Consumers Health Forum of Australia

SUBMISSION

CONSULTATION: CHANGES TO A NUMBER OF DEFINITIONS AND THE SCOPE OF THE MEDICAL DEVICE REGULATORY FRAMEWORK IN AUSTRALIA

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P: 02 6273 5444
E: info@chf.org.au

twitter.com/CHFofAustralia
facebook.com/CHFofAustralia

Office Address
7B/17 Napier Close,
Deakin ACT 2600

Postal Address
PO Box 73
Deakin West ACT 2600

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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 in response to proposed changes to a number of definitions and the scope of the medical device regulatory framework in Australia.

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

QUESTIONS: DEFINITIONS

Do you have comments about the proposed changes to the definitions (refer Appendix A)?

The CHF in principle support the proposed changes to the definitions. The proposed changes could better align the Australian regulatory framework with other international regulatory frameworks. They should allow for increased accessibility of therapeutic goods to Australian consumers without reducing existing requirements to demonstrate safety and efficacy.

By clarifying and broadening the scope of what is included in the definition of a "medical device", this will ensure that products being made available to consumers for medical uses undergo appropriate assessment for safety, efficacy and quality.

The CHF in principle supports any changes to the regulatory framework that improve the quality and accessibility of therapeutic goods to Australian consumers, on the proviso that the requirements to demonstrate both safety and efficacy of those therapeutic goods are maintained or strengthened. The CHF strongly opposes any regulatory changes that reduce requirements for therapeutic goods to demonstrate quality, safety and efficacy.

In the current consultation documentation potential areas of changes to the regulatory framework definitions based on the EU MD Regulation are only identified, with a general "proposal to incorporate". While the CHF is broadly supportive of all the areas identified, without confirmation of the specific details of the proposed definition wording and how they will be incorporated are articulated, the CHF is unable to unequivocally support the proposed changes.

Are you a consumer, patient, consumer advocacy group, healthcare provider, industry stakeholder, industry representative body or other?

Consumer Advocacy Group

Will you be affected by the proposed definition changes? If yes, how?
We represent all Australians who consume therapeutic goods, who will be affected by the proposed changes.

What benefits or disadvantages might be there for patient, consumer or public health and safety in these proposed definition changes?
The potential advantages and disadvantages of the proposed changes lay in the details of what changes are specifically made, where they are made and how they are made.

The proposed changes could lead to greater standardisation and harmonisation between Australia's regulatory framework and international regulatory frameworks. If this happens this may have a benefit for consumers by increasing the availability of safe and effective medicines in Australia.

Additionally it will lower the regulatory barriers required for medicines approved for usage internationally to be listed in Australia, potentially increasing both the speed at which Australian consumers can access new medications and the number of new medications made available to Australian consumers. If regulatory barriers are lowered Australian consumers may potentially see a reduction in cost for medications as well.

Lastly, by clarifying and broadening the scope of what is included in the definition of a "medical device", this will benefit consumers by ensuring devices with medical uses undergo appropriate assessment for safety, efficacy and quality.

The primary potential disadvantage is the possibility of lowering of the regulatory requirements for specific therapeutic goods to demonstrate quality, safety and efficacy based on how the proposed definitions are incorporated. The CHF strongly opposes any potential changes that could lead to this.

Additionally there is the potential for devices to be made unavailable in Australia due to changes in how they are regulated when the new definitions are incorporated. However the CHF believes that the proposed transitional arrangements will provide sufficient time to sponsors and manufacturers to ensure their medical devices are compliant with the new regulations.

QUESTIONS: PRODUCTS WITHOUT INTENDED MEDICAL PURPOSE

Are you a consumer, patient, consumer advocacy group, healthcare provider, industry stakeholder, industry representative body or other?
Consumer Advocacy Group

Are you affected by the proposal to regulate as 'medical devices' a prescribed list of specified groups of products that don't have an intended medical purpose? If yes, how?
We represent all Australians who consume therapeutic goods, who will be affected by the proposed changes.

What benefits or disadvantages are there for patients, consumers or public health and safety in regulating specified products without an intended medical purpose as medical devices?

The primary benefit of the proposal to regulate these products as medical devices is that it should improve the quality, safety and efficacy of products used by Australian consumers.

Would a prescriptive list of specified products that do not have an intended medical purpose regulated as medical devices simplify the regulatory expectations around such products?

The CHF notes some concern that the priority is on simplifying the regulatory process. The TGA and its regulations are intended to protect Australians and ensure they have access to quality, effective and safe therapeutic goods. The priority should be designing and enforcing a regulatory framework that meets that intention, concerns about regulatory complexity on commercial entities should be secondary.

Rather than a prescriptive list of products, CHF would advocate for a list characteristics of which products are assessed against to determine if they require to be regulated as a medical device. This could include characteristics such as materials used to construct the device and any intended use of the product to interact with the human body; with illustrative examples of what products do and don't need to be regulated and why.

In essence, any device or product that may have a medical effect even if they do not have a specific intended medical purpose should be regulated in a manner consistent to comparable medical devices.

The CHF perceives a risk of a prescriptive list permitting products to be unregulated by omission from inclusion on the prescriptive list and thus exposing Australian consumers to unnecessary hazards without appropriate risk/benefit considerations.