Consumers Health Forum of Australia

SUBMISSION

TGA Consultation: Proposed regulatory options for medical devices containing nanomaterials

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Consumers Health Forum of Australia (2020) *Submission to the TGA Consultation: Proposed regulatory options for medical devices containing nanomaterials.* Canberra, Australia

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Overview

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. The reforms will continue to improve the safety, performance, and quality of medical devices in Australia and improve health outcomes for patients who require medical devices. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms. The TGA conducted this consultation as part of the reform program.

In 2015, the Report of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) made 58 recommendations for reform of the regulatory framework for medicines and medical devices in Australia. The Australian Government Response to the Review of Medicines and Medical Devices Regulation was released in September 2016. The Government accepted 56 MMDR recommendations including Recommendation Twenty which provided that the regulation of medical devices, wherever possible and appropriate, align with the European Union (EU) framework including the classification of medical devices.

The focus of this consultation was to seek feedback on whether the Australian medical device regulatory framework should be aligned to the new EU framework for medical devices containing nanomaterials introduced in 2017, and how this could occur.

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. CHF is pleased to make this submission in response to this TGA Consultation on enhancing medical device adverse event reporting.

Note that this consultation was administered as an online survey and this document has been adapted from the CHF submission to that survey.

CHF Submission to online questions

1. What is your name?

Consumers Health Forum of Australia.

2. What is your email address?

info@chf.org.au

3. Would you like to receive updates on this consultation by email?

Yes.

4. What is your organisation?

Consumers Health Forum of Australia.

5. Should specific requirements for medical devices containing nanomaterials, be introduced in the Australian MD Regulations?

Yes.

6. If so, what option/s should be adopted?

Option 1 - no change
Option 2 - add definitions and amend essential principles
Option 3 - add new classification rules

Option 3

7. What impacts—including any that we may not have anticipated and are therefore unintended—do you anticipate the new definitions, essential principles and/or classification rules may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?

We note that we specifically would support the adoption of *both* Option 2 and Option 3, given the reasoning articulated in the discussion paper that Option 3 would work best when combined with Option 2.

The primary impact would be greater protection for consumers from negative health effects caused by un-regulated nanomaterial considerations. A corollary impact would be greater consumer confidence that the TGA is making sure nanomaterials undergo rigorous scrutiny before being approved for use in medical scenarios.

A secondary benefit would be greater consistency in device quality and safety for consumers through international alignment, allowing for more devices to be accessible to consumers across different jurisdictions.

8. Are there any further issues and questions we should consider when implementing these changes (including areas that can/should be clarified in our guidance)?

We note that consumers can have mixed views as to whether they perceive the use of nanomaterials in general to be something that is acceptable and safe. Given the importance of having not only high quality levels in medical devices but also high levels of consumer confidence in medical devices, requiring any devices that do or may contain nanomaterials to comply with higher standards of safety and quality is a self-evidently good regulatory action. We would argue that this more than outweighs any concerns about the additional regulations being more "onerous" for device manufacturers. Especially given the new regulations will be aligning with the European Union.

9. If Option 3 – add new classification rules proceeds, what criteria should be used to decide whether a device has a negligible, low, medium and high potential for internal exposure? Should the term 'potential for internal exposure' 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 would defer to other experts for the specifics but in the broad sense we would expect some of the criteria would include, but not be limited to: the quantity of nanomaterials in the device, the nature of the materials that are in the nano-scale, the expected usage period of the device, the expected purpose/use of the device, the method with which the device is put into the body, whether the device has any transient properties which affect its general nature (e.g. going from liquid to solid).

We are neutral on the questions of providing a specific definition of 'potential for internal exposure'. The phrase seems sufficiently self-explanatory and being too precise with a definition could potentially result in some forms of nanomaterials exposure being unintentionally excluded from coverage under the regulation.

10. Are there any groups of medical devices containing nanomaterial that should be given particular consideration or treatment?

Not to our knowledge.

11. Nanoparticles may be generated as a consequence of the degradation of medical devices not containing nanomaterials or abrasive wear or grinding of a material. Should we clarify whether such devices will be affected by the proposed new rules?

Yes, we believe this should be clarified.

Yes, we believe they should be covered by the new rules.

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

We believe a 12 month period following the regulatory change is appropriate and will give manufacturers more than sufficient notice to ensure they are compliant.

We believe it is acceptable to align the TGA/Australian transitional arrangements with the European transitional arrangements with a six month delay as outlined in the discussion paper. While we would prefer that the transitional arrangements align exactly to ensure the additional consumer protections are brought in as soon as possible, we recognise that potentially manufacturers would struggle to comply with changes in regulations in two jurisdictions with only slightly more than 2 years notice.