Consumers
Health Forum
*of Australia*

**CHF Submission to the Senate Community Affairs Committee**
***Inquiry into the Regulatory Standards for the Approval of Medical Devices***

**July 2011**

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## *Inquiry into the Regulatory Standards for the Approval of Medical Devices*

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The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF welcomes the opportunity to provide a submission to the Senate Community Affairs Committee (the Committee) *Inquiry into the Regulatory Standards for the Approval of Medical Devices*. CHF has addressed the Inquiry's Terms of Reference. In particular, we have focused on:

a) The role of the Therapeutic Goods Administration (TGA) in regulating the quality of devices available in Australia
d) The processes in place to ensure that approved products continue to meet Australian standards
f) The processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices
g) The effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified

We have also provided comments on the adequacy of consumer information on medical devices.

Our submission highlights CHF's views and builds on our work in the area of medical devices and their regulation. CHF's recommendations are aimed at achieving:

- Stronger regulation and post-market surveillance processes
- increased consideration of consumer experiences
- improvements to the reporting of adverse events
- greater availability of consumer information on medical devices.

Our submission draws on consultation with our membership, which includes organisations advocating for older consumers, disease specific groups and networks, state and territory peak consumer organisations and individual consumers.

## The Role of the TGA in Regulating the Quality of Devices

Consumers involved in previous CHF consultations have expressed concerns about the TGA's regulation of the quality of devices, particularly in relation to post-market surveillance.

In recent CHF engagements focusing on the transparency of the TGA and adverse event reporting, consumers indicated that they are unaware of adverse events reporting schemes. Although the Therapeutic Goods Act requires sponsors to report adverse events, there is no requirement for doctors to do so and it is, in fact, limited. Consumers often report an adverse event to their doctor rather than the manufacturer or sponsor of a device.[1] Often, the sponsor is not aware of adverse incidents. In instances requiring that they act, the requirement is that they report 'significant incidents.' This means that the sponsor decides what should be reported, although there are regulations that outline what is required to be reported and the timeframes in which such reports must be made.

In these consultations, consumers called for the strengthening of regulations so that sponsor judgement is not a factor in determining what is to be reported. Consumers also called for initiatives to develop and support increased awareness of the TGA's Incident Report and Investigation Scheme (IRIS) among consumers and health professionals, and increased awareness of the TGA's other post-market surveillance processes.

**Recommendation 1: That regulation is strengthened to ensure that sponsor judgement is not a factor in determining what adverse events are to be reported to the TGA.**

**Recommendation 2: That initiatives to build and support increased awareness of the Incident Report and Investigation Scheme and other post-market surveillance processes are developed.**

In CHF consultations relating to the HTA Review, consumers expressed a strong view that the post-market surveillance function should be the responsibility of an agency separate from the one that conducts the original assessment of health technologies.[2] The Australian Commission for Safety and Quality in Health Care (ACSQHC) and the Australian Consumer and Competition Commission (ACCC) were suggested as agencies that could be given responsibility for post-market surveillance, as these bodies already have related functions. Whether the recommendation to separate the processes is accepted, or the TGA remains responsible for post-market surveillance as well as assessment, consumers argued that surveillance and review processes need to be appropriately governed, funded and evaluated.

If the TGA is to remain responsible for post-market surveillance, consumers argued that a separate division of the TGA should be created to conduct reviews, ensuring greater separation of assessment and review functions.

[1] CHF (2011) *Community Quality Use of Medicines and Diagnostics Project: Adverse Medicine Events in the Community: Report from the National Consumer Workshop*. CHF: Canberra.
[2] CHF (2009) *Consumer Participation in the Review of Health Technology Assessment: Report on outcomes of consumer consultations*. CHF: Canberra.

**Recommendation 3: That the Committee consider a greater separation of post-marketing surveillance responsibilities from the original assessment of health technologies.**

## Ensuring that Products Meet Australian Standards

CHF notes that the TGA divides its role into pre-market assessment and post-market surveillance. In pre-market assessment, the TGA uses a risk stratification method that organises devices into groups based on their level of risk. There are five levels:

- Class I
- IIA
- IIB
- III
- Active Implantable Medical Devices (AIMD).

The TGA assesses only the Class III and AIMD. Class I medical devices receive automatic entry to the ARTG after undergoing electronic review of specific information. Ninety per cent of all devices fall within the first three classes, and this means that ninety per cent of medical devices used in Australia do not undergo assessment by the TGA, although the TGA reviews evidence about the device to show that the device has been subject to a level of regulatory scrutiny equivalent to that which would be applied if the device was presented to the TGA for assessment (through review of overseas evidence or a Mutual Recognition Agreement certificate).[3] Around two per cent of devices undergo a full TGA Conformity Assessment.

Many of the devices that gain automatic entry on to the ARTG have a significant risk of causing harm. Until recently, joint replacements had been judged to be low risk despite the fact that many fail, requiring re-operation and creating an increased risk of mortality for some people. Quality of life is clearly impacted by this risk.

In consultations on the HTA Review, consumers argued that the TGA should apply risk categories and assess evidence for applications with consumers' safety as their priority consideration. It was noted that consumers are the ones who endure the consequences if assessment processes fail to take into account the level of risk or the inadequacy of evidence deeming products to be safe.

**Recommendation 4: That the TGA apply risk categories and assess evidence for applications with consumers' safety as the priority consideration.**

### Engaging Consumers in the Approval of Medical Devices

In assessing the suitability of medical devices, consumers have previously argued that the system currently fails to consider the lived experience and needs of consumers, the social value of a new technology and how the approval of a medical device may impact on equitable access to health care of both public and private patients. This point was strongly put forward by consumers consulted by CHF as part of the HTA Review. Consumers, as

[3] Therapeutic Goods Administration (2010) *Reforms in the Medical Devices Regulatory Framework.* Therapeutic Goods Administration: Canberra.

users and beneficiaries of health technologies, are well placed to contribute to the assessment of social value of technologies.

Consumers strongly endorsed the view that the assessment of any device or procedure should include the 'journey' of the consumer as he or she uses the device, considering the risks and benefits for consumers of having the new technology on the market. Consumer stories were considered to put 'flesh on the bones' of the solely technological value and cost effectiveness of a device. It is important that the 'human side' of health technology is considered in the review process. The impact of these devices on consumers' quality of life must be considered for a comprehensive picture of their value and safety to be determined.

It was suggested that one way to collect relevant consumer data to contribute to the assessment process, categorically endorsed by consumers, would be the development and use of Health Technology Consumer Impact Statements (CIS), similar to Environmental Impact Statements or Pharmaceutical Benefits Advisory Council (PBAC) CISs. Such statements could be used across all committees to inform their decisions. The views of a wide cross-section of consumers would ideally be considered in completing CISs, but particularly those of consumers most likely to be affected by the device or technology.

**Recommendation 5: That the Committee considers the development of mechanisms to take into account consumer experience in the approval of devices. This may include:**
**- Consumer representatives on committees**
**- The use of consumer impact statements**
**- Public reporting of consumer experiences with devices and technologies**
**- Other models that have been effective internationally.**

## Prostheses with High Revision Rates: Identified Products and Notifying the Public

The identification of prostheses with high revision rates relies on the capture of information from consumers, health professionals and manufacturers about the use of products once they are on the market. Consumers have emphasised repeatedly the importance of ensuring that many avenues are available for the capture of such information, and then for its aggregation, public reporting and feedback into the review process.[4]

Consumers have suggested several sources of information for the rapid identification of devices with high revision rates:

- Manufacturers, who should be compelled to report adverse events of all levels of severity using a routine approach (current regulations do describe what events are required to be reported, with penalties for non-compliance).
- Doctors and other health professionals, who should be encouraged to report adverse events, including through the use of financial incentives if necessary.

[4] CHF (2011) *Improving the Transparency of the Therapeutic Goods Administration: A Consumer Consultation Report*. CHF: Canberra.

- Consumers, who should have an easy to use mechanism for adverse event reporting allowing them to report any problems they have and be confident that these will be addressed.
- State and Territory Health Ombudsmen, in the role of collection of incident and adverse event information, who should have an avenue for reporting this information to the review agency.

Many consumers consulted by CHF have expressed support for more registries being established to collect data, for example following the model of the National Joint Replacement Registry (NJRR), which collects data after each joint replacement procedure. These registries should be set up for those technologies for which post-market surveillance is most needed. Consumers emphasised that increased awareness of post-market surveillance mechanisms would be required, via public education, to enable and equip consumers and doctors to use the system.

Consumers consulted specifically on the adverse event reporting processes argued that information on adverse event reports should be made available in real time to all, including clinicians and consumers. Participants also felt that it was important that formal feedback on each adverse event is given to all stakeholders involved in the reporting, so that consumers and clinicians feel confident that action is being taken, making them more likely to report adverse events in the future.

Finally, consumers also suggested that a body could be established to oversee the reporting and follow-up of adverse events, along with other aspects of quality of care. Other bodies currently perform some of these functions, but consumer calls for a new body suggest that they are dissatisfied with how these functions are being performed.

**Recommendation 6: That information on adverse events collected by the TGA is made available in real time to all stakeholders, including consumers.**

**Recommendation 7: That the TGA provides formal feedback on its response to adverse events reports to the parties involved in the reporting process, including consumers.**

## Other Issues: Consumer Information on Medical Devices

Consumers have expressed concern about the inadequacy of information about medical devices, for which there is no Consumer Medicine Information (CMI), Product Information (PI) or AusPAR-type equivalent. There is arguably an increased need for information about medical devices, as their use cannot be ceased in the way that medications can be when a problem occurs. Consumers need access to high quality, independent information before a device is implanted, and CHF urges the Committee to consider this issue.

**Recommendation 8: That the Committee consider initiatives aimed at improving the availability of consumer information on medical devices.**

## Conclusion

CHF welcomes the opportunity to comment on the Senate Community Affairs Committee's *Inquiry into the Regulatory Standards for the Approval of Medical Devices*. We have drawn on extensive consultation with members, particularly consultations relating to adverse event reporting and the HTA Review.

CHF's recommendations are aimed at achieving:

- Stronger regulation and post-market surveillance processes;
- increased consideration of consumer experiences;
- improvements to the reporting of adverse events; and
- greater availability of consumer information on medical devices.

We welcome the establishment of this Inquiry and look forward to reviewing the Committee's report.

Representing consumers on national health issues

Consumers Health Forum of Australia

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach thousands of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.