Dear Sir/Madam,

At Melbourne information session of devices regulatory reform proposals on 23rd of November, there were objections from various companies against TGA proposal 3 and 4. We as Australian dental products manufacturer, however, strongly support TGA proposals, i.e. publish ARTG numbers on the medical device labels; and publish device product information on the TGA website. These two proposals will increase transparency of the TGA regulatory approval for medical device, and enhance identification to legally supply approved medical devices.

One example can back our opinion. On marketplace, there are two equivalent approved medical devices, ARTG entries 167979 and 160241. They are actually same product and same GMDN code, however, they have different classifications - ARTG entry 160241 is Class IIa, while ARTG entry 167979 is only Class 1. Because ARTG numbers and product information are not published with the devices, it causes confusion about correct classification and safe use of the product.

Also, when ARTG number is published on a product label, healthcare providers and consumers will have confidence in use of the product. Therefore we are in favour of proposal 3 and 4.

Regards,

Dentalife Pty Ltd