



Australian
Patients
Association

Australian Patients Association Limited

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21st July 2021

Therapeutic Goods Administration

E PersonalisedDevices@health.gov.au

Dear Madam / Sir

Re : Proposed refinements to the regulation of personalised medical devices

We welcome the opportunity to comment on the proposed changes. The Australian Patients Association (“APA”) is Australia’s peak body for protecting patients’ interests and advocating on behalf of patients. It also supports, educates and informs patients. In general, the APA remains in favour of maintaining the current regulation for patient-matched medical devices. Rigorous quantitative safety and efficacy monitoring of personalised medical devices must continue in order to deliver the best patient outcomes. The current regulatory framework is providing patients with a high level of confidence in device safety and efficacy. In general, patients don’t see the benefits of adopting the proposed refinements for regulating personalised medical devices. They fear that patient safety may be compromised and they are most concerned about any industry self-regulation which is prone to abuse.

Yours sincerely

Stephen Mason
CEO