COMMUNITY AFFAIRS

Senate [redacted] Committee

Tabled Document

Inquiry: MEDICAL DEVICE

Date / Time: 27/9/11 1.40pm

Witness Name: MSCAROL BENNET

Organisation: CONSUMER HEALTH FORUM

Good afternoon Senators, and thank you for the opportunity to speak with you today.

Australian health consumers have an interest in effective regulation of medical devices in Australia. It is absolutely essential that we have strong systems in place to ensure the safety of medical devices, and to address any issues quickly when they arise. Consumers will suffer the consequences if this does not occur.

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 is not like stopping taking a medication if there is an adverse reaction. It requires traumatic, invasive revision surgery that puts the consumer's health – and life – at risk.

Australia is currently experiencing a period of considerable review and reform of medical device regulation. The Review of Health Technology Assessment in Australia, the review of transparency of the Therapeutic Goods Administration and proposed reforms to the medical devices regulatory framework have all identified that there are improvements to be made, and have put forward solutions and recommendations, which are at various stages of consideration and implementation by Government. It has been pleasing to see some level of consumer involvement and consultation in all of these processes.

Of particular concern for health consumers are the current processes for managing adverse events and failures of medical devices, and this is what I would like to address in the remainder of my opening remarks.

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 where necessary. The recent Depuy ASR hip episode, in which hip prostheses continued to be used even after high failure rates had been identified, provides a particularly compelling case study.

The Review of Health Technology Assessment – the HTA Review – recognised the need for improvements in the post-market surveillance system in Australia. Recommendations 13, 14 and 15 called for changes and improvements to existing post-market surveillance processes.

Recommendation 13 was that, in order to improve the contribution of post-market surveillance to patient safety, the TGA should take steps to increase the rate of reporting of adverse events, including by health service providers and consumers. This is something that has been repeatedly 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 an adverse event, to increase confidence that action has been taken and encourage future reporting of adverse events. The importance of this recommendation is reflected in Recommendation 19 of the TGA transparency review, which 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 clear that improvements in this area are urgently needed.

Recommendation 14 of the HTA Review 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. Again, this is something that would be most welcome to consumers. It is essential that we use the available data to assess the safety and effectiveness of devices to determine whether they should be on the market, and to identify an appropriate level of reimbursement. Consumers have also called for stronger links between current processes for determining clinical safety effectiveness and level of reimbursement. Recent moves in this area have been welcome, but there is more work to be done.

Recommendation 15 called for registers of high-risk implantable medical devices and/or procedures to be established, following the successful model of the National Joint Replacement Registry. Consumers have seen the benefits of the registry model, and would welcome the establishment of additional registries, in conjunction with other strategies to enhance adverse event reporting and action.

Regrettably, and to the disappointment of consumers, it is recommendations 13, 14 and 15 that remain subject to further consideration by Government, 19 months after the public release of the HTA Review report. Consumers at a workshop held prior to the Joint Medicines Policy Conference in

August argued vehemently for the implementation of these recommendations as a matter of urgency.

Improvements are also necessary in the communication of adverse events and potential issues to consumers and health practitioners. This is recognised in the recommendations of the TGA Transparency Review, particularly recommendation 15, calling for a feasibility study of an early post marketing risk communication scheme for therapeutic goods; recommendation 16, that the TGA actively promotes the distribution of safety information, and examine mechanisms for improving the timely communication of alerts and recalls; and recommendation 21, that the TGA and state and territory governments work to improve the visible management of adverse event reporting in support of consumer safety. All the recommendations of the TGA Transparency Review remain under consideration by Government. Several months after the release of the report.

CHF recognises that the Government is operating in a tight fiscal environment, and that the implementation of these recommendations is likely to require investment. But CHF argues strongly that post-market surveillance, and timely communication of adverse events and recalls, are areas that will reduce health costs in the long term by ensuring that adverse events don't require increased health interventions. It will improve the health and safety of Australian consumers.

Significant and well considered reviews have been undertaken in this area of regulation. The question is why key recommendations of these reviews remain on the shelf, with little government resourcing or commitment.

I urge the Committee, in its reporting and recommendations, to recognise that these are major gaps that are yet to be addressed, and to call on the Government to resource and implement the recommendations of the HTA Review and TGA transparency review.