Greater regulatory accountability for dental laboratory products is the outcome of revised mandatory reporting standards for manufacturers and importers introduced by the Therapeutic Goods Administration (TGA). Welcomed by the Australian Dental Industry Association (ADIA), the peak business organisation representing manufacturers and suppliers of dental products, the changes provide greater guidance on when the TGA needs to be notified about activities concerning the manufacture and importation of a range of custom-made medical devices including dental crowns, dental bridges and dentures.

“There had been some uncertainty across the dental community about the reporting obligations. As a result of ADIA’s engagement with the TGA, there is now much greater clarity concerning the mandatory reporting framework and this has been welcomed by industry,” said Troy Williams, ADIA Chief Executive Officer.

A dental laboratory or dental prosthetist making a custom-made medical device in Australia must provide the TGA with their (the manufacturer’s) name and business address in addition to a description of the kind/s of medical devices being custom-made by the manufacturer.

There are similar requirements for an entity importing and supplying a custom-made medical device from overseas. They are to provide not only their own details to the TGA, but also the manufacturer’s name and business address plus a description of the kind/s of medical devices being custom-made by the manufacturer.

The regulations require that the TGA be notified within two months of manufacture or importation of the custom-made medical device and it is this notification period that changed.

“Local manufacturers and importers have long had an obligation to advise the TGA of their activities but, rather curiously, the regulations were silent as to when this should happen. Working with our members in the sector, ADIA was pleased to secure an amendment to the regulations that provided clarity on the compliance obligations,” Mr Williams said.

According to Mr Williams this change is one of many that ADIA has been working towards to ensure that there is a level playing field where local manufacturers and importers of dental laboratory products are required to meet the same regulatory standards.

“On behalf of the sector ADIA has been working with the TGA to ensure that the same standards for design, safety and manufacturing quality associated with custom-made medical devices are applied, irrespective of the country of manufacture,” Mr Williams concluded.

ADIA and the TGA have organised briefings on the changes and for information on these visit: www.adia.org.au/training/tga-briefing

Ends.

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