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Re: Reforms in the Medical Devices Regulatory Framework

The Cosmetic Physicians Society of Australasia (CPSA) welcomes the opportunity to provide comment to the Therapeutic Goods Administration's proposal to reform the regulatory framework for medical devices.

The CPSA represents over 200 doctors whose focus is the provision of non- and minimally-invasive cosmetic medicine. For some time, our members have been becoming increasingly alarmed at the proliferation of laser and other light source equipment and their use by untrained, unqualified personnel, including beauty therapists who have no medical contact.

The CPSA agrees with increasing regulatory constraints by the TGA to ensure medical devices, such as intense pulsed light (IPL) and laser machines, supplied to the Australian market are manufactured under appropriate quality controls, are safe to use and new provisions are introduced to regulate IPL and laser machines.

The CPSA's members are also concerned with home laser hair removal devices which can be purchased by consumers to use, unassisted by trained personnel, at home. Although some home laser devices are low powered, the CPSA is concerned that the risk of consumers misusing the devices remains dangerously high in terms of incorrect skin typing and misuse on tanned skins (whether through sun exposure or fake tanning).

The CPSA agrees and recommends that a national framework is necessary if the TGA's legislative requirements are to be upheld to ensure the quality, safety and performance of medical devices.

About the CPSA

The CPSA is a professional organisation formed in 1997 to represent qualified doctors who focus on providing cosmetic procedures. The CPSA now represents the largest group of doctors with a focus on cosmetic medicine in Australia. Its twin aims are:

- to raise standards in the provision of cosmetic medicine by providing members with relevant training and information; and
- to provide the public with up-to-date information about cosmetic medicine and help it locate

qualified doctors whose focus is on providing cosmetic procedures.

The CPSA has played a significant role in the development of standards to protect the public in recent years and actively works to highlight and eradicate bad practices. For example, it was involved in formulating the NS10010 National Standard – Accreditation of Cosmetic Clinics which caters for cosmetic medicine practices where minimally invasive procedures are performed. The organisation is well placed to make a greater contribution in the years ahead.

Our members have seen many patients suffering complications arising from unregulated use of technologies such as lasers and IPLs in the hands of non-medical personnel. Such cases have been documented by programs such as *Today Tonight* (see http://au.todaytonight.yahoo.com/article/7056739/health/hair-removal-hazard).

The CPSA believes the current practice which allows the use of such machinery by unqualified and/or unsupervised personnel is an issue that requires regulation to ensure adequate levels of patient safety. The CPSA believes that the current review presents the ideal opportunity to extend the regulations to include intense pulsed light sources and hair-removal lasers which have the potential to cause permanent and frequent damage if not properly operated.

It is therefore our recommendation that the legislation currently under review should be expanded to include the regulation of IPLs as well as medical laser technologies. It is also our recommendation that the TGA works with the Government to work through the COAG processes to establish a national regulatory framework to enhance patient protection in this fast-growing area of cosmetic medicine.

In direct response to the TGA calling for comments in the discussion paper on proposed changes to the regulation of devices, the CPSA is concerned that patient safety is at risk when IPLs and lasers are being operated by persons who are not medically-trained to accurately assess skin phototypes and recognise skin conditions which could be cancerous.

I trust that these views and comments are of use. My colleagues and I would welcome the opportunity to meet with representatives of the Office of Device Authorisation to explain in greater detail why, in particular, we believe that IPLs and similar technologies pose a very real threat to patient safety.

Yours sincerely,

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