

13 February 2019

Ms Miranda Lauman  
Branch Head  
Medical Devices Branch  
Therapeutic Goods Administration  
PO Box 100  
Woden  
ACT 2606

[Submitted via online consultation submission form]

Dear Ms Lauman

**Re: Consultation paper: Changes to a number of definitions and the scope of the medical device regulatory framework in Australia**

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to make a submission to the Therapeutic Goods Administration *Consultation paper: Changes to a number of definitions and the scope of the medical device regulatory framework in Australia*. The RANZCP understands that this consultation is part of the Australian Government's reform program following release of its response to the Report of the Review of Medicines and Medical Devices Regulation (MMDR) in September 2016. The RANZCP contributed to the MMDR in 2015 and, as part of its response, consistently emphasised the importance of the appropriate regulation to ensure the safety and quality of medicines and medical devices available in Australia.

This consultation considers whether EU Regulation on medical devices may be appropriate in Australia by introducing a number of new and amended definitions, and a revised scope of the products regulated as medical devices. Of particular interest to the RANZCP in this consultation is the recommendation that devices without an intended medical purpose must meet the same requirements as the analogous devices with a medical purpose. This includes *'equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.'*

In August 2018 the RANZCP published a [Clinical Memorandum on transcranial direct current stimulation \(tDCS\)](#). tDCS is an emerging neuromodulation technique that is being offered in some private clinics in Australia and overseas as a treatment for depression. In Australia the Therapeutic Goods Administration (TGA) has approved devices for tDCS for use in depression and other psychiatric and neurological disorders. However, as tDCS kits are available to purchase directly from commercial suppliers, tDCS is also being used in a 'do-it-yourself' setting by members of the public, believing it to be useful for cognitive enhancement or as a treatment for disorders. As there is no good evidence that tDCS is useful for cognitive enhancement in healthy people, it is the view of the RANZCP that it should not be used for this purpose outside of ethically approved research trials. The RANZCP is therefore supportive of ensuring that brain stimulation devices without an intended medical purpose are subject to the same requirements as those with a medical purpose. The RANZCP is



supportive of implementing consistent regulation on medication devices and, accordingly, welcomes the proposals as outlined in the consultation paper.

If you would like to discuss any of the issues raised in this correspondence, please contact Rosie Forster, Senior Manager, Practice, Policy and Partnerships via [REDACTED] or by phone on [REDACTED].

Yours sincerely

[REDACTED]

Dr Kym Jenkins  
President

Ref: 1379

Attachment: Royal Australian and New Zealand College of Psychiatrists. Clinical Memorandum. Transcranial Direct Current Stimulation (tDCS). August 2018.