Medical Technology Association of Australia

# *Submission to Senate Standing Committee on Community Affairs Inquiry into Medical Devices, in particular PIP breast implants April 2012*

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MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

# 1. Executive summary

The Medical Technology Association of Australia (MTAA) takes the opportunity of a further review by the Senate Standing Committee on Community Affairs to outline the current processes for regulation of medical devices addressed in the terms of reference and to highlight areas where reform is currently underway to address the concerns identified in the terms of reference.

MTAA is not responding to the specific issues connected with the approval, monitoring and recall of the Poly Implant Prosthèse (PIP) breast implant as it does not have specific knowledge of this product. The distributor of the PIP breast implant in Australia is not a member of the MTAA. MTAA points out that the criminal issues associated with the manufacture of PIP breast implant should be separated from the discussion of the regulation of medical technology in Australia.

The terms of reference raise wider issues that impact on the regulation of all medical devices and MTAA has responded to these terms of reference.

As MTAA outlined in its submission[1] to the previous Senate Committee inquiry into the regulation of higher risk medical devices[2], Australia has a risk-based system of assessment to manage the approval and registration of medical devices. The greater the risk carried by the product in terms of how invasive within the human body the product is, the duration of use and the risk it poses to the patient, user or other person, the greater the evidence required to support registration.

The system used by the regulator in Australia, the Therapeutic Goods Administration (TGA) is similar in concept to that used in the European Union. Both regulatory systems require manufacturers to comply with a comprehensive set of essential principles of safety and efficacy. Manufacturers usually adopt internationally agreed standards to achieve this. The international quality management system standard for medical devices, ISO13485: 2003, requires manufacturers of medical technology to establish and maintain the high quality of design, manufacturing and postmarket monitoring necessary for the commercialization of medical technology, is a pre-requisite for either TGA or overseas conformity assessment body certification. Assessment and certification of these quality management systems occurs before manufacturers are approved to supply their products. Through demonstrated compliance with those international standards applied to a medical device, manufacturers are able to provide evidence to the TGA of conformity of the product to the Australian legislative requirements. Continued adherence to the quality

[1] http://aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_ctte/medical_devices/submissions.htm

[2] http://aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_ctte/medical_devices/tor.htm

management system requirements is also assessed through regular surveillance audits.

All medical devices carry a risk associated with their use. By complying with the requirements of the legislation, manufacturers can demonstrate that the risks identified with the use of the device have been adequately mitigated through the design, development and manufacture of technology so that the clinical benefits outweigh the risks of using the device.

MTAA supports moves by the TGA to improve the collection of information about a medical device once it is in the market, including enhanced processes for reporting by patients, doctors, and end users.

## 2. About the medical technology industry

MTAA represents the manufacturers, exporters and suppliers of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from commonplace, everyday consumable items such as bandages and syringes, to high technology implantable devices such as cochlear implants, cardiac defibrillators and orthopaedic joints, diagnostic imaging equipment, and products which use biological materials.

Medical technologies provide life-saving assistance to patients in need, deliver long-term sustaining quality of life, and provide aid to improve the day-to-day comfort of patients. Without medical technologies patients would not be able to walk (implantable hips and knees), to hear (cochlear implants and hearing aids), to see (intraocular lenses), or to survive (cardiac pacemakers and implantable defibrillators). Each of these advances has significantly changed the way people with life-threatening or life-challenging conditions are cared for.

The medical technology industry had sales in Australia of more than $8.02 billion in 2010-11 and employs more than 17,500 people. It is strongly research-based with clinical input from healthcare professionals to design and develop products for improved patient benefit. MTAA represents companies supplying approximately 70% of all non-pharmaceutical medical products on the Australian market.

## 3. Term of reference (b):

> The procedures TGA has in place to continuously monitor relevant information in relation to device manufacturers and sponsors, including the legal or approval issues both in Australia and overseas

In addition to the evidence supplied by a manufacturer and their Australian sponsor when applying for registration, the manufacturer has ongoing legislated obligations to monitor and report on the performance of approved medical devices. These requirements apply to all medical devices irrespective of risk classification. The

ongoing obligations include the collection of clinical data during the entire lifetime of a device and the continuous updating of the clinical evidence file which has to be verified by the conformity assessment body responsible for quality system certification and surveillance.

It is the manufacturer's responsibility to demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any side effects, are minimized and acceptable when weighed against the benefits which the patient derives from the intended performance. Furthermore the manufacturer must show that any claims about the device's performance and safety are supported by suitable evidence.

Postmarket responsibilities need to be put into the overall context of the regulatory oversight process in Australia and many overseas countries, with an understanding of the realistic and effective balance between the premarket requirements to gain marketing approval and the ongoing legislated postmarket responsibilities to maintain to support that approval.

It is generally accepted by regulators that it is not feasible for any regulatory agency to test every medical device as part of an approval process given the volume and range of medical devices and high demand for improved therapeutic technology. However, regulators and the population at large need to be assured that medical devices are safe and function appropriately. This dilemma was addressed in Australia in 2002 by adopting a regulatory system which requires a greater level of documented and audited development and testing programs by manufacturers than was previously required. Introducing a risk based regulatory system meant that the level of testing and compliance requirements for manufacturers, specified by internationally recognised standards and test methods, increased commensurate with the risk to the users of the medical technology. It also required increasing levels of independent auditing and certification of the design, development, testing and postmarket surveillance procedures by manufacturers.

Under this legislated system it is the responsibility of the manufacturer to apply and document the standards and test methods applicable to the device to demonstrate the safety and effectiveness of the device. It is the responsibility of conformity assessment bodies such as the TGA and European Notified Bodies, to assess and certify that a medical device complies with a set of comprehensive legislated safety and effectiveness requirements known as the Essential Principles.

Through agreements between Australian, European and Canadian governments the TGA accepts certification from the authorised conformity assessment bodies of those countries, as evidence that the medical technology complies with the Australian legislation before it can be supplied in Australia. In addition to this the TGA audits each application and the certification and other evidence supporting those applications for the highest risk medical devices before approval. The TGA will also audit any other application if necessary to be assured that the certification has been issued correctly and that the evidence developed by the manufacturer

demonstrates compliance with the regulations and that its medical devices are safe and effective. This provides a realistic balance for a regulator between obtaining evidence of the safety of a medical device and not testing each and every device that requires marketing approval.

Once marketing approval has been gained in Australia, a manufacturer is required[3] to notify the TGA, or the sponsor, as soon as practicable after becoming aware of any serious adverse event. These are events which might have caused (or may cause) serious injury or death of a patient and which may have been associated with the medical device. These include events which may be related to malfunction or deterioration in the characteristics or performance of a medical device, and any inadequacy in the design, production, labelling or *Instructions for Use* of the device. These requirements also extend to "near misses" where the event did not result in patient harm but may do if it happens again.

If the event represents a serious threat to public health a sponsor is required to report that information to the TGA within 48 hours after they become aware of it.

There is a requirement for a thorough manufacturer investigation of the event to identify the root cause. Such investigations often are conducted with the active involvement of TGA or other regulators. The manufacturer is required to implement corrective actions which may include changes to product design, labelling or production process, issue of advisory notices to users or product recall.

A manufacturer is also required to notify the TGA or the sponsor with information relating to any technical or medical reason for a malfunction or deterioration that has led the manufacturer to recall a product. Recalls conducted in Australia must be notified to TGA and are required to be supervised and audited by TGA.

In addition, a manufacturer is required to "systematically review information gained after the device was supplied in Australia"[4]. This information can come from sponsor feedback, expert user groups, customer surveys, customer complaints and warranty claims, service and repair information, literature reviews, user feedback other than complaints, device tracking and registration registers, user reactions during training programs or adverse event reports from users.

Following is a table which sets out the obligations on a sponsor once a product is in the Australian market[5].

[3] Schedule 3 of the *Therapeutic Goods Regulations (Medical Devices) 2002*
[4] Therapeutic Goods Administration, *Australian Regulatory Guidelines for Medical Devices* (Version 1.1)
[5] Extracted from the ARGMD at page 297 see http://tga.gov.au/pdf/devices-argmd.pdf

| Requirement | Example(s) | Legislative reference |
|---|---|---|
| Allow entry and inspections of premises | • allowing a person authorised by the TGA to enter and inspect any premises, including outside Australia, where the devices are manufactured or located<br>• while on the premises, to inspect the premises and medical devices on the premises<br>• to take samples of medical devices from the premises | section 41FN(1) of the Act |
| Deliver samples upon request | • providing samples of the medical device to the TGA upon request | section 41FN(2) of the Act |
| Availability of information | • access to the technical documentation that demonstrates compliance with the Essential Principles<br>• access to the evidence that appropriate conformity assessment procedures have been applied<br>• on request, provide this information to the TGA within specified timeframes | section 41FN(3) of the Act |
| Advertising material | • ensuring any advertising material relating to the medical device complies with the TGA requirements | section 41FN(5) of the Act |
| Report details of certain incidents and performance issues to the TGA | • reports events in accordance with the requirements laid out in the Therapeutic Goods Act 1989 and the Medical Device Regulations 2002 and the ARGMD | section 41FN(3)(d) of the Act |
| Report any overseas regulatory actions to the TGA if the product involved is from the same batch or production run that was supplied in Australia | • an adverse event has occurred with a product in another country and the ensuing investigation by the manufacturer determines that a batch of the product should be recalled. If the batch is supplied in Australia the sponsor should notify the TGA of the overseas action to determine if the same action should occur in Australia | section 41FN of the Act |
| Report results of investigations undertaken by the manufacturer to the TGA | • Rrlay the results to the TGA of an investigation into a returned sample associated with an adverse event report | section 41FN of the Act |
| Assist the TGA and the | • pass information to the TGA and the | section 41FN of the |

| Requirement | Example(s) | Legislative reference |
|---|---|---|
| manufacturer in investigations if an incident occurs | manufacturer during an investigation of an adverse event<br>• assist in the gathering of information and samples from the user | Act |
| Take corrective action when necessary | • recall medical devices<br>• inform the public about medical devices that do not comply with requirements | section 41KA of the Act |
| Maintain distribution records for product supplied in or exported from Australia | • Regulation 8.1(b)<br>• records of delivery to:<br>o distribution warehouses<br>o manufacturing sites<br>o retails outlets | section 41FO of the Act |
| Conditions imposed when medical devices are included in the ARTG | • for Class III, Class AIMD, and Class IIb implantable devices to provide annual reports for first three years that the device is available in Australia | section 41FO(2) of the Act |

TGA undertakes ongoing monitoring to ensure that regulatory compliance and safety of the medical devices continues after supply to the Australian market. These monitoring activities may include[6]:

- reviews of technical and clinical information to ensure that compliance with the Essential Principles and conformity assessment procedures is demonstrated
- testing to confirm compliance with the Essential Principles
- inspections of manufacturer's or sponsor's records and documentation
- on-site testing of medical devices or taking samples for off-site testing
- audits of distribution records
- audits of the traceability of raw materials used in the manufacture of therapeutic goods and tracking of component parts
- trend analysis and reporting to sponsors

Action is undertaken by the TGA and the sponsor and/or manufacturer after any of them becomes aware of information about a medical device supplied in Australia, such as adverse event reports, malfunctions, or results of testing.

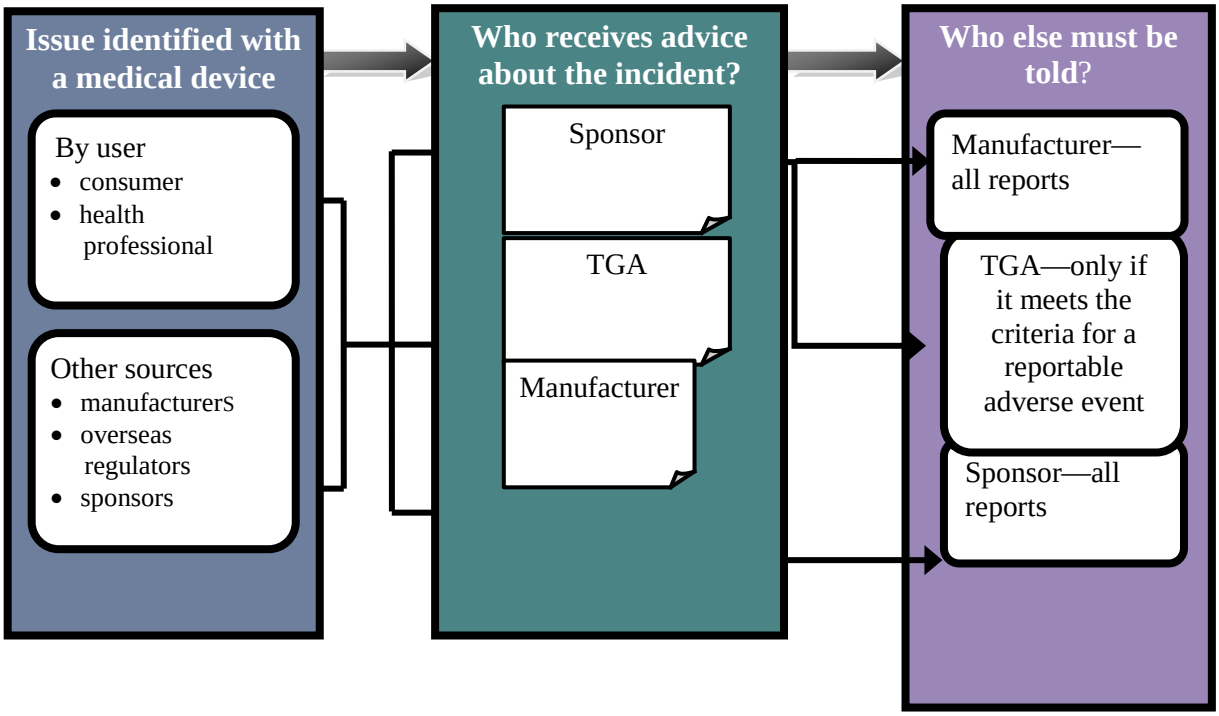
As a result of the various Mutual Recognition Agreements for medical device regulation and its participation in the Global Harmonization Task Force (GHTF), the

[6] ARGMD at page 301

TGA exchanges vigilance information with overseas regulatory agencies[7]. This includes where corrective action, including a recall, is to be taken or where there is a serious risk to the safety of patients or other users, but where the corrective action is still being determined.

MTAA considers that the postmarket responsibilities for sponsors and manufacturers of medical technology are effective and realistic requirements for an industry dedicated to producing safe and effective products for the benefit of patients and other users of that technology.

**Who is notified when there is an issue with a medical device?[8]**




The TGA has a voluntary reporting system for users of medical devices to report faults or issues with the products they use. The users range from medical practitioners and nursing staff to individuals who have purchased a medical device. These reports are investigated by the TGA and can involve the manufacturers assisting the TGA to determine the cause of any reported issues.

TGA has recently implemented a more accessible process for the reporting of medical device incidents[9]. While the reporting process has always been available to healthcare professionals and to patients, it is now more accessible on the TGA website with more explicit directions to healthcare professionals on how to report an incident.

[7] ibid
[8] ARGMD at page 305
[9] http://tga.gov.au/hp/problem-device-reporting-incidents.htm

Following considered examination by the manufacturer, sponsor and the TGA , if a problem report or issues discovered by a sponsor or manufacturer require a recall of a product, and those products were either prescribed for or implanted in patients by medical professionals, it is imperative that information made available to patients is done in a very considered way bearing in mind that the dataset may be incomplete until a properly considered cause has been determined. It would be inappropriate to require sponsors to directly inform patients as it would adversely interfere with the doctor-patient relationship in which the care of the patient is guided by the healthcare professional. The health professional's judgement about the health care of the patient is paramount in advising a patient about the best course of action.

MTAA supports increased education on, and awareness of, processes to report adverse events by patients, end users and healthcare professionals. The information collected by the TGA should be used to provide the Department of Health and Ageing with insights into any potential problems with medical devices so that they can work with industry, healthcare professionals, industry associations and consumers to prevent further problems.

## 4. Term of reference (e):

The procedures the TGA has in place to assess the risk to Australian patients if devices available in Australia are the subject of warnings or withdrawals overseas

Adverse events that occur in Australia are required to be reported to the TGA by the sponsor. Adverse events that occur overseas for devices supplied in Australia do not need to be reported but records of these events should be available if requested by the TGA. A sponsor is also required to report any remedial action that arises overseas for devices supplied in Australia.

TGA receives advice about overseas incidents through the National Competent Authority Report Exchange program (NCAR) system. The purpose of the NCAR system developed by the Global Harmonisation Task Force is as a "… linked system incorporating adverse event reporting, and vigilance and post-market surveillance components to improve the protection of the health and safety of patients, users and others by reducing the likelihood of repeated similar adverse events. This occurs through the dissemination of information that could be used to prevent the repetition of the adverse events or to alleviate the consequences of such repetition.

Following the receipt of an adverse event report submitted by the manufacturer or its authorized representative, National Competent Authorities (NCA) determine the necessity/urgency of disseminating this information to member

NCAs via the National Competent Authority Report (NCAR) exchange program."[10]

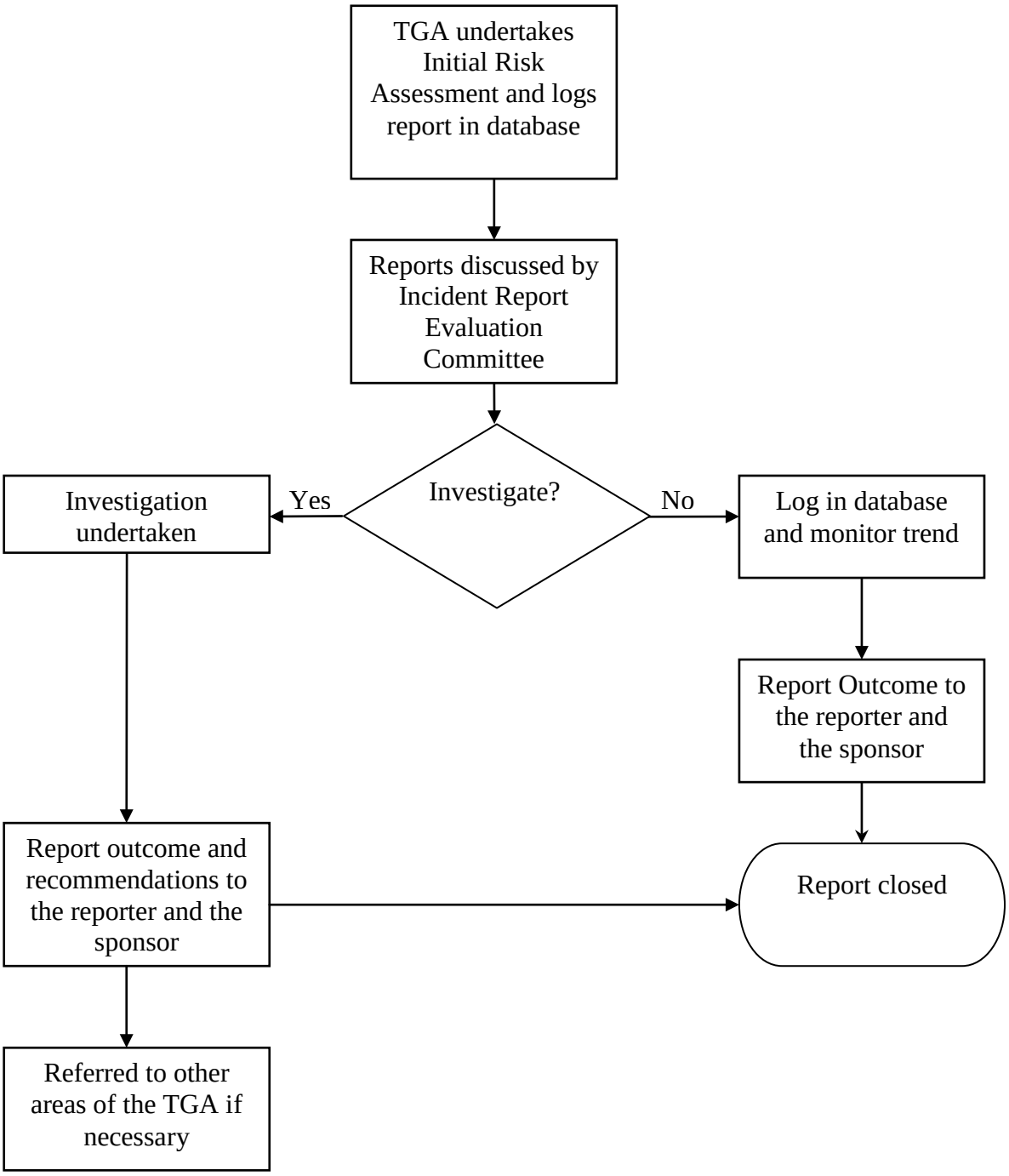
## 5. Term of reference (f):

The procedures the TGA has in place to communicate device information (including withdrawal information) to the general public, with a focus on affected patients

As outlined above in response to Term of Reference (b), it is the responsibility of the sponsor to advise TGA of an adverse event once the sponsor is aware of that event. The following flow chart (taken from the ARGMD) sets out the process involved once TGA receives notice of an adverse event. While there is provision for the outcome to be reported back to a 'reporter' (which could include a healthcare professional), apart from notifying sponsors of outcomes relating to Device Incident Reports, there is no formal mechanism to notify the world at large about the outcome of a review of an adverse event report received by the TGA. A sponsor is required to make an announcement about a recall and the information is repeated on the TGA website following announcements to recall coordinators in each state and territory.

[10] GHTF *Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form* GHTF/SG2 N79/R11)

**What the TGA does when it receives an adverse event report[11]**




[11] ARGMD at page 315

A panel of scientific, engineering, and clinical experts assesses all reports and determines what level of investigation will take place. TGA's guidance is that isolated incidents or problems with a very low clinical risk and no impact on device performance are not usually investigated[12].

The outcome of an investigation may include one or more of the following[13]:

- referral to other areas of TGA for regulatory actions, such as auditing of the manufacturer
- recall of the devices to:
    - remove the devices from supply in Australia
    - allow correction at the user's site
- the issue of a Safety Alert where there is a need to reinforce the manufacturer's *Instructions for Use* to those responsible for the use of the device or those affected by the problem
- product improvement for problems that are not safety related - carried out by the manufacturer
- report in the TGA News, on the TGA website and/or appropriate journals.

The Uniform Recall Procedure for Therapeutic Goods (URPTG), available on the TGA website, sets out detailed information about the action to be taken by health authorities and sponsors when medical devices available in Australia are to be removed from supply or use, or are subject to corrective action. The sponsor has the prime responsibility for implementing recall action on behalf of the manufacturer, and for ensuring compliance with the recall procedure at its various stages. However, no recall, regardless of level, may be undertaken without consultation with the Australian Recall Coordinator within the TGA and without agreement on the recall strategy.

TGA has the responsibility to provide advice and assistance to the sponsor in relation to letters, advertisements and recall strategies, and notifying agreed third parties, such as state/territory health departments, overseas regulatory agencies, the Australian Competition and Consumer Commission.

[12] ARGMD at page 315
[13] ibid