February 15, 2019

Australian Government
Department of Health
Therapeutic Goods Administration
Submitted online and to devicereforms@tga.gov.au

Re: Comments on January 2019 Consultation: Potential reclassification of active medical devices for diagnosis and patient therapy[1]

I note that the Therapeutic Goods Administration (TGA) is currently reviewing its medical device regulations with a view to strengthening them in its ongoing efforts to safeguard and enhance the health of the Australian community.

Among the proposed changes, I understand there is one to up-classify continuous positive airway pressure (CPAP) devices to class III from class IIa. This appears a burdensome and unnecessary step. Class IIa (low-medium risk) is appropriate for this common, low-risk, externally applied therapy. In no way does CPAP equate to the risk profile of devices such as an automated external defibrillator (proposed in the consultation as class III) or implants (currently Class III).

I am advised that changing the classification of CPAP from IIa to III will lead to a substantial additional implementation burden, with extra clinical experimentation that appears unnecessary for a technology which is very well established and has a long history of safe and effective use. The result will be increased costs and delays in bringing these devices to market, ultimately disadvantaging patients.

Obstructive sleep apnoea (OSA) is a common burdensome condition with substantial associated morbidity. Approximately 8.7% of the Australian community have the problem to a moderate or severe degree. CPAP therapy is the gold standard therapy for OSA, relieving troublesome symptoms, comorbidities, accident risk and impaired productivity. It is important that such a therapy is widely available and Australian healthcare policy should help facilitate its ready accessibility and affordability. The proposed change threatens to hinder these efforts and does not appear to have any advantage given the relatively simple and safe principles involved in application of the therapy.

It is worth noting that CPAP therapy for OSA is an Australian invention that has culminated in a highly successful Australian industry. Unnecessarily hindering production of the therapy in its home market by over-zealous regulation would be a regrettable development.

Sincerely,

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[1] https://www tga gov au/sites/default/files/consultation-potential-reclassification-active-medical-devices-diagnosis-and-patient-therapy pdf