Australian Government
Department of Health

Deputy Secretary

Mr Jason Lange
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
One National Circuit
BARTON ACT 2600

Email: helpdesk-OBPR@pmc.gov.au

Dear Mr Lange

Re: Regulation Impact Statement – RIS first pass final assessment - Proposed regulatory scheme for personalised medical devices, including 3D-printed devices - OBPR ID number 24680

I am writing in relation to the attached draft Regulation Impact Statement (RIS). I believe the RIS meets best practice requirements and is consistent with the ten principles for Australian Government policy makers.

I submit the draft RIS to the Office of Best Practice Regulation for formal comment.

Thank you for your recent feedback on the RIS, and many thanks to your staff who have been very accommodating in working with the TGA team to clarify questions and comments in order to achieve compliance with the Government's RIS requirements.

I am pleased to note the OBPR's comments that the RIS provides sound analysis of the imperative to harmonise with international reforms, and addresses operational impacts on suppliers and manufacturers.

I note also the feedback that the report takes a detailed, well considered and defensible approach in assessing the regulatory burden arising from this proposal, and that OBPR agrees with the regulatory costings. Accordingly, these costings have not been revised in the attached second-pass document. However, I can confirm that the TGA has undertaken a final check and is comfortable with the expert advice feeding into the assumptions and calculations. In addition, the Noetic report is now included in the RIS as an integral attachment (Appendix 2).

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We have made significant changes to the document in response to the feedback and to improve readability, including abbreviating the section titles where appropriate.

The RIS provides an analysis of the proposed regulatory change and its impact on stakeholders across the healthcare ecosystem. We have endeavoured to support the analysis using data or evidence, although in some parts this analysis is supported only by partial data or examples. Available data quantifying use of personalised medical devices is very limited. The RIS explores the scale and scope of the problem logically setting out the issues associated with the regulatory lacunae including the risks associated with the absence of sufficient regulatory *requirements* and *oversight*.

To address the feedback provided from OBPR on the draft RIS, we have further explained:

The scale and scope of the problem, including specific risks and harms posed by the current regulatory arrangements (and any examples of cost implications)

- Introduced the dimensions of the problem in the problem section
- Amended the sections covering scale, scope, broader implications, potential risks and harms, and indicative costs that might be borne by society, including text that explains that:
  - The technology is emerging and rapidly changing, which means that there are not mature systems in place to track and measure most aspects of the production and use of personalised medical devices.
  - Whilst the TGA has some systems in place to support the minimal current regulations (such as the custom-made medical device database) these are not intended to capture the data or track it, and the entry requirements for industry at the moment are minimal.
- Strengthened the case for Government intervention.

The rational for why only one option beyond the status quo is considered viable, including the extent to which its six elements need to be considered as an indivisible package in order to be effective

- We have included a third option originally discounted from the first pass RIS due to the associated regulatory burden and potential impact on the availability of devices
- Articulated the analysis which was undertaken when determining the options – including other non-regulatory options we considered
- More clearly articulated the reasons why option 2 needs to be implemented as a complete package to be effective.

The extent to which proposed the proposed changes could have flow-on impacts on demand and other actors in the medical system and device market or to aspects of the health system more broadly, including medical professionals and the health workforce, hospitals, the insurance sector, and consumer behaviour

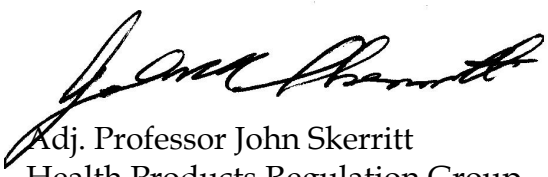
- A range of additional content has been included to address OBPR feedback including **examples** of potential impacts on the broader health ecosystem. However, the lack of data on the use of personalised medical devices mean these impacts cannot be qualified.

Implementation and Evaluation

- The evaluation section has also been redrafted to address the methods and timeframes that the TGA will utilise to assess the efficacy of the reforms, and inform the potential requirement for any further adjustment to the regulatory settings.

I submit the RIS to the Office of Best Practice Regulation for formal final assessment.

Yours sincerely



Adj. Professor John Skerritt
Health Products Regulation Group

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