



19<sup>th</sup> June 2013

The Dental Board of Australia Response

[dentalboardconsultation@aphra.gov.au](mailto:dentalboardconsultation@aphra.gov.au)

Dear Sir or Madam,

Thank you for the opportunity to provide feedback to the Dental Board of Australia on the proposed changes to the Scope of Practice Registration Standard.

SomnoMed is an Australian ASX listed company specialising in the manufacture of Mandibular Advancement Splints, SomnoDent. We are the global leaders in oral appliance treatment of Sleep Disordered Breathing (SDB) conditions. Somnomed has over 130,000 patients worldwide who have been fitted with SomnoDent devices by a network of over 5000 dentists educated by SomnoMed globally.

Our medical devices comply with ISO standard 13485, and are TGA, CE and FDA approved.

Our splints are custom made for the patient on the referral of Sleep Physicians, Ear Nose and Throat physicians and other referring specialists. The fitting dentist is a part of a treatment team.

Sleep related breathing disorders such as Obstructive Sleep Apnea are serious medical conditions diagnosed through medical tests carried out in our sleep labs or at the patient's home. Clinical research has proven that there are significant links to co morbidities such as cardio vascular problems and diabetes, serious conditions which are potentially life threatening. Because of that it is practice in most of the 22 countries SomoMed is operating in that SBD patients should only be treated by formally educated dentists who

- have received education in Dental Sleep Medicine
- are able to screen for symptoms of Sleep Apnea
- refer patients for in lab or home sleep tests to medical specialists
- evaluate for suitability with oral appliance therapy from a dental perspective
- take accurate impressions and a bite registration
- fit the device and train the patient in care of their device
- assist in the ongoing management of the patient
- report health outcomes to the Medical Specialist



Our eight year experience in this specialised area has proven the potential dangers from and negative impact of the involvement of untrained dentists, or worse, of non dentists such as hygienists or medical specialists (such as ENTs) without the direct involvement of a dentist. Consequences observed include

- TMJ pain and discomfort
- Tooth Movement
- Occlusal bite change
- Fitting of devices without a Sleep Study resulting in inappropriate and dangerous treatment

We note on page 8 of the proposal the key deletion.

*"Dentists may supply and fit dental appliances for the treatment of sleep disorders. They must work in cooperation with the patient's medical practitioner who is responsible for the medical aspects of the management of sleep disordered breathing."*

**We believe this clause must be maintained to ensure active supervision of a trained dentist in the treatment, care and safety of the patient being treated for a medical condition.**

Recently our SomnoDent device was exclusively used in a three year Medical trial funded by the Australian Federal Government comparing Mandibular Advancement Splints (SomnoMed) and CPAP (Resmed S8). The result of that trial was "similar health outcomes" when comparing the two modes of treatment (ref: 1). This study, together with an increasing number of clinical research carried out around the world (including 16 studies involving the SomnoDent device) have helped to increase the acceptance of oral appliance therapy from medical practitioners.

SomnoMed is globally at the forefront of prompting this most comfortable and patient friendly treatment as an effective way to help the high percentage of patients rejecting CPAP treatment.

SDB are more and more recognised as a fast growing chronic disease with serious health impacts. Left untreated the health outcomes of Sleep Apnea are

- Mortality
- Morbidity
- Depression
- Cardiovascular disease
- Vehicle and workplace accidents
- Relationship breakdown

(ref: 2,3,4,5,6,7,8)



In our efforts to gain more acceptance from medical specialists for oral appliance therapy the assurance that only specialised and educated dentists are involved in the medical treatment of SBD patients is of great importance to build support and confidence from the medical side. SomnoMed has been leading efforts to build a bridge between educated dentists and medical specialists which has helped to increase the referral rate from medical practitioners in all countries we are operating in.

Health outcomes should remain the focus of any treatment plan and we encourage the board to maintain the importance of educated dentists working with the Medical Professional in the treatment of Sleep Related Breathing disorders.

We would welcome the opportunity to speak to you in person and answer any questions you might have.

We attach our clinical references.

Yours sincerely,

Peter Field  
National Manager ANZ

Chris Bedford  
General Manager,  
Global Production and Technology

Reference 1



Phillips et al\_AJRCCM  
2013.pdf

Reference 2



Published  
SomnoDent Studies.d

Reference 3



Marin 2005. Long  
Term Cardiovascular

Reference 4



Pantin et al 1999  
Dental side effects of

Reference 6



Ferguson 2006.pdf

Reference 7



resp12140.pdf

Reference 8



BP for OA review.pdf