Consumers Health Forum of Australia

13 July 2021

Adjunct Professor John Skerritt
Deputy Secretary,
Health Products Regulation Group
Symonston, Canberra, 2609

Via *Department of Health Consultation Hub*

Dear A/Prof Skerritt,

Re: Proposed refinements to the regulation of personalised medical devices

We would like to thank you for the oppourtunity to provide feedback into this consultation on potential refinements to the recently updated regulatory framework for personailsed medical devices.

The 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 consumer affairs, including health-based research. We have over 250 members reflecting a broad spectrum of organisations including state-based consumer peaks, condition-specific groups, volunteer patient groups, professional associations, Primary Health Networks (PHNs) and the research community. We work in collaboration with our members, national partners and research collaborators to influence policy, programs and services to ensure they are in the consumer and community interest.

Broadly speaking we do not support the "exclusion" of any medical device given that means the device is not subject to any regulation by the TGA. We believe such a classification is a fundamental failure of the TGA to uphold its responsibility to the Australian people to ensure that all medical devices are safe, effective and of high quality. The exception to this, as observed in the consultation paper, are products that are in fact not medical devices. While noting this in the regulation may seem redundant, we acknowledge that clarity can be beneficial even in such matters.

Additionally we on principle do not support 'exempting' certain devices the TGA based solely on the oversight mechanisms of third parties, particularly when those

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third parties are not the equivalent medical device regulators from other jurisdictions. While other parties' requirements, e.g. professional accrediting bodies accreditation processes may have overlap with the processes by which the TGA assesses if a medical device is appropriate, it is in our view entirely inappropriate for the regulator to entirely defer their responsibility onto these parties who are likely not subject matter expert on medical devices and safety requirements as the TGA. We would instead recommend that these other bodies processes be adapted into TGA processes as part of 'special conformity assessment procedures for inclusion in the ARTG'. Where the TGA regularly audits the external bodies systems and processes to ensure it is maintaining the standard required by the TGA and thus continues to be an appropriate alternative conformity assessment procedure.

Finally, we strongly oppose self-assessment declarations of conformity by manufacturers being an allowed regulatory standard, given the obvious conflict of interest. Current issues in the therapeutic good advertising regulatory space show that trusting all industry players to self-conform with regulation requirements is ineffective. While we are sure many would do the right thing, this is a situation where "one bad apple ruins the bunch". In lieu of 'self assessment' we believe that the TGA should develop and maintain a list of approved, independent parties who are able to assess for conformity with the principles which can be used in place of direct TGA assessment, whether being used entirely in place (for example, an overseas medical device regulator assessment) or partially in place (an alternative accreditation process) where it accelerates the ARTG listing process but does not fully replace the TGAs role.

Given this, in summary we believe that the proposed refined mechanisms as articulated on page 11 of the consultation should be redefined as follows:

Exclusion from regulation	Products that: • do not meet the definition of a medical device (for the sake of clarity);
Exemption from inclusion in the ARTG	Products that: • meet the definition of an accessory that do not pose significant harm to the individual (including due to inappropriate use of the product);and

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	• meet the definition of a medical device but are predominantly used for cosmetic purposes and do not present a risk of harm.
Alternative conformity assessment procedure	Class I non-sterile, non-measuring patient-matched medical devices where there are alternative mechanisms of oversight for the manufacture and use of the device. Class IIa patient-matched devices where: • there are alternative mechanisms of oversight for the manufacture and an alternative use of the device; and • the manufacturer obtains conformity assessment from an approved, independent body showing that they meet the regulatory requirements as part of the alternative mechanism.

Finally- we note that the proposed principle of "not regulating products where there is no risk to safety" (page 7) is fundamentally flawed and should not be one the TGA entertains. Primarily there is because there is no such thing as zero risk in any activity. But more pertinently- since consumers are being provided with a medical device in the first place there is evidently sufficiently high risk levels of a negative health outcome to warrant a medical intervention, thus meaning there is sufficiently high risk to warrant those medical devices being properly regulated.

Yours sincerely,

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