Consumers Health Forum of Australia

25th March 2019

Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear TGA Medical Devices Branch
,

Re: Proposed reclassification of spinal implantable medical devices

We would like to thank you for the invitation for the Consumers Health Forum of Australia (CHF) to provide input into your consultation on whether the TGA reclassify spinal medical devices.

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.

In regards to this consultation, the CHF supports the proposal to reclassify Spinal Implantable Medical Devices from Class IIb to Class III. We believe that given the spine is a high risk area for implanting medical devices that any devices that are used should undergo the highest level of assessment for safety, efficacy and quality.

While we are generally supportive of the proposed scope of devices included in the definition of 'Spinal Implantable Medical Device'; we do not support the proposed exclusion ancillary components such as screws and plates. Given the rationale for the proposed upscaling of device classification is due to the location being a high risk area, it does not make sense to exclude these devices when they are still being implanted in the same high risk area.

Additionally we are concerned that the proposal to exclude these devices is based on the supposition that the European Union "appears to have considered" these devices and determined their risk as different due to their ancillary role. We would argue that such a decision should be done in a much more rigorous, transparent and evidence based way to ensure risks and benefits are appropriately considered. The TGA should consult with

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the EU, other regulators, industry and academia to confirm that such ancillary devices do in fact have a different risk profile.

The CHF supports the proposed transitional arrangements. We believe it is crucial that consumers have ready and affordable access to such medical devices as they can be critical in improving an individual's health status. We believe that the proposed transitional arrangements give industry more than ample time to ensure their relevant devices meet the level of assessment required to be approved as a Class III device.

Finally we believe it is crucial for the TGA to ensure that the section reviewing device applications is appropriately resourced to manage the higher level of assessment for Class III devices. If the section does not have an increase in resources to manage the increased assessment levels, device approval times will be delayed. This will negatively impact the ability of consumers to access these important devices.

Yours sincerely

Leanne Wells

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