Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 1

Topic: Gel approved for PIP breast implants

Hansard Page: 32

Senator Xenophon asked:

"I go to a question I asked in estimates on 2 or 3 June 2010. I asked about whether the gel that was initially approved for use in PIP breast implants was the same gel found in independent testing by the TGA. The answer given to me, in part, was that the samples tested by the TGA—in other words, the approved gel and the gel in the PIP implants—were polysiloxane based materials. It confirmed that the samples tested by the TGA contained a gel that had superior physical properties to the approved gel. Specifically, if the shell were to rupture, the viscosity of the gel was such that it would be less likely to leak when compared to the originally approved gel material. Dr Richards, what I cannot quite understand is, where the answer was that it had superior physical properties to the approved gel, does that mean that it was not the actual approved gel that the TGA discovered back then; in other words, it was something different but it was found to have superior physical properties. I have never quite understood that."

Answer:

The tests conducted by the TGA in 2010 investigated whether the gel in samples of PIP breast implants supplied in Australia met the requirements of international standards that apply to the cohesiveness of the gel, the strength and durability of the shell and toxicity. The tests for cohesiveness (viscosity) passed the requirements of the international standard. The testing carried out by the TGA in 2010 on the gel from PIP breast implants did not provide definitive evidence to show that the gel used in PIP breast implants sold in Australia was not the approved gel.

Since the TGA did not have a sample of a PIP breast implant that was known to contain the approved gel, in 2010 the TGA formulated a gel using the approved (Nusil Med 3 6300) ingredients and found that the PIP gel appeared more viscous than the gel prepared in the TGA laboratory. This did not necessarily demonstrate that the gel in the PIP breast implant was not the authorised gel. Subsequently, the gel in the PIP breast implant was found by the TGA to have a similar viscosity to the gel from another brand of breast implant that was manufactured using the same gel that had been approved for PIP breast implants (Nusil Med 3 6300).

Testing of the viscosity of PIP breast implants by the TGA has not provided evidence to indicate that the viscosity of the PIP gel would be a factor in the rupture rate of these implants.

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9 May 2012

Question no: 2

Topic: Clinical Registers

Hansard Page: 35

Senator Moore asked:

"What do we have to do to get an effective register so that if sometime in the future, and it will happen, when there is a device that someone is upset about, we will know that we will be able to contact the 20,000 Australians or thereabouts that have used device X? Consumers put a recommendation this afternoon at the hearing *[Ms Carey, p3 of Hansard]* about using the pre-existing admitted hospital register. Could we get some advice on notice on that, and the whole opt-in, opt-out arrangement?"

Answer:

The data collected using the Admitted Patient Care (APC) National Minimum Data Set (NMDS) is compiled from data supplied by state and territory health authorities. The electronic confidential data supplied include demographic, administrative and length of stay data, as well as data on the diagnoses of the patients, the procedures they underwent in hospital and external causes of injury and poisoning.

The data supplied is for each hospital admission, not for each patient, so patients who were admitted more than once in the year have more than one record. Medical devices implanted during a patient's episode of care are already recorded using the Australian Classification of Health Interventions (ACHI).

The APC NMDS can provide the number of implantable medical devices, but cannot track implantable medical devices as the dataset does not identify patients or surgeons performing the procedures. The data is supplied to the Commonwealth on an annual basis. These factors would constrain its value in facilitating urgent recall of patients who had a particular device implanted or to enable early identification of problems with the devices.

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.

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9 May 2012

Question no: 3

Topic: Poly Implant Prothese (PIP) Magnetic Resonance Imaging (MRI) Services

Hansard Page: 37

Senator Moore asked:

If I am living in Brisbane, I should be able to get an MRI referral fairly easily; if I am living somewhere else, is there any provision to help me undertake this process?

Answer:

To ensure timely imaging for affected patients, the Government extended access for the PIP items beyond the current arrangements for Medicare-eligible MRI services. This included the extension of requesting rights to GPs and Medical practitioners for the PIP MRI items.

The extension of requesting rights to GPs and Medical practitioners for the PIP MRI items meant that a patient could see any GP or Medical Practitioner in any region and obtain a Diagnostic Imaging referral request for an MRI.

This also enables patients with normal results to be managed in the primary care setting.

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Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 4

Topic: Poly Implant Prothese (PIP) Magnetic Resonance Imaging (MRI) Services

Hansard Page: 37

Senator Moore asked:

I know we can look at the map but can we just find out for the sake of the women what the process would be if they cannot do it—that would be really useful;

Answer:

To assist Doctors and patients to identify practices that can provide the PIP MRI services, concurrent with the Ministers announcement on 10 March 2012, the department published information on the PIP MRI items on its website at www.health.gov.au

This information included what affected patients should do, who could refer the PIP MRI services, the associated costs, and information for MRI providers. The information also included the TGA Breast MRI hotline number (1800 217 257) and the phone number for the MRI section within the department (02) 6289 9100.

The department's switchboard was also informed of the announcement and was advised to transfer patient's calls to MRI section.

The Department also briefed the Australian Diagnostic Imaging Association (ADIA) and the Royal Australian and New Zealand College of Radiologists (RANZCR).

The Department of Human Services (Medicare Australia) also published information regarding the PIP MRI items on their website, and their call centre staff were briefed on the PIP MRI items to assist patients.

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HEALTH AND AGEING PORTFOLIO

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 5

Topic: Poly Implant Prothese (PIP) Magnetic Resonance Imaging (MRI) Services

Hansard Page: 37

Senator Siewert asked:

(With regard to access to MRI services with a breast coil) What about northern Australia?

Answer:

The Northern Territory has one Medicare-eligible MRI unit located at Royal Darwin Hospital. This unit has recently procured a breast coil and will be accepting PIP patients from 5 June 2012.

Patients who sought to have a scan prior to NT Medical Imaging announcement on 15 May 2012 were advised to contact the Territory Health Department. Each state and territory government administers a travel and accommodation assistance scheme for people requiring specialised health care not available within a specified distance from their place of residence http://www.health.nt.gov.au/Hospitals/Patient_Assistance_Travel_Scheme

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HEALTH AND AGEING PORTFOLIO

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 6

Topic: CMO's Report

Written Question on Notice

The Committee asked:

How and on what date was the Chief Medical Officer's report into Poly Implant Prothese (PIP) Breast Implants made publicly available?

Answer:

The Chief Medical Officer's report was placed on the Department of Health and Ageing website on Monday 7 May at 6.41pm.

A link to the report was added to the TGA website. The operators of the HealthInsite website were also asked to provide a link to the report.

The Chief Medical Officer emailed a pdf copy of the report, associated fact sheets, Q&As, and the link to the location of the materials on the health website, to the following stakeholders on Tuesday morning 8 May with the request that they bring it to the attention of relevant members or consumers:

CMO's Clinical Advisory Committee Members:
Professor Claire Jackson
Dr Christopher Pyke
Dr Daniel Fleming
Professor Liz Wylie
Assoc Prof Rod Cooter
Prof Richard Murray
Dr Steven Hambleton
Dr Helen Zorbas
Maxine Morand
Karen Carey
Prof John Horvath

Royal Australian College of General Practitioners
Australian College of Rural and Remote Medicine
Australian Society of Plastic Surgeons
Australasian College of Cosmetic Surgery

Royal Australasian College of Surgeons
Breast Surgery Society of Australia and New Zealand
AMA
Australian General Practice Network
State and Territory Chief Health Officers
Cancer Australia/NBOCC
Breast Cancer Network Australia
McGrath Foundation
Olivia Newton-John Cancer and Wellness Centre
Cancer Council Australia
Cancer Voices Australia
Consumers' Health Forum
State and Territory Breast Screening Services

It was also emailed to individual stakeholders Diane Arnold Reed and Darlene Watkins, who had previously spoken directly to the CMO.

From 8.30am 8 May, the Breast Implant Information Line commenced call backs to over 2230 callers who had left their contact details with the Line since its inception in January 2012. The nurses making the call backs are advising the callers of the release of the CMO's Report, its main findings and its location on the health website. For those contacts that remain outstanding, two additional attempts will be made at different times of the day and different days of the week.

Callers who do not have internet access are also being offered to have a copy of the report and associated materials mailed to them. As at 8.30pm on Tuesday 15 May, 102 callers had requested the report be mailed to them and 122 callers had requested the report be emailed to them.

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9 May 2012

Question no: 7

Topic: Communication between TGA and DOHA

Written Question on Notice

The Committee asked:

When did the TGA first communicate concerns about PIP implants to DOHA?

(a) What was DOHA's response?

(b) What systems are in place to facilitate this exchange of information?

Answer:

The TGA is a division of the Department of Health and Ageing.

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HEALTH AND AGEING PORTFOLIO

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 8

Topic: Information exchange with overseas regulators

Written Question on Notice

The Committee asked:

a) What measures does the TGA have in place to monitor events overseas that could be relevant to Australia, such as withdrawals?

b) Do these measures extend beyond strictly regulatory matters, to include information that could indirectly affect the TGA's operations, such as media reports relating to medical device companies?

Answer:

a) The TGA exchanges information with overseas regulatory agencies through a range of mechanisms including National Competent Authority Reports (NCARs), and the Global Harmonisation Task Force (GHTF). Issues and actions taken by TGA and other agencies are exchanged using NCARs. The TGA's medical device incident reporting & investigation scheme (IRIS) team is the Secretariat of the NCAR program. GHTF members exchange information about actions and issues relating to adverse events with medical devices. The TGA Recalls Unit undertakes routine investigations of all product recall notifications received from overseas regulators. Where the product is on the Australian Register of Therapeutic Goods and recall action has not already been undertaken in Australia, the Australian sponsors/manufacturers are contacted and advice is sought on whether the overseas recall is relevant to Australia. If appropriate, recall action is initiated in Australia.

b) In addition to the formal 'recall' processes (eg NCARs), regulators also use informal networks to advise each other of safety issues and regulatory incidents (including withdrawal of products from supply). Regulators with which TGA has confidentiality arrangements in place will sometimes include more detailed information in this advice. On occasion, the TGA has used these informal networks to seek more detailed information from overseas regulators with which TGA has collaborative arrangements in place, in response to reports in the international media regarding products also supplied in Australia. This solicited information has, on occasion, assisted the TGA to make regulatory decisions regarding these products.

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HEALTH AND AGEING PORTFOLIO

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 9

Topic: Problems with PIP and media coverage

Written Question on Notice

The Committee asked:

a) Was the TGA aware of the problems with PIP and its founder before they were reported in the media? If so, how long before?

b) What action did the TGA take on this information?

Answer:

Please refer to Attachment 1 of the Department's submission to the Committee for a full chronology of the regulatory, communication and other activities undertaken regarding PIP implants.

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ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 10

Topic: Collection of further information by the TGA

Written Question on Notice

The Committee asked:

Many submitters have raised the issue of the 'unknowns' in this situation – for example the exact rupture rate, the affects of the contaminated gel on a person's health. What is the TGA doing to collect information in these areas so that the Australian public can be provided with accurate information?

Answer:

The TGA continues to gather evidence about the safety of PIP implants, including by:

- conducting scientific tests on available samples of PIP implants, including explanted devices;
- consulting with Australian and international experts (including scientists, clinicians and consumers), to monitor the emerging Australian and international evidence;
- working closely with international regulators including the FDA and European authorities;
- seeking more detailed information from surgeons and consumers regarding adverse events reported to the TGA; and
- regularly updating its public advice as new evidence emerges.

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HEALTH AND AGEING PORTFOLIO

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 11

Topic: Communication by the TGA

Written Question on Notice

The Committee asked:

The Australasian College of Cosmetic Surgery was quite critical in its submission of the way the TGA has communicated with the public. In effect, the submission says that the TGA has done a lot of work behind the scenes to obtain evidence to make good decisions, but the way this has been communicated to the public doesn't make this work clear. How does the TGA respond to this?

Answer:

On 8 December 2011, the Parliamentary Secretary for Health and Ageing released a document entitled '*TGA Reforms: a Blueprint for TGA's Future*'.

Consistent with this report, the TGA will adopt a strong focus on communication and engagement with the community.

The Government will work to adopt the recommendations of the recent review to improve the transparency of the Therapeutic Goods Administration (the Transparency Review) and has asked the TGA to progressively implement them over the next four years.

Over the next 12 to 18 months the TGA will give priority to actively engaging with the community and providing improved information and education materials.

The TGA will also establish an Australian Therapeutic Goods Advisory Council. Representation on this Council will come from across the stakeholder base to encourage wider input into the work of the TGA, including the implementation of the Transparency Review's recommendations. Stakeholders will also be able to provide direct feedback and comment to the TGA through attendance and participation in biannual public fora.

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. This will include working with stakeholders to develop consultation principles to deliver transparent stakeholder engagement in regulatory policy making on emerging issues, and to promote accountability to the public.

Central to effective communication is the implementation of a communication strategy to inform and educate stakeholders. Of critical importance in this strategy, is the development of information products that inform consumers, health professionals and the regulated industry about emerging health issues pertinent to the work of the regulator.

The TGA website will be continuously improved and updated to ensure that it provides high quality information in a variety of formats.

The TGA will develop and publish a policy on the disclosure of commercial in confidence information broadly consistent with international counterpart regulators; and will work with state and territory governments to improve the visible management of adverse event reporting.

Although the TGA cannot give individual clinical advice regarding medical devices or other therapeutic goods, as each patient's circumstances are different, the TGA has provided weekly updates on its website in relation to PIP breast implants since early 2012. These updates have provided the latest scientific information available to the TGA and are designed to provide information to medical practitioners and patients necessary for them to jointly make informed decisions in light of the individual circumstances of each patient.

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Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 12

Topic: Implementation of the recommendations of the Transparency Review

Written Question on Notice

The Committee asked:

Concerns were raised in the previous inquiry into medical devices and in submissions to this inquiry about the delay in adopting recommendations from the TGA Transparency Review.

(a) Can the department provide more information on the timeframe for this?

(b) Has there been specific funding set aside for implementation? How much?

(c) Surely this particular issue demonstrates how important the implementation of these recommendations is?

Answer:

(a) A wide range of reforms was encompassed in *TGA Reforms: a blueprint for TGA's future* (the Blueprint), announced by the Parliamentary Secretary for Health and Ageing on 8 December 2011. The TGA is currently developing a comprehensive project plan for the implementation of the reforms, which should be completed by 30 June 2012. Once finalised, the high level plan will be made available to the public on the TGA website.

(b) The full cost of regulating therapeutic goods is met through cost recovery from the regulated Industry. The proposed reforms will be resourced through the TGA's fees and charges, including through savings generated by internal efficiencies.

(c) The Blueprint includes a commitment to implement the recommendations of the Transparency Review.

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HEALTH AND AGEING PORTFOLIO

Inquiry into the role of the Government and the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothese breast implants

9 May 2012

Question no: 13

Topic: Concerns from the previous inquiry

Written Question on Notice

The Committee asked:

Concerns were also raised in the previous inquiry in relation to further research that needed to be done on particular types of devices, to determine whether there were specific design flaws that made the devices unsafe (in that instance, metal-on-metal joint replacements).

a) Does the TGA have any capability to conduct or commission such research?

b) Can the TGA make recommendations to DOHA that research be undertaken?

c) Has any recommendation been made in relation to metal-on-metal devices, especially given the increased concerns about them in recent times?

d) If not, why not? If so, when will this take place?

Answer:

Responses to particular recommendations from the previous inquiry are a matter for Government.

a) TGA may expend funds held in its special account in relation to the objects of the Therapeutic Goods Act 1989 (the Act). The TGA has no authority under the Act to conduct or commission clinical research involving individual patients to investigate the impact on health outcomes from the use of a device included on the ARTG. The TGA may conduct its own tests, generally in accordance with accepted international standards, on a particular device in order to evaluate any specific concerns about the manufacturing quality or performance of the device itself.

b) TGA, with other parts of DoHA, has held discussions with the organisers of an international study designed to monitor the health over 5 years of approximately 5000 recipients of the ASR metal-on-metal hip prosthesis. The National Joint Replacement Registry (NJRR) will be a partner in the study which is to be run from the USA. The analysis of Co and Cr levels in patients' blood will be conducted as part of this study to evaluate any correlation with device performance and patients' health.

On a related matter, TGA has been approached to gauge our interest in a smaller local

study involving analysis of Co/Cr levels in approximately 350 Australian recipients of the ASR implant. This will look for a correlation between blood levels of these elements and device revisions.

c) TGA is in the process of consulting with its Orthopaedic Expert Working Group and the Commonwealth Chief Medical Officer to formulate updated advice in relation to metal-on-metal hips following recent publication of scientific research and statements by other regulators. TGA also recently worked with NJRR and the sponsor of another metal-on-metal hip prosthesis with a high revision rate to have the device withdrawn from the Australian market.

d) Updated advice is expected to be finalised by July 2012.