



— Submission GMP Fees and Charges Reform

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

It addresses the proposed reform to the Therapeutic Goods Administration's (TGA) Good Manufacturing Practice (GMP) fees and charges.

Content —

This submission reviews the Good Manufacturing Practice Fee Model Review issued by Therapeutic Goods Administration. It has been prepared following extensive engagement with the membership of the Australian Dental Industry Association (ADIA), the peak business organisation representing manufacturers and suppliers of more than 95% of products used in Australian dentistry

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Executive Summary —

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) review into the Good Manufacturing Practice (GMP) fee model.

ADIA is a strong supporter for regulatory framework for dental products, and medical devices more broadly, that is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden.

It is in this capacity that ADIA recognises that as the TGA administers the regulatory framework it operates on a cost-recovery model. This means that the TGA must recover the costs of its regulatory activities on the context of the *Australian Government Cost Recovery Guidelines* published by the Department of Finance. To this end, while ADIA supports reasonable reform, grounded in evidence, that enable to the TGA to seek appropriate fees and charges, it does so with the obligation to ensure that changes are reasonable, commensurate to the activities that are being undertaken, and fair.

Based on feedback from businesses in the dental industry, ADIA tenders the following recommendations:

Recommendations —

1. The TGA should complete its deficient industry impact analysis by measuring the impact of the reforms on sponsors of the changes to GMP clearance application fees;
2. The TGA should adopt Option 2 as outlined in the review paper; and
3. If the TGA were to adopt Option 3, it should reduce the proposed increase of the GMP clearance application fee and delay implementation until 1 July 2019

ADIA looks forward to working with the TGA to assist in the development of a GMP fee and charges construct that enables it to appropriately recover its costs while at the same time ensuring that the dental industry is not burdened with compliance costs that disproportionately negatively impact low-volume sponsors and small-medium enterprises.

[REDACTED]

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Section 1 – Impact on sponsors

Issue Summary –

The TGA's reforms stand to impact sponsors of medicines. In the dental context, this will impact suppliers of scheduled medicines, which includes local anaesthetics and fluoride solutions, in the form of increased compliance costs. Given that the TGA's preferred reform option would see these fees increase by over 100%, it is imperative that the TGA undertake analysis of the impact of its reforms on sponsors. However, the industry impact analysis in the review paper solely measures the impact on manufacturers and not sponsors. The TGA must therefore measure the cost to sponsors in the same manner that is compliant with Australian Government regulatory standards.

Key Issues –

Insofar as the proposed reforms will increase the TGA's GMP fees and charges they stand to impact the dental industry through an increase in the compliance costs associated with the supply of medicines.

These reforms will primarily impact suppliers and sponsors of local anaesthetics and fluoride solutions. From the perspective of the dental industry, suppliers of local anaesthetics and fluoride solutions primarily act solely as sponsors of these products. As such, their primary exposure to GMP fees and charges are the form of 'GMP Clearance Application Process Fees'. These fees are charged per manufacturer, per site, per sponsor and currently amount to \$390.

While the industry impact analysis section of the review document ostensibly makes one reference to analysing the impact of the reforms on sponsors, the analysis that follows appears to be solely dedicated to the impact on manufacturers. At no point does the review appear to actually measure the impact of the proposed reforms on sponsors.

This is of particular concern to ADIA given that Option 3, the TGA's 'preferred option', would see GMP clearance application process fees, the primary fees incurred by sponsors, increase by over 100%. Further, this is the single largest increase of an existing fee in percentage terms.

Given the above, it is imperative that the TGA undertake further analysis of the impact of its proposed reforms on sponsors who rely on GMP clearance application process fees. This will fulfil the TGA's obligations with respect to Australian Government regulatory guidelines as set out by the Office of Best Practice Regulation (OBPR). This is particularly important in the context that the TGA intends to double the compliance burden on sponsors without measuring the impact of doing so.

Recommendations –

1. The TGA should complete its deficient industry impact analysis by measuring the impact of the reforms on sponsors of the changes to GMP clearance application fees

Section 2 – Evaluation of reform options

Issue Summary –

The options canvassed in the Review paper have varying degrees of impact on industry. As such, ADIA has identified the benefits of each option while noting their potential impact on the dental industry. Based on this analysis, ADIA is able to lend its support to Option 2. The dental industry may only support Option 3 if it is modified to minimise the burden on industry and that this burden is considered in a regulatory impact statement.

Key Issues –

Having analysed the options canvassed in the Review paper, ADIA submits that Option 2 would best strike the balance between enabling the TGA to meet its cost-recovery objectives while minimising unnecessary regulatory burden and compliance costs on industry. ADIA supports the broader reform contained in Option 3 only if the proposed increase of GMP clearance application processing fees is lowered so that sponsors, particularly those supplying in low-volumes, are not disproportionately impacted. Further, should the TGA select Option 3, it should be implemented

Option 1 – Uniform increase across all fees

ADIA submits that while Option 1 which would see a uniform increase across all fees and benefits associated with the simplicity of its implementation and a more even distribution of cost burden across industry, it acknowledges that it may not be consistent with the TGA's cost-recovery obligations. As such, ADIA supports this option only if it were to be demonstrated that it would allowed the TGA to meet its statutory cost-recovery obligations.

Option 2 – Minimal changes to the fees and charges construct

This option will allow the TGA to recover all inspection hours and simplify the regulatory process through the introduction of a single annual manufacturing charge. Further, it appropriately responds to the finding that the largest contributor to TGA under-recovery is the lack of cost-recovery for all inspection hours. The dental industry supports this reform option as it enables the TGA to collect appropriate fees to satisfy its cost-recovery model without disproportionately burdening sponsors.

Option 3 – Efficiently optimise the fees and charges construct

This option would see GMP clearance application processing fees, the primary fees incurred by sponsors, increase from \$390 to \$790. This fee increase exceeds 100% and is the largest proposed fee increase relative to existing charges. This will have a significant impact on the dental industry, with sponsors of anaesthesia and other medicines used by oral healthcare practitioners to an overnight compliance cost increase of 100%.

While ADIA acknowledges that while an increase in GMP clearance application processing fees may be justified given the TGA's need to operate on a cost-recovery basis, it contends that the magnitude of the proposed increase of over 100% represents an excessive burden on the dental industry.

Low-volume sponsors, typically small to medium enterprises, will be hardest hit by this change. An overnight doubling of compliance costs will have a significant impact on the commercial viability of the supply of many of the low-volume medicines sponsored by the dental industry. The direct result of these changes will be a significant contraction of the range of medicines supplied in Australia by the dental industry to dental professionals.

Further, as noted in Section 1 of this submission, the industry impact of the TGA's proposal to increase GMP clearance application fees by over 100% has not been considered by the TGA. In this context, it would not be entirely unreasonable to draw a connection between the lack of an analysis being undertaken to measure the impact on reforms on sponsors and the fact they are facing the largest increase in fees relative to the current fee structure.

Finally, ADIA member businesses have already completed their budgets for the 2018/19 financial year on the basis that compliance costs will not double overnight on 1 July 2018. Given that as at 5 March 2018 the TGA has still not formerly adopted any fee increase, businesses will have less than four months to prepare for a 100% increase in their compliance fees should Option 3 be implemented on 1 July 2018. This will threaten the financial sustainability of small to medium enterprises over FY2018/19. To fulfil the TGA's transparency requirements with respect to the *Australian Government Cost Recovery Guidelines*, and as is permitted under the same, the TGA should postpone the implementation of the increase of GMP application process fees until 1 July 2019.

Given the above, ADIA's preferred reform is Option 2 which will have a limited detrimental impact on the dental industry while at the same time enabling the TGA to meet its cost-recovery requirement. Option 3 should only be adopted by the TGA if its implementation is delayed until July 2019 and the degree of fee increase for GMP clearance application processing fees is reduced so as to not adversely impact low-volume sponsors and small to medium enterprises.

Recommendations —

2. The TGA should adopt Option 2 as outlined in the review paper.
3. If the TGA were to adopt Option 3, it should reduce the proposed increase of the GMP clearance application fee and delay implementation until 1 July 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

Abbreviations —

ADIA	Australian Dental Industry Association
GMP	Goods Manufacturing Practice
TGA	Therapeutic Goods Administration
IDM	(Association of) International Dental Manufacturer

■ ADIA MEMBER BUSINESSES ■

3DMEDiTech 3M Oral Care 3Shape Australia A. R. Medicom AADFA Acteon Australia/New Zealand A-dec Australia ADR Dental AHP Dental & Medical Ainsworth Dental Air Liquide Healthcare AJ Barber Ajax Dental Supplies Alldent Alliance Medical Finance Alphabond Dental Amalgadent Dental Supplies Ampac Dental Andent Anthos in Australia ANZ Banking Group Ark Health Auspharm Australasian Dentist Australian Imaging Australian Medical Suction Systems Babich Maintenance and Steriliser Services Biodegree Biomedex Bite Magazine BOQ Specialist Borg Dental Bourke Dental Supply Cal-Dent Denture Cleaner Carestream Dental Carl Zeiss Cassin & Sons (Aust.) Cattani Australia Centaur Software City Dental Supplies Clare Martin & Associates CMA Ecocycle Colgate Oral Care Coltene-Whaledent International Commodore Dental and Medical Fitouts Core3dcentres Create Dental Credabl Critical Dental Curaden Swiss Data Vision Australia Dentacast Australia Dental Axess Dental Business Brokers Dental Concepts Dental Depot (QLD) Dental Education Centre Dental Essentials Dental Fitout Projects Dental Implant Registries Dental Innovations Dental Installations Dental Premium Engineering and Supplies Dental Profit System Dental Protection Dental Tribune International Dental Wear Dentalife Dentaurum Australia Dentavision Dentequip Dentplex Dentpro Designs for Vision Dr Mark's HyGenie Dental Supplies DURR DENTAL AG Solutions Empire Dental Devices EMS Dental Health Supplies & Services Garfield Refining GC Australasia Dental GlaxoSmithKline Golden Medical Gritter Hayes Handpiece Australia Heine Australia Henry Schein Halas HICAPS Hogies Australia Horseley Dental Supplies Hu-Friedy Mfg Co. Inc. I Dental Studio Impulsedent Australia Independent Dental Supplies Inline Medical & Dental Innovative Medical Technologies Invisalign Australia Ivoclar Vivadent Kavo Kerr Kulzer Australia Leading Dental Levitch Design Australia Livingstone International Lorchant Dental Macono Orthodontic Laboratories McLaren Dental Med & Dent (WA) Medfin Australia Medical Dental Solutions NQ Medical Equipment Services Medi-Dent Medifit MediGrow MegaGen Australia Miniflam Australia Minimax Implant (Dentium Australia) Mocom Australia Momentum Management My Dental Marketing Myofunctional Research Co. NAOL Australia Neoss Australia New World Office Fitouts Nobel Biocare NOVA iT Group novaMED NSK Oceania NuMedical Odontex Dental Labs 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 Sale Search Praktika Presidential Prime Practice Professional Dentist Supplies Profile Financial Services Purus Health and Medical Technologies Race Dental Ray Australia RCR International Rhodium Dental Labs Australia Ridley Dental Supplies RJ Dental Sales & Service Roland DG Australia RutiniDent Dental Supplies SDI Ltd Septodont Sieverts Radiation Protection Consultancy Smile Marketing Software of Excellence South Austral Southern Implants Australia Stoneglass Industries Straumann Supreme Orthodontic Supply (Aust) Surgical Images Teamwork Technology The Health Linc Tomident TrollDental Ultimate Dental Supplies Ultimo Health Technologies Ultradent Products Urban IT Vatech Medical VOCO Australia W&H West Coast Dental Depot Westpac Whiteley Corporation William Green Wisbey Dental XAND Innovations Xcellent Dental World XYZ Dental Zimmer Biomet



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