Consumers Health Forum of Australia

Submission

CONSULTATION: POTENTIAL RECLASSIFICATION OF ACTIVE MEDICAL DEVICES FOR DIAGNOSIS AND PATIENT THERAPY

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Introduction

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

CHF appreciates the opportunity to provide a comment to the Therapeutic Goods Administration (TGA) proposal to potentially reclassify active medical devices for diagnosis and patient therapy.

At the heart of CHF's policy agenda is patient-centred care. Our responses to the TGA's consultation questions have been formed with a patient-centred approach in mind.

Consultation Questions

What impacts—including any that are unintended—do you anticipate the reclassification may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?

We expect the primary impact of the reclassification for consumers will be a greater level of quality for Active Medical Devices in terms of reliability, safety and effectiveness. By putting these medical devices into a higher class they will undergo more rigorous assessment prior to becoming available to consumers, decreasing the risk to consumer health of the devices not functioning as intended.

The CHF acknowledges that there is potential for a delay in accessibility for critical medical devices should certain devices be reclassified into a higher Class. However we believe that it is crucial that any such critical devices be rigorously assessed for safety, efficacy and quality before being made available to ensure faulty or ineffective devices are not given to consumers. Additionally we believe the proposed transitional arrangements should give manufacturers and sponsors sufficient time to ensure their devices are assessed appropriately and are able to be made available to consumers when the new classification applies.

Are there any further issues and questions we should consider when implementing this change (i.e. areas that need to be clarified in our guidance)?

Given the critical function that these devices play, clear guidance needs to be given as to the party responsible for replacing these devices should be found to have problems post-market. This includes both who must logistically organise the timely replacement of faulty devices and who is responsible bearing the financial cost of replacing them.

The CHF believes both of these should be borne by the Sponsor of the device.

Other medical devices covered by the EU MD Regulation Rule 22 (in addition to AEDs and closed loop systems) may include:

- *external pacemakers*
- *continuous positive airway pressure (CPAP) devices*
- *intravascular heating/cooling system control units*
- *hyperthermia systems, temperature mapping units*
- *intraperitoneal-circulation hypothermia system control units*
- *mechanical bloodstream indicator injectors.*

We seek your feedback whether reclassification of any or all of these devices in Australia to Class III is appropriate.

The CHF believes that reclassification of all of these devices to Class III is appropriate. If a device has a high risk of causing serious harm or death to a consumer if it fails or is faulty, which is the case for the listed example devices, then the device should be classified as Class III to ensure it goes through the highest safety, efficacy and quality assessments.

Are there any other groups of devices that we have not considered which might fall within the scope of this proposed change?

The CHF believes that any medical device that has a high potential of causing significant harm to a consumer in the event the device fails or is faulty should be considered for classification or reclassification as a Class III device.

Do you have any comments regarding the transitional arrangements proposed in this paper?

The CHF believes the proposed transitional arrangements are appropriate.