommends that professional bodies, particularly the ASPS and ACCS, ensure through formal advice that surgeons are aware of their responsibilities to ensure that they provide an ongoing advisory role to their patients even after medical treatment has concluded.

Response:

The Australian Government agrees with the recommendation in principle, and undertakes to bring it to the notice of the Medical Board of Australia (MBA). The MBA may wish to work with professional associations to implement this recommendation.

Professional associations are independent bodies that guide the practice of individuals engaged in a profession and represent the interests of their members. It is a matter for them to determine the advice they provide to their members, noting their role in enforcement of professional standards and protection of the public.

Recommendation 12
The committee recommends that the clinical advisory committee established by the Chief Medical Officer should develop advice, based on current evidence regarding breastfeeding and PIP breast implants, as soon as possible, and that this information be included in future Chief Medical Officer reports on this issue.

Response:

The Australian Government agrees with the recommendation.

The Chief Medical Officer, in consultation with the clinical advisory committee, provided advice regarding breastfeeding and PIP breast implants on 2 July 2012 (www.health.gov.au/internet/main/publishing.nsf/Content/PIP-breast-implants-breastfeeding.htm).

Recommendation 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.

Response:

The Australian Government agrees with the recommendation.

The Australian Government, through the Report of the Chief Medical Officer, has advised that currently available information cannot confirm or exclude the possibility that PIP implants rupture more than other implants but the number of reported ruptures in Australia to date is within an expected range. The TGA continues to review its advice in the light of further information as it becomes available, including information from the final report of the UK's expert committee convened to review the safety of PIP implants released on 1 February 2013.

The TGA will consider data obtained from the Government subsidised Magnetic Resonance Imaging when providing information to the public on the extent of ruptured PIP implants.