Australian Dental Industry Association | ADIA

ADIA Policy Statement P12 — Medical Device Regulation (3D Printed Dental Products)

Statement

That the Therapeutic Goods Administration (TGA) should view 3D printed dental products as custom-made medical devices for regulatory purposes and that a risk-based approach to regulation be used.

Principle/s

- The Australian community has an expectation that therapeutic goods are safe and of high quality. Owing to the various types of 3D printed dental products that may exist into the future, it is appropriate that a risk-based approach to regulation be undertaken.
- A prescriptive approach to 3D product regulation is to be avoided as it may frustrate further innovation in this emerging technology and its deployment.

Background

The Australian community has an expectation that therapeutic goods are safe and of high quality, to a standard equal to that in comparable countries. The objective of the *Therapeutic Goods Act (Cth) 1989* is to provide a national framework for the regulation of therapeutic goods in Australia, so as to ensure their quality, safety, efficacy and timely availability. This legislation is enforced by the Therapeutic Goods Administration (TGA).

The emergence of 3D printing in dentistry is likely to see this used as a manufacturing process for a range of products ranging from instruments to implantable devices.

In a document entitled *The Therapeutic Goods Administration's risk management approach to the regulation of therapeutic goods* the TGA sets out an approach to risk assessment and risk management that is thought by ADIA to be relevant to, and suitable for, the regulation of 3D-printed medical devices.

The TGA's framework provides for the use of 3D printing for mass production and also for patient-specific devices, the latter being the custom-made medical device regulatory framework. ADIA believes that this framework can, with minor amendment, be effectively used to regulate 3D printed dental products and other types of medical devices.

Engagement & Advocacy Partners

- Internal: ADIA-DRC Dental Regulation Committee
- Stakeholder: N/A
- Government: Therapeutic Goods Administration & Minister for Health

Endorsement

ADIA-PRPC Product Regulation Policy Committee: 04/05/2017 ADIA Board: 23/05/2017

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