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Advertising Compliance Unit
Regulatory Practice, Education and Compliance Branch
Therapeutic Goods Administration
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Re Therapeutic Goods Advertising Code

The Australasian Sleep Association (ASA) is the peak scientific body in Australia & New Zealand representing clinicians, scientists and researchers in the broad area of Sleep. Our vision is the provision of world standard research, education and training, and establishment of clinical standards to ensure clinical best practice in sleep medicine resulting in an informed community with healthy sleep practices.

A recent Sleep Health Foundation/Deloitte Access Economics Report has shown that inadequate sleep in 2016-17 cost Australia a total of \$26.2billion with direct costs to the health system of \$1.8billion. Research has indicated that approximately 10% of the population suffer from sleep disorders that can be treated, the most common of which are insomnia and obstructive sleep apnoea.

It is vital that sufferers have a correct diagnosis and then receive the most appropriate treatment for their particular condition. For those suffering from Obstructive Sleep Apnoea (OSA), Continuous Positive Airway Pressure (CPAP) has long been recognised as the gold standard of treatment; however, there are effective treatment alternatives, which must be discussed with the patient by a well-trained sleep physician, with no conflict of interest in order for the patient to be prescribed the most appropriate treatment. For those suffering from Insomnia, there are also a number of good options for treatment and it is imperative that each patient is aware of these, is able to discuss the options with an impartial, trained sleep physician and seeks appropriate diagnosis and treatment.

Currently there are a number of corporate entities that are by-passing the medical diagnosis of Sleep Disorders, and are selling treatments for which there is absolutely no evidence of benefit, to manage a disease that has not been properly diagnosed. CPAP is considered a Class 3 Medical Device, the sale of which is currently not restricted. Additionally, many pharmacies and other entities sell aids to improve the symptoms of both sleep apnoea and insomnia, with no advice on the advertising stating that medical advice should be sought before starting treatment or that there is no scientific evidence for the effectiveness of the particular product. This is particularly problematic for patients with sleep apnoea. OSA causes significant cardiovascular, metabolic and neurobehavioural morbidity. It is associated with hypertension, myocardial infarction, diabetes and dementia. One of the most common symptoms of OSA is snoring and many patients seek a cure for their snoring, without recognising that OSA is the underlying serious medical condition. Patients may use an advertised over-the-counter product for snoring (eg nasal tubes or sprays), which are unlikely

to improve the snoring but also divert attention away from the need to obtain a diagnosis and then treatment for their disease (OSA). This results in failure to recognise and treat a serious medical condition.

It is absolutely vital that the treatment of serious medical conditions, such as obstructive sleep apnoea or insomnia, should be based on the highest medical standards. This includes a carefully considered diagnosis, discussion with the patient as to the most effective treatment and careful prescription of the best treatment. This is clearly not the case if patients are not adequately diagnosed, if they are not managed by physicians trained in managing these disease conditions and if the treatments prescribed are not the most appropriate for the individual patient. Those purported treatments which have no scientific evidence to support their efficacy, should be clearly labelled as such.

For the above reasons, the Australasian Sleep Association strongly recommends that:

1. CPAP be available only on the prescription of an appropriately trained medical practitioner; and
2. Treatments being sold to treat sleep disorders must have solid science to backup their effectiveness or should be labelled to indicate that there is no evidence to support their efficacy.

The ASA endorses the proposal that Medical Devices should be treated in the same way as Pharmaceuticals.

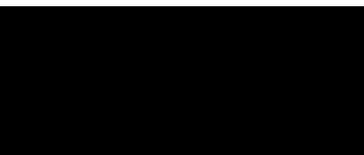
The ASA supports the introduction of a more self-regulated regime, as long as adequate guidelines are available and educational programmes are put in place to assist advertisers understand their obligations, including those recommendations proposed in section 4.3 of the proposal.

Price Information Code of Practice should remain and be promoted to the public. It should remain in the new Code, and not have different legislation.

The ASA would like to see stringent advertising restrictions, currently not applicable to medical devices, expanded to include medical devices, such as CPAP machines. Any device that is advertised to treat insomnia, snoring or obstructive sleep apnoea should have solid, level 1 scientific substantiation of the benefits of treatment. Treatments purporting to treat snoring or obstructive sleep apnoea must be available only on medical prescription from a medicine practitioner trained in the area.

Should you require any further information in this regard please do not hesitate to contact me on 

Kind regards



Maree Barnes
President