Australian Dental Industry Association | ADIA

– Submission

Proposed regulatory scheme for personalised medical devices, including 3D printed devices

This submission is tendered by the Australian Dental Industry Association (ADIA), the peak business organisation representing manufacturers and suppliers of dental products.

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Association of International Dental Manufacturers MEMBER

CAMPAIGN ASSOCIATE

Australian Chamber of Commerce and Industry Member

Comments –

The Australian Dental Industry Association (ADIA), as the peak business organisation representing dental product manufacturers and suppliers, welcomes the opportunity to submit this response to the Therapeutic Goods Administration (TGA) consultation on the proposed changes to regulatory requirements of personalised medical devices.

Overall, ADIA supports the changes outlined in the consultation paper, but has outlined below some specific areas which ADIA considers require further review by TGA as precedents exist that diretcly impact the appropriateness of the scope of scope of some of these proposed changes.

ADIA submits that TGA consider exemptions for low risk custom made medical devices from some of the proposed changes, particularly with regard to the additional information prosed to be provide to TGA.

ADIA provides specific comments below on each of the proposed regulatory changes:

1. Introduce new definitions for personalised medical devices

ADIA notes that the new definitions are consistent with the recently issued IMDRF guidance document "Definitions for Personalised Medical Devices".
ADIA supports international harmonisation of regulatory controls for medical devices, and the minimisation of unique Australia specific regulatory definitions, and requirements.

ADIA supports the proposed new definitions for personalised medical devices.

ADIA believes it will be very important that TGA provides guidelines that include a comprehensive series of examples of medical devices that fall within the different definitions, to educate Industry in making categorisation assessments of their personalised medical devices moving forward.

2. Change the requirements for supplying custom-made medical devices in Australia, so that additional information must be provided to the TGA and to patients and, to allow the TGA to inspect manufacturing sites.

ADIA notes that the proposed changes to the regulatory requirements for custom made medical devices are now to be aligned with the requirements of the EU Medical Devices Regulations. ADIA is supportive in principle but has some specific concerns.

It is proposed to change the regulatory requirements for custom-made devices to require:
- that the manufacturer's statement about a custom-made device is provided to the patient receiving the device;
- that the TGA be allowed to enter and inspect custom-made device manufacturing sites, in accordance with the authority it has to inspect all other medical device manufacturers;

• that a manufacturer in Australia, or a sponsor of an overseas-manufactured custom-made device, provides an annual report to the TGA of the custom-made devices it has supplied; and
• that documentation about an implantable custom-made device is retained for a minimum period of fifteen (15) years; as the current specification of a five (5)-year retention period is considered inadequate

It is important to note that the proposed requirement for annual reporting of custom-made medical devices is a new requirement. This will add regulatory burden for SME's that operate in the custom made sector for dental devices – such as prosthetists and dental laboratories; and other SME's operating in other custom made device categories, represented by other stakeholder groups: Optical Distributors and Manufacturers Association of Australia (ODMA) , and Assistive Technology Suppliers Australasia (ATSA).

With respect to the proposed change to provide the manufacturers statement about a custom-made medical device to the patient, it is appropriate to note that in late 2017 when TGA changed the requirements for providing patient information cards for implantable medical devices, a number of lower risk implantable medical devices were exempted from these requirements. These include many implantable dental devices: including dental filings, dental braces, tooth crowns, general (endosseous) dental implants.

ADIA suggests that TGA adopt a consistent approach to the requirements for provision of information about low risk custom made devices.
ADIA proposes that low risk, custom made medical devices are exempted from the requirements to provide the manufacturers statement to the patient, consistent with the TGA requirements for patient information leaflets for low risk implantable medical devices.

ADIA supports the introduction of annual reporting for medium to high risk custom made medical devices to TGA, and extending record keeping period for medium to high risk implantable medical devices.

However, ADIA questions whether there is justification from a risk benefit perspective for extending the record keeping requirements to 15 years for low risk implantable devices, such as those listed above that are exempted from the requirements to provide patient information leaflets. It is requested that the RIS should assess the impact of this expanded record keeping proposal on the SME's involved in the supply and manufacture of implantable custom-made medical devices, and that the increased regulatory burden of this change for low risk implantable custom-made medical devices is justified.

3. Introduce a framework for regulating medical device production systems which will allow healthcare providers to produce lower risk personalised devices for treating their patients, without the need for manufacturing certification
ADIA supports this proposal

4. Update the classification rule for medical devices that record diagnostic images so that it includes any device for this purpose and not just X-rays, for example 3D-printed models of patient anatomy

ADIA supports the amendment of Classification Rule 5.4 to apply to all devices that

record diagnostic images, and it be agnostic to the technology involved.

ADIA supports the exemption of health professionals and hospitals from conformity assessment requirements.

5. Regulate medical devices with a human origin component, for example a 3D printed implant incorporating cells from the patient, as medical devices with a biological component rather than as pure biologicals

ADIA supports the proposal that these medical devices are more appropriately regulated as medical devices with a biological component, rather than as a biological.

6. Clarify that any modifications or adaptations to personalise a medical device that has already been supplied must have been intended by the original manufacturer of the device.

ADIA support the proposal to provide greater clarification for all stakeholders in the supply of personalised medical devices

ADIA appreciates the opportunity to engage in this consultation.

[redacted]

29 March 2019

ADIA An Introduction —

Formed in 1925, the Australian Dental Industry Association (ADIA) is the peak business association representing manufacturers and suppliers of ninety-five percent of the products used in Australian dentistry.

The ADIA membership ranges in size from the local operations of multi-billion dollar corporations through to small family-owned entities. They share common aspirations for the growth of their business, the creation of jobs and an industry that's sustained through the provision of quality products and services to dental professionals.

ADIA supports a regulatory framework for dental products and services that is based upon a risk-management approach designed to ensure public health and safety, while at the same time freeing business from an unnecessary regulatory burden. To this end, ADIA is a strong advocate for reforms that cut red-tape and allow businesses in the dental industry to grow, create jobs and operate sustainably.

Australia's largest healthcare trade show, *ADX* Sydney, is convened biennially by ADIA and attracts nearly ten thousand stakeholders from across the Asia-Pacific's dental and oral healthcare community. ADIA also convenes regional trade shows in Adelaide, Brisbane, Melbourne and Perth that provide a platform for the growth of member businesses.

Working with members to ensure that the dental industry has ongoing access to a workforce of skilled professionals, the Association supports skills development across the dental industry. An pioneering partnership with MEGT sees the group training model used to employ apprentices and trainees across the industry and the *CSU – ADIA Graduate Certificate in Small Business Management* provides support for mid-career professionals. Consistent with ADIA's role as the peak body for manufacturers and suppliers, ADIA is a member of the Australian Chamber of Commerce & Industry (AusChamber), the nation's foremost grouping of employer organisations. Amongst other affiliations is ADIA's membership of the association of International Dental Manufacturers (IDM), the Swiss- based global body for the dental industry.

The ADIA national office is based in Sydney and the Association is active in all mainland states.

More information can be found online at www.adia.org.au

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