Consumers
Health Forum
of Australia

Submission to the Senate Community Affairs Committee Inquiry into the role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prosthese (PIP) breast implants

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The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to the Senate Community Affairs Committee (the Committee) Inquiry into the role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prosthese (PIP) breast implants (the Inquiry).

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 and its members have provided numerous submissions in recent years to inquiries and consultation processes relating to the regulation of therapeutic goods, including, but not limited to, reviews of the transparency of the TGA, therapeutic goods advertising and promotion, the regulatory framework for medical devices, complementary medicines regulation and Health Technology Assessment. CHF also provided a submission to the Committee's 2011 Inquiry into the Regulatory Standards for the Approval of Medical Devices, and gave evidence at a public hearing of the Inquiry.

Our submission draws on consultation with our membership in relation to these prior reviews. CHF's membership includes organisations advocating for older consumers, disease specific groups and networks, state and territory peak consumer organisations and individual consumers.

CHF considers that the current Inquiry provides a valuable opportunity to review the Government's response to the numerous recent regulatory reviews outlined in *TGA Reforms: A blueprint for the TGA's future*, which was released in December 2011. However, we note that the TGA is still in the process of implementing the recommendations agreed to by Government, and that there are likely to be further reforms to TGA processes and policies.

Recommendations

CHF's submission makes six recommendations. Further detail is provided throughout our submission.

1. CHF recommends that the Committee calls for the TGA to maintain a proactive public presence on safety issues of priority to consumers.

2. CHF recommends that the Committee calls for the TGA to further improve transparency by sharing information about what is unknown, as well as what is known, and providing the public with information on timeframes for the gathering of evidence.

3. CHF recommends that the Committee critically reviews the Government's response to recent regulatory reforms, as outlined in *TGA reforms: A blueprint for TGA's future.*

4. CHF recommends that the Committee calls for the urgent implementation of the recommendations of the TGA Transparency Review, particularly those that relate to post-market surveillance and the management of adverse events.

5. CHF recommends that the Committee calls for the urgent implementation of reforms to the medical devices regulatory framework.

6. CHF recommends that the Committee calls for the urgent implementation of recommendations 13, 14 and 15 of the HTA Review, noting that this was also a recommendation of the Committee's 2011 inquiry into the regulatory standards for medical devices.

The case for reform

Australian health consumers have a keen interest in the regulation of medical devices in Australia. Strong systems to ensure the safety of medical devices, and to address any issues quickly when they arise, are essential, or consumers are the ones who suffer the consequences. This is particularly the case for medical devices that are implanted into the body. In these circumstances, it is not a straightforward matter to remove the device if something goes wrong. It requires traumatic, invasive revision surgery that puts the consumer's health, and sometimes their life, at risk.

Of particular interest for consumers are processes for managing adverse events and failures of medical devices. The TGA's approach to risk minimisation means that post-market surveillance is critical to ensuring the safety of medical devices, as in many cases it is not until devices are on the market that failures become apparent. Consumers want to know that, when a device is failing at unacceptable levels, action will be taken promptly to contact and assist those who are already using the device and to prevent the use of the device in any further procedures.

CHF has therefore welcomed the numerous recent regulatory reviews, including the review of TGA transparency and proposals for medical device regulatory reforms. CHF provided input to both of these reviews, and welcomed many of their recommendations.

The TGA has proposed a number of reforms to the medical devices regulatory framework in response to a recommendation of the Review of Health Technology Assessment (HTA), including reclassification of joint implants, increased pre-market scrutiny for implantable medical devices and publication of device product information on the TGA website.

The Final Report of the Transparency Review was released by Government in July 2011, and included 21 recommendations aimed at enabling the TGA to better communicate its regulatory processes and decisions to the community and other stakeholders. In relation to medical device regulation, CHF particularly welcomed recommendations relating to active promotion of therapeutic goods safety information and consideration of mechanisms for improved communication of safety alerts and recalls; more effective facilitation of adverse event reporting by health practitioners and consumers; and the promotion of the adverse event reporting system.

The Government's response to these and other reviews will be discussed below. It is clear, however, that there is a need for reform, as has been recognised by successive reviews over the past decade. This Inquiry highlights that the systemic issues that continue to plague the regulation of medical devices remain a serious concern that requires attention.

Government and TGA response to PIP breast implant issues

While CHF has previously raised a number of issues about how the TGA and Government more broadly have responded to past adverse event issues (particularly in relation to communication with the public about these issues), we consider that the response to the PIP breast implant issues represents a welcome move towards increased transparency and improved consumer communication from the TGA.

Since questions of the safety of these implants arose late last year, the TGA has acted with reasonable timeliness to respond and provide information to consumers and health professionals about safety risks and treatment options. The Government has convened two committees to guide its response: a high level group advising the Chief Medical Officer, and an expert panel consisting of members of the TGA's advisory committees on the safety of medicines and medical devices, and representatives from the Royal Australian College of Surgeons, the Australian Society of Plastic Surgeons and the Australasian College of Cosmetic Surgeons. Consumers are also represented on these committees.

Particularly valued elements of the TGA's response, indicating a welcome shift towards transparency, include:

- Publication of regular updates as further evidence emerged on risks associated with the implants
- Publication of information specific to the Australian context, including information on the number of PIP implants used in Australia and the number of rupture reports for these implants received by the TGA, the TGA's activities in testing the implants, the availability of these implants in Australia, and the absence of any reports of Anaplastic Large Cell Lymphoma in Australian women who had received PIP implants
- Provision of specific, separate information for consumers and health professionals
- Inclusion of information on reporting adverse events in some communications about PIP implants.

CHF also welcomed the measured advice provided by the Government in relation to removal of the implants, which stated that removal of the implants in the absence of evidence of rupture is not routinely required.

Other elements of the Government's response, including establishment of a 24-hour information line for individuals concerned about breast implants and Medicare rebates for MRI services for women with PIP implants, were also welcome.

Our only area of concern was the TGA's failure to be transparent about what was *not* known, and how that gap in information limited the TGA's, clinicians' and consumers' ability to make truly informed choices. While CHF understands that the reasons for the 'unknowns' were entirely outside the control of the TGA, and related first to the difficulty in receiving accurate information from other regulators, and then to the long-term timeframes for some testing to be conducted, we believe that the TGA should not only communicate what is known, but also what is unknown and possible timeframes for additional information to become available. Had the TGA done this, we believe that much of the criticism levelled at the TGA for delay and inadequate testing would have been resolved, and consumers would have been better able to understand the reason for delaying their own treatment choice until key information became available.

While the Inquiry is likely to receive evidence about how the TGA and Government response could have been improved, CHF considers that the response has demonstrated a willingness to share key information with consumers to enable them to make informed decisions about how they will respond to potential implant issues.

CHF recommends that the Committee calls for the TGA to maintain a proactive public presence on safety issues of priority to consumers.

CHF recommends that the Committee calls for the TGA to further improve transparency by sharing information about what is unknown, as well as what is known, and providing the public with information on timeframes for the gathering of evidence.

Government commitment to reform

This submission has outlined the case for reform, and the benefits of a more transparent approach from Government and the TGA when something goes wrong with a device. While, as outlined above, CHF welcomes the increased transparency that we have seen to date, we are concerned that the Government's response to other elements of the various reform processes, including those that relate to medical devices, demonstrates a reluctance to implement the wholesale reform that is needed.

In December 2011, the Government released *TGA reforms: A blueprint for TGA's future* (the blueprint). The blueprint contains the Government's response to:

- the review to improve transparency of the TGA
- the working group on the promotion of therapeutic products
- public consultations on the regulatory framework for advertising therapeutic goods
- the Auditor-General's report on *Therapeutic Goods Regulation: Complementary Medicines*
- an informal working group examining the regulation of complementary medicines and reasons for low compliance rates
- public consultations on the medical devices regulatory framework.

Of particular relevance to this Inquiry are the Government's responses to certain recommendations arising from the review of TGA transparency and public consultations on the medical devices regulatory framework, and further detail is provided on each of these below. CHF has outstanding concerns about the Government's response to the other reviews, but has not explored these in this submission as they are not directly relevant to the terms of reference. Further detail can be provided on request.

CHF also has considerable concerns about the long delay in the Government's response to recommendation 13, 14 and 15 of the Review of Health Technology Assessment in Australia (HTA Review).

CHF recommends that the Committee critically reviews the Government's response to recent regulatory reforms, as outlined in *TGA reforms: A blueprint for TGA's future*.

Review of TGA Transparency

As noted above, the Final Report of the Review of TGA Transparency contained 21 recommendations. Of these, some have particular relevance to regulation of medical devices, particularly mechanisms for the management of adverse events:

- The TGA conduct, and report on, a feasibility study into the development of an early post-marketing risk communication scheme for therapeutic goods, with consideration of international models (recommendation 15)
- The TGA actively promote the distribution of therapeutic good safety information, and examine mechanisms for improving the timely communication of alerts and recalls, to health practitioners and to consumers (recommendation 16)
- The TGA more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers, and promote the adverse event reporting system (recommendation 19)
- The TGA make its Adverse Events Database available to, and searchable by, the public in a manner that supports the quality use of therapeutic goods (recommendation 20)
- The TGA work with State and Territory governments, stakeholders, and other relevant agencies, to improve the visible management of adverse event reporting in support of consumer safety and consistent with the findings of the Horvath Review into Immunisation (recommendation 21).

While the Government has agreed to all of these recommendations, and the majority of the other recommendations of the transparency review, CHF remains concerned about how the implementation of these valuable reforms will be funded. The final report of the review stated:

> *It does not seem likely that the proposals could be implemented within the TGA's present budget without a reduction in the functions presently being performed. The panel is strongly of the view that the work of the TGA should not be diminished in any way. Accordingly, if the government is to accept and give effect to the Panel's recommendations, it will be necessary for resources additional to those currently available to be found.*[1]

In the blueprint, the Government states that:

> *As has been the case since 1998, the full cost of regulating therapeutic goods will continue to be met by cost recovery from the regulated industry. […] In order to deliver the fundamental reforms, a modest increase in the TGA's fees and charges will be required*.[2]

CHF understands that there is considerable industry resistance to any increase in the TGA's fees and charges. It would be of significant concern to consumers if the implementation of these important reforms is delayed as a result of resourcing implications.

> **CHF recommends that the Committee calls for the urgent implementation of the recommendations of the TGA Transparency Review, particularly those that relate to post-market surveillance and the management of adverse events.**

[1] Report of the Review to improve the transparency of the Therapeutic Goods Administration, online at www.tga.gov.au/pdf/consult/review-tga-transparency-1101-final-report.pdf
[2] Australian Government 2011 *TGA reforms: A blueprint for TGA's future*. Commonwealth of Australia, Canberra.

Reforms to the medical devices regulatory framework and the 2011 Senate Inquiry

The TGA has made a number of proposals relating to the medical devices regulatory framework, following a recommendation of the HTA Review. The Review was undertaken in 2009, and recommendation 8c was that the TGA should:

> *…increase the rigour of regulatory assessment of higher risk medical devices, to ensure an appropriate level of evidential review is undertaken to ensure safety, quality and efficacy of these devices prior to entry on the ARTG [Australian Register of Therapeutic Goods] and to provide a sound evidence basis for Commonwealth HTA processes.*[3]

The TGA has undertaken consultation on these proposals, and adapted them based on the outcome of these consultations. In general, CHF is supportive of these proposals.

The Government response to the revised proposals is included in the blueprint. However, the Government response is, for three of these proposals, limited to 'noting' the recommendations, and further noting that these recommendations are *'linked to further recommendations in Senate Community Affairs Committee inquiry into 'The regulatory standards for the approval of medical devices in Australia''*.[4] CHF notes that the report of this Inquiry was released in November 2011, and that Government has indicated that it will respond to the report 'in the first half of 2012'.[5] CHF awaits the Government's response with considerable interest, particularly given that it appears that some of the reforms relating to the medical devices regulatory framework are on hold until this response is tabled.

> **CHF recommends that the Committee calls for the urgent implementation of reforms to the medical devices regulatory framework.**

Recommendations 13, 14, 15 of the HTA Review

As noted above, the HTA Review was undertaken in 2009, with a report released by the Government in December 2009. The report included 16 recommendations, many of which reflected issues raised by consumers in a series of consultations conducted by CHF as part of the review process.

Since the release of the report, the Australian Government has agreed to recommendations 1 to 12 and 16 from the report, and these are at various stages of implementation. However, *recommendations 13, 14 and 15, which relate to post-market surveillance and are of considerable relevance to the current Inquiry, remain the subject of further Government consideration, more than two years after the release of the report.* The lack of action on these recommendations is of considerable concern to CHF and its members, and CHF urges the Committee to consider these recommendations in the context of the current Inquiry.

Recommendation 13 called for the TGA to take steps to increase the rate of reporting of adverse events, including by health service providers and consumers, in order to improve the contribution of post-market surveillance to patient safety. The reporting of adverse events has

[3] TGA 2011 'Reforms to the medical devices regulatory framework: proposals'. Online at http://www.tga.gov.au/newsroom/consult-devices-reforms-110923.htm. Accessed 16 April 2012.
[4] Australian Government Op cit.
[5] Ibid.

repeatedly been identified by consumers as a necessity. Many health consumers would not know where to begin if they wanted to report an issue with a device, and health professionals have also identified concerns with current adverse event reporting processes. Consumers have also identified the importance of providing formal feedback to all stakeholders involved in the reporting of adverse events, to increase confidence that action has been taken and encourage future reporting of adverse events.

CHF notes that recommendation 19 of the TGA transparency review, which has been accepted by Government, addresses similar issues and calls for the TGA to more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers and promote the adverse event reporting system. It is unclear, however, if the Government considers that their acceptance of recommendation 19 of the transparency review also addresses recommendation 13 of the HTA Review.

Recommendation 14 called for the Department of Health and Ageing to explore options for consideration by Government to facilitate the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions for devices and procedures, in order to improve the contribution of post-market surveillance to the sustainability of the health system and the longer-term regulatory efficiency of HTA processes. This recommendation was strongly welcomed by consumers.

Recommendation 15 called for the establishment of register for high-risk implantable devices and/or procedures. The recommendation followed the successful implementation of the National Joint Replacement Registry. Consumers have seen the benefits of the registry model, and would welcome the establishment of additional registries, with appropriate stakeholder consultation and involvement, in conjunction with other strategies to enhance adverse event reporting and action.

CHF is disappointed at the continued delay in any Government response to these recommendations, and would welcome their implementation, particularly in the context of the recent, highly-publicised issues with medical devices. We note that the report of the Committee's 2011 inquiry into the regulatory standards for medical devices in Australia recommended the timely implementation of these recommendations, and we urge the Committee to reiterate this recommendation, in recognition of the improvements to the safety of medicines and devices that are likely to result.

> **CHF recommends that the Committee calls for the urgent implementation of recommendations 13, 14 and 15 of the HTA Review, noting that this was also a recommendation of the Committee's 2011 inquiry into the regulatory standards for medical devices.**

Conclusion

CHF welcomes the opportunity to comment on the Senate Community Affairs Committee's Inquiry into the role of the Government and the TGA regarding medical devices, particularly PIP breast implants. While we consider that the Government and TGA's response to the issues with PIP breast implants represents a welcome move towards increased transparency in the management of adverse events, we consider that considerable additional reform is necessary.

CHF has expressed concerns about the Government's response to recent reform processes, including most notably the lack of any Government response to three recommendations of the HTA Review, more than two years after the release of the report of the Review. CHF is also concerned at the delay in the implementation of the TGA Blueprint recommendations, particularly those relating to the management of adverse events.

We welcome the establishment of this Inquiry, which is critical to addressing key safety issues for Australian consumers within the current regulatory framework, 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.

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