Consumers Health Forum of Australia

SUBMISSION

CHF combined submission to TGA Medical Device Reforms April 2019 Public Consultations

May 2019

Consumers Health Forum of Australia 2019 *CHF combined submission to TGA Medical Device Reforms April 2019 Public Consultations*

Canberra, Australia

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

Consumers Health Forum of Australia is funded by the Australian Government as the peak healthcare consumer organisation under the Health Peak and Advisory Bodies Programme

CONTENTS

Contents

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 oppourtunity to provide input into the following five concurrent public consultations on the regulations of medical devices:

- Proposed medical device classification for human cells, tissues and organs storage solutions and IVF media
- Proposed changes to the classification of medical devices used in direct contact with the heart, central circulatory or central nervous systems
- Proposed new medical device classification for substances introduced into the body via a body orifice or applied to the skin
- Proposed changes to the classification of active implantable medical devices and their accessories
- Proposed new classification rule for medical devices that administer medicines or biologicals by inhalation

The CHF is generally supportive of the proposed changes to the regulation of medical devices. We believe that they will both clarify and raise the standards medical devices are required to conform to in order to be made available in Australia, reducing the risk of medical complications due to devices used by Australian consumers.

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

Given recent developments with medical device regulation, such as with implantable mesh, there has been a general demand from consumers for medical devices to be regulated more rigorously and at higher classifications. While the timing and logistics of these five public consultations prevented the CHF from obtaining detailed consumer input on each specific consultation, the positions we have articulated are based on that general demand and input we have received in other areas of medical device regulatory reform.

Response: Proposed medical device classification for human cells, tissues and organs storage solutions and IVF media

We support the proposal to introduce a new classification rule in the Australian MD Regulations to classify "non-invasive medical devices that are substances or a mixture of substances intended to be used in vitro, in direct contact with human cells, tissues, organs or with human embryos before implantation/administration" as Class III (high-risk) medical devices.

We believe that given the nature and risks of these medical devices, they should be required to undergo the most stringent assessment for safety, efficacy and quality before being made available to consumers.

We also believe that the proposed amendments to the existing classification rules 2.2 and 2.3 in Schedule 2 of the Australian MD Regulations will improve the clarity of the rules and hence reduce costs of compliance with the regulations.

The outlined transitional arrangements are appropriate and should prevent any supply shortages. Manufacturers will have more than sufficient time to ensure their devices are compliant with the higher assessment standards. As such there should be no impact on the ability for consumers to access suitable devices as they require them.

Consultation Paper Questions

- Is the proposed new classification for IVF media and medical devices that are substances used for storing human cells, tissues and organs to Class III appropriate?

Yes. We believe that give the nature of the materials stored by such devices they should be classified and regulated at the highest level.

- What groups of devices do you consider fall within the scope of the proposed change?

We believe that the broadest possible interpretation should be applied when considering what groups of devices should fall within the scope of the proposed change. This will ensure that the MD Regulations cover not only current technology and techniques but also future ones that may be developed. Failing to do so risks future devices undergoing lower levels of assessment due to gaps in the regulations despite their usage and risk profile.

However, we note it is difficult to determine what devices or groups of devices will not be within the scope based on the consultation paper. Potential criteria for exclusion and examples of devices that would or could be excluded should produced. We would advocate for all the examples of devices and device groups listed on pages 9 and 18 of the consultation paper at minimum be included scope for the proposed changes.

- What questions should we consider when clarifying amendments to classification rules 2.2 and 2.3?

The key question to ask is whether the clarifications are too specific or tied into current technology or techniques. The amendments should ensure that the revised classification rules 2.2 and 2.3 are broad enough to ensure new devices or techniques that brought to Australia for the same purpose are not excluded from the higher level of regulation due to narrow definitions.

Response: Proposed changes to the classification of medical devices used in direct contact with the heart, central circulatory or central nervous systems

We support the proposal to reclassify any surgically invasive medical device intended for use in contact with the heart, CCS or the CNS to be a Class III (high risk) medical device regardless of the duration of use and/or intended indications.

We believe that given the nature and risks of these medical devices, they should be required to undergo the most stringent assessment for safety, efficacy and quality before being made available to consumers.

The outlined transitional arrangements are appropriate and should prevent any supply shortages as manufacturers will have more than sufficient time to ensure their devices are compliant with the higher assessment standards.

Consultation Paper Questions

- Is reclassification of any or all of these devices in Australia to Class III appropriate?

Yes, the reclassification of all of these devices to Class III is appropriate.

- Do you have any comments/views regarding any definitions or other provisions (refer Appendix A) discussed in this consultation paper?

The definitions and provisions listed in Appendix A all appear to be appropriate for effecting the proposed changes in a suitable and clear manner.

Response: Proposed new medical device classification for substances introduced into the body via a body orifice or applied to the skin

We support the proposal to introduce a new classification rule in the Australian MD Regulations to classify all devices that are "composed of substances (or combination of substances) that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body" as Class IIa, Class IIb or Class III devices depending on where in the human body they are intended to be located.

We believe that given the nature and risks of these medical devices, they should be required to undergo stringent assessment for safety, efficacy and quality before being made available to consumers. As such these higher-level classifications seem appropriate.

The outlined transitional arrangements are appropriate and should prevent any supply shortages as manufacturers will have more than sufficient time to ensure their devices are compliant with the higher assessment standards. As such there should be no impact on the ability for consumers to access suitable devices as they require them.

Consultation Paper Questions

- Do you have any comments/views regarding defining the scope of medical devices that should be covered by the proposed new classification rule?

We believe that the definition adopted should be as broad in scope as possible to ensure that the MD Regulations cover not only current technology and techniques but also future ones that may be developed. Failing to do so risks future devices undergoing lower levels of assessment due to gaps in the regulations rather than due to their actual risk profile.

- Do you have any comments/views regarding defining the terms injured skin or mucous membrane in the Australian MD Regulations?

We believe these terms should be defined to improve clarity in the Australian MD Regulations. Adopting the definition used in EU MD Regulations would be a sensible step to take as it is a broad definition that will provide consistency across the global market while covering future device technology and techniques.

- Do you have any comments/views regarding the meaning of the term systemically absorbed (or systematic absorption)? Should this term be clarified in our guidance or defined in the Australian MD Regulations? If yes, what definition do you propose for the meaning of this term?

We advocate for a definition being constructed and inserted into the Australian MD Regulations. However as non-Subject-Matter-Experts we feel we are not well placed to generate the specific wording of the definition. We note that any definition adopted should be as broad as possible to ensure that the MD Regulations not only cover current technology and techniques but also future ones that may be developed.

Response: Proposed changes to the classification of active implantable medical devices and their accessories

We support the proposal to reclassify AIMD, their accessories, active devices "intended for controlling, monitoring or influencing the performance of an AIMD" and software that drives or influences the use of an AIMD to be Class III (high risk) medical devices.

We believe that given the nature and risks of these medical devices and their accessories, they should be required to undergo the most stringent assessment for safety, efficacy and quality before being made available to consumers.

We note that this reclassification does not lower the level of assessment these devices currently undergo and is simply streamlining the current AIMD and Class III classifications into a single classification.

The outlined transitional arrangements are appropriate and should prevent any supply shortages as manufacturers will have more than sufficient time to ensure their devices are compliant with the higher assessment standards. As such there should be no impact on the ability for consumers to access suitable devices as they require them.

Consultation Paper Questions

- Do you have any comments/views regarding all or some of non-implantable accessories to AIMD that are proposed to be reclassified to Class III? Is reclassification of these devices in Australia to Class III appropriate?

We believe that given the risk associated with AIMDs, any and all accessories that are used in conjunction with these devices should be required to undergo an equally high and rigorous assessment for safety, quality and efficacy. Having accessories assessed to a lower standard introduces an unacceptable and avoidable weakness in the safety regulations that exposes consumers to unnecessary additional risk.

Response: Proposed new classification rule for medical devices that administer medicines or biologicals by inhalation

We support the proposal to introduce a new classification rule in the Australian MD Regulations to classify all devices that are "intended to administer medicines or biologicals by inhalation" as Class IIa unless "their mode of action has an essential impact on the efficacy and safety of the administered therapeutic good or they are intended to treat life-threatening conditions" in which case they are classified as Class IIb.

We believe that given the nature and risks of these medical devices, they should be required to undergo stringent assessment for safety, efficacy and quality before being made available to consumers. As such these high levels of classification seem appropriate for such devices.

The outlined transitional arrangements are appropriate and should prevent any supply shortages as manufacturers will have more than sufficient time to ensure their devices are compliant with the higher assessment standards. As such there should be no impact on the ability for consumers to access suitable devices as they require them.

Consultation Paper Questions

- Do you have any comments/views regarding defining the scope of medical devices that should be covered by the proposed new classification rule?

We believe that the broadest possible interpretation should be applied when considering what groups of devices should fall within the scope of the proposed change. This will ensure that the MD Regulations cover not only current technology and techniques but also future ones that may be developed. Failing to do so risks future devices requiring lower levels of assessment due to gaps in the regulations rather than due to their usage and risk profile.

However we note it is difficult to determine what devices or groups of devices potentially will not be within the scope based on the consultation paper as no potential criteria for exclusion or examples of devices that would be excluded were provided in the consultation. We would advocate for all of the examples of devices and device groups listed on pages 10-13 of the consultation paper to be included within the scope the proposed changes at minimum.

- Should the proposed classification rule refer specifically to medicines and biologicals, or should it refer to any therapeutic good?

We would advocate that the classification rule should use the broader terminology of 'any therapeutic good' rather than specify only medicines or biologicals. This ensures that future devices are not required to undergo lower levels of conformity assessment due to narrow definitions of the regulations despite their usage and risk profile.

- Do you have any comments/views regarding the meaning of the terms essential impact or life-threatening conditions? Should these terms be clarified in our guidance or defined in the Australian MD Regulations? If yes, what definitions do you propose for the meaning of these terms?

We would support for definitions to be provided to increase clarity in the regulatory framework, with a preference for the definitions to be included in the Australian MD Regulations. We would advocate for a broad definition to be generated and adopted into the Regulations to prevent gaps being formed through narrow definitions. However as non-subject-matter-experts in that specific area we do not feel appropriately placed to generate the precise definitions ourselves.

- Do you have any comments/views on whether manufacturers of invasive medical devices that are intended to administer a medicine in such a way that the medicine and the device form a single integral product which is intended exclusively for use in the given combination and which is not reusable (may be multi-dose) should have evidence to demonstrate compliance of the device with the relevant essential principles/General Safety and Performance Requirements?

We absolutely support the requirement for any and all medical device to be required to demonstrate compliance with the *Essential Principles* and *General Safety and Performance Requirements.* We find it unacceptable that any medical device would not have to demonstrate such compliance and shocking that higher risk devices such as invasive medical devices in particular would not have to demonstrate compliance with these regulations.