Australian Dental Industry Association | ADIA

ADIA Policy Statement –

Policy	**R6 – Medical Device Regulation (Custom-made medical devices)**
Statement	That the information provided to patients receiving dental laboratory products (custom-made medical devices) be improved by mandating a requirement for a statement of manufacture to be provided to patients, and retained by the dental practitioner.
Principle/s	That patients have a right to access information concerning the manufacturer of dental laboratory products and who is lawfully responsible for the supply of the product in Australia.
Background	▪ The TGA's role is to safeguard and enhance the health of the Australian community through effective and timely regulation of dental products and other therapeutic goods. It does this through the application of the *Therapeutic Goods Act (Cth) 1989* and subordinate legislation. ▪ Dental laboratory products (e.g. dental crowns and bridges) are deemed to be custom-made medical devices and therefore fall within the scope of the *Therapeutic Goods (Medical Devices) Regulations (Cth) 2002*. ▪ In 2011 the senate community affairs references committee, when undertaking an inquiry into the regulatory standards for the approval of medical devices, noted that "…dental professionals and patients alike are unaware that up to 50 per cent of custom-made dental prostheses are manufactured overseas, with no validation at the source of manufacture". ▪ All custom-made medical appliances, whether manufactured in Australia or overseas, are required to meet the same regulatory standards in terms of product design, performance and safety. In ADIA's view, these standards are appropriate to the currently quantified level of risk thus no further revision to those regulatory standards is required at this point in time. ▪ In the United Kingdom there is a legal requirement that patients receiving a custom-made dental appliance be offered a statement of manufacture. Further, healthcare practitioners are obligated to retain this statement for the lifetime of the prosthesis and record whether this was provided to the patient or not. ▪ Senators, in their report of the aforementioned senate committee inquiry, recommended that the TGA investigate whether the approach used in the United Kingdom of requiring a statement of manufacture to be provided to patients, and retained by the dental practitioner, has merit.
Framework Documents	▪ ADIA Advocacy Agenda ▪ ADIA Stakeholder Engagement Strategy
Engagement & Advocacy Partner/s	▪ Internal: ADIA-DRC Dental Regulation Committee ▪ External: TGA
Currency	ADIA-DRC Endorsement: 28/1/2015 ADIA Board Approval: 18/2/2015 (Reference 1.9.2)