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Therapeutic Goods Administration
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[redacted]

Confidential Submission:

Proposed refinements to the regulation of personalised medical devices

Inquiry into approval processes for new drugs and novel medical technologies in Australia

I thank both the [redacted] and the Therapeutic Goods Administration for the opportunity to contribute to these two important inquiries.

[redacted]

I am concerned that these two inquiries may be working at cross purposes, with current industry peak body proposals before the TGA to deregulate many medical devices working counter to the objectives being pursued by the Standing Committee to ensure safe and timely access to novel medical technologies.

Patient-Matched Medical Devices are game-changing

New technologies like 3D-Printing, robotics, AI and genome-testing empower MedTech companies to diversify their offering, opening up fertile opportunities to invest in R&D and commercialisation of health solutions which were previously unimaginable.

Treatments are increasingly individualised to suit the unique anatomy and medical needs of their recipient; and while this causes an upheaval which complicates the system of regulation and control that governs healthcare, the patient benefits make this upheaval worthwhile.

Australia is a world leader in personalised medicine and healthcare – the Federal Government has pioneered the regulatory reform that will ensure the recipients of personalised medical goods and services are protected by robust systems of monitoring and control.

The transition from low-volume hand-crafted Custom Devices to regulated mass manufactured Patient-Matched Medical Devices (PMMD) is a transformative period in the health sector which should be actively encouraged though government policy.

The delivery of PMMD within a digital supply chain brings a range of benefits:

- The ability to independently assess and improve patient safety
- The ability to independently assess and improve clinical efficacy
- The ability to apply traditional conformity assessment
- The ability to apply a quantitative cost benefit analysis to decide whether there is value in taxpayer reimbursement

In addition to the clinical benefits, the mass personalisation of devices offers substantial healthcare savings to patients, taxpayers and insurers.

Proposed refinements fail cost-benefit analysis

The "proposed refinements" being considered by the TGA would shield a selective portion of the health supply chain from compliance with the Essential Principles (including safety and efficacy rules) and allow self-regulation by commercial peak bodies in respect of conformity assessment.

In respect of this proposal it is important to note:

- No patient benefit has been articulated in respect of proposed exclusions or exemptions;

- The refinements are not targeted at smaller volume/start-up producers, and would allow the excluded and exempted entities to mass produce utilising advanced manufacturing technologies in direct competition with regulated entities;

- No consideration seems to have been afforded to the significant ongoing investment into the PMMD sector in Australia all of which has been into entities which would remain regulated but would have to compete against unregulated entities; and

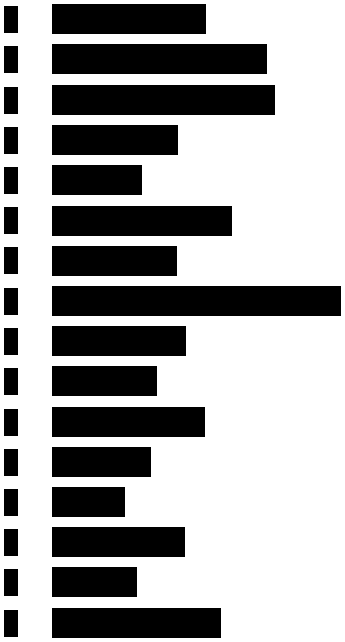
- Some of the proposed "refinements" would place Australia in a position of having much lower safety standards than either Europe or the United States.

Some elements of the proposed refinements sought by these commercial peak bodies seem very poorly considered.. For example, since 2020 The U.S. Code of Federal Regulations 21CFR872.5470 has mandated orthodontic clear aligners as "Device Class II" as regulated by the FDA. All of the leading global players in this device category meet that standard already and so easily meet the requirements for Australian Risk Class variant IIa. Industry proposals to down-classify orthodontic clear aligners in Australian to Risk Class I would only serve to facilitate the entry of low-quality market entrants currently not able to meet European or United States regulatory requirements. There is no articulation of any patient benefit whatsoever from this proposal.

Proposed refinements are a serious risk to investment in this emerging Australian Industry

Australia's regulatory leadership in the PMMD space has been noted globally and has led to a boon in R&D and commercialisation venture capital which sees Australia at the forefront of an investment tidal wave which is only just beginning.

Companies currently each investing many millions of dollars into the Patient-Matched Medical Device space in Australia currently include:



At my count this list represents several hundred million dollars in risk capital already spent, with much more committed into future years, much of it from offshore.

This significant investment creates not only high technology jobs and better health outcomes for Australians, it means Australian patients will receive these health benefits sooner.

Arbitrarily changing the regulation of PMMD to create unregulated competitors to these businesses puts at risk our status as one of the top go-to destinations globally for PMMD investment.

In short, the “proposed refinements” represent a high risk event which would cost Australia many millions in advanced technology investments and a significant volume of high value jobs.

I urge the [redacted] and the Therapeutic Goods Administration to work together to reject the proposed refinements.

Please do not hesitate to contact me for further information or input.

Yours sincerely

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