



— Submission

Consultation on proposed clarification of the regulatory requirements for medical device systems and procedure packs

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

General 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 changes to several definitions and the scope of the medical device regulatory framework in Australia.

ADIA is a strong supporter for a regulatory framework for dental products, and medical devices more broadly, which is based on a risk management approach designed to ensure public health and safety, whilst at the same time not imposing unnecessary regulatory burden.

ADIA is supportive of the TGA's decision to implement these reforms to provide greater consistency with Europe, and introduce separate definitions for *"system"* and *"procedure pack"*.

It is important that the TGA also considers in the process of addressing risk mitigation for higher risk medical device systems, the impact of regulatory change on low risk systems, which may include a medical device and an excluded good/ non TGA product, will not be adversely impacted.

In the regulation of medicines, the legislation enables supply of a "kit" that includes a medicine and an article that is not a therapeutic good. This kit can be listed as a low risk medicine without the non therapeutic good being reclassified as a medicine (example of a Headlice treatment and comb).

It is unclear under the proposed new definitions if the combination of a medical device and an excluded good/article can be included on the ARTG as a system, (example of a medical device for headlice treatment and a comb), or whether a system can only be comprised of medical devices.

The consultation paper is rightly focussed on addressing the criteria for, and application of, the special conformity assessment procedure for SOPPS that are medical devices used for a special purpose. ADIA supports the proposal to amend the Regulations to more closely align with the intent provided in Article 22, EU MD Regulation, noting the exemption from Conformity Assessment for SOPP's containing Class I medical devices.

ADIA would also seek to reaffirm that for the amendments to Clause 7.5 Schedule 3, the wording relating to *"manufacturer of a SOPP holds evidence in the form of a conformity assessment document from the TGA, a comparable overseas regulator or assessment body for each medical device they put into the SOPP,"* should be qualified to include the exemption *"other than Class I medical devices or Class I IVD's"*

ADIA considers that the proposed 4 year transition period is adequate.

ADIA appreciates the opportunity to engage in this consultation.

Kym De Britt
ADIA Chief Executive

16 October 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. A 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

■ ADIA MEMBER BUSINESSES ■

3DMEDiTech 3M Oral Care 3Shape Australia A.R. Medicom AADFA Acteon Australia / New Zealand A-dec Australia ADR Dental Aesthetic Prosthetics AHP Dental & Medical Ainsworth Dental Air Liquide Healthcare AJ Barber Ajax Dental Supplies Alldent Alliance Medical Finacne Alphabond Dental Amalgadent Dental Supplies Ampac Dental Andent Anthos in Australia ANZ Banking Group Ark Health Australasian Dentist Australian Imaging Australian Medical Suction Systems Babich Maintenance & Steriliser Services Biodegree Bioholistic Biomedex Biomil Dental Products Bite Magazine BOQ Specialist Bank Borg Dental Cal-Dent Denture Cleaner Carestream Dental Carl Zeiss Cassins Healthcare Design & Construct Cattani Australia Centaur Software City Dental Supplies Clare Martin & Associates CMA Ecocycle Colgate Oral Care Coltene-Whaledent International Commodore Dental and Medical Fitouts Core3D Credabl Crown Dental & Medical Curaden Swiss Dentacast Australia Dental Axxess Dental Concepts Dental Depot (QLD) Dental Education Centre Dental Essentials Dental Fitout Projects Dental Focus Marketing Dental Implant Registries Dental Innovations Dental Installations Dental Premium Engineering & Supplies Dental Profit System Dental Protection Dentalife Australia Dentaforum Australia Dentavision Dentplex Dentpro Dentsply Sirona Designer Surgeries Designs for Vision Dr Mark's HyGenie Durodent Dental Supplies Services Elite Fitout Solutions Empire Oral Care Essential Medical Dental Insurance Services First Dental Dental Geistlich Pharma Australia Gulmohar Dental Gunz Dental Hayes Henry Schein Halas HICAPS Hogies Hu-Friedy Mfg Co. Inc. Impulsedent Inline Medical & Dental Innovative International Invisalign Australia INZ Dental Supplies Ivoclar Vivadent Kavo Kerr Kulzer Australia Leading Dental Levitch Design Australia Lorchant Dental LoveSmiles Macono Orthodontic Laboratories Med & Dent (WA) Medfin Australia Medical Dental Solutions NQ Medical Equipment Services Medi-Dent Medifit Design and Construct Minimax Implant (Dentium Australia) MIPS Mocom Australia Momentum Management My Dental Marketing Myofunctional Research Co. NAOL Australia Neoss Australia Nobel Biocare NOVA IT Group novaMED NSK Oceania NuMedical One Dental Optima Healthcare Group Orien Dental Supplies Osseo Dental Osstem Australia Osteon Medical Ozdent Dental Products Australia Pacific Dental Specialties Pegasus Dental Services Perfect Practice Philips Oral Healthcare Practice Sales Search Praktika Presidential Prime Practice Professional Dentist Supplies Race Dental Ray Australia RCR International Rhodium Dental Labs Australia Ridley Dental Supplies RJ Dental Sales & Service Roland DG Australia Rosler International RutiniDent Dental Supplies SDI Ltd Septodont Sieverts Radiation Protection Consultancy Smile Right Software of Excellence South Austral Straumann Supreme Orthodontic Supply (Aust) Teamwork Technology The Dentists Workshop The Health Linc Tomident TrollDental Ultimate Dental Supplies Ultimo Health Technologies Ultradent Products Australia Urban IT Vatech Medical VOCO Australia W&H Wealthpreneur West Coast Dental Depot Westpac Whiteley Corporation William Green Wisbey Dental XAND Innovations Xcellent Dental World Xpress Tex XYZ Dental Zimmer Biomet Dental



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