Consumers
Health Forum
of Australia

17 December 2010

Dr Rohan Hammett
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Therapeutic Goods Administration
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Dear Dr Hammett,

Reforms in the Medical Devices Regulatory Framework

Thank you for the opportunity to comment on the Therapeutic Goods Administration's (TGA) *Reforms in the Medical Devices Regulatory Framework Discussion Paper* (the paper).

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.

We welcome the opportunity to comment on the paper. The regulation of medical devices has long been an area of concern for CHF. Our submission is based on extensive consultation with consumers, particularly consultations conducted by CHF in 2009 around the *Review of Health Technology Assessment* (HTA Review). CHF's consultations included an information paper, focused teleconferences and a national forum.

Proposal 1
CHF supports the addition of a new classification rule to Schedule 2 of the Medical Device Regulations to reclassify all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices.

Although the risks to consumers undergoing implant surgery are similar regardless of the type of joint being implanted (for example, risk of infection, failure of the implant, etc), the biomechanics of the joint from a partial implant are different to that of a complete implant. For this reason, consumers consulted by CHF in 2009 supported the reclassification of these joint replacement implants.

We note that this proposal is based on adverse experiences identified by Australian orthopaedic surgeons, as well as data obtained from the Australian National Joint Replacement Registry (NJRR) regarding adverse events and revision rates for these types of implants.

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Proposal 2
Proposal 2i would amend the medical device Regulations to no longer require Australian medical device manufacturers to hold TGA conformity assessment certifications. Proposal 2ii would amend the subregulations of devices requiring a TGA Conformity Assessment Certificate, instead requiring manufacturers to hold TGA conformity assessment certificates that can be issued for all Class III and AIMD implantable medical devices.

Proposal 2iii aims to provide a safeguard by increasing recognition of third party assessment bodies and initiating a program of 'confidence building' between the TGA and designated Notified Bodies under the Mutual Recognition Agreement (MRA) with the European Commission. CHF supports proposals 2i, 2ii and 2iii provided they are taken together.

In consultations conducted by CHF in 2009, consumers agreed that the TGA, rather than device manufacturers, should collect the data on international approvals. Consumers also wanted to see greater harmonisation between Australian and international processes. On this basis, CHF has no objection to the adoption of proposals 2i and 2ii provided the TGA undergoes a program of information sharing with bodies recognised under the MRA, and remains up-to-date with current international trends as outlined in proposal 2iii.

Proposal 3
Currently, the regulator does not hold records of the models of devices supplied under each entry into the Australian Register of Therapeutic Goods (ARTG). This inhibits the ability to monitor the safety, performance and regulatory compliance of devices once they are supplied to the market. The current regulations also mean that subsequent models which include new technologies are not assessed prior to supply and that consumers cannot identify whether a device has been assessed by the TGA and is available for supply in Australia. Consumers have identified concerns in relation to both of these issues in CHF consultations.

CHF would therefore welcome the proposed requirement for sponsors to itemise the devices or various models that are supplied under the same ARTG entry. CHF also supports proposal 3ii, which would require sponsors of medical devices to publish the ARTG number on the information that accompanies a medical device (for example, the product labels, instructions for use or packaging of the device).

In consultations, consumers have also called for greater clarity around which agency or group is responsible for reviewing obsolescence of devices/technologies, and defined criteria by which obsolescence is determined (for example, when a certain number of equivalent or superior devices are on the market or when uptake of the product is very low).

Proposal 4
CHF supports the publishing of more comprehensive device product information on the TGA website. CHF supports the inclusion of the following:

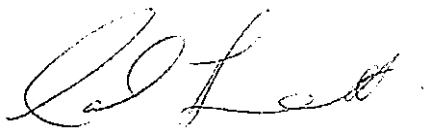
- General announcements of device approvals
- Copies of approval letters
- Summaries of safety and effectiveness data
- Instructions for use
- Consumer instructions
- Links to general resource information, such as information from National Institutes of Health (NIH) information or clinical papers.

Consumers have also called for greater access to information about post-market surveillance. The National Joint Replacement Registry (NJRR) is often cited an example of good practise, collecting data after each joint replacement procedure. Consumers have said they would like to see registries 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.

CHF welcomes improvements to implant classification and hopes that new re-classifications will provide better safety, quality and efficacy for consumers.

Please do not hesitate to contact me should you wish to discuss any aspect of this submission further.

Yours sincerely,



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