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Chair
Joint Standing Committee on
Trade and Investment Growth
Parliament House
PO Box 6021
CANBERRA ACT 2600

Dear Chair

RE: ADIA Submission – Inquiry into the Trade System and Digital Economy

As the peak business organisation representing manufacturers and suppliers of innovative dental products, the Australian Dental Industry Association (ADIA) takes this opportunity to tender advice concerning the Joint Standing Committee on Trade and Investment Growth's inquiry into the trade system and the digital economy.

The ADIA membership supplies more than ninety-five percent of the products used by dentists and allied oral health professionals nation-wide. It is in this context that we can advise that the position set out below can be considered to represent that of the entire sector.

The membership is highly engaged on matters of trade and the digital economy. Both have facilitated increased growth, innovation, and job creation in the dental industry. However, the digital economy and digital disruption have also introduced a number of new threats and risks to businesses in Australia's dental industry. What these are, and specific recommendations to remedy these, are addressed in the body of this submission.

The Committee's attention is also drawn to the submission from the Australian Chamber of Commerce and Industry (AusChamber). The commentary and recommendations set out in that document reflect those of both ADIA and its membership.

E-Commerce and Porous Borders

E-commerce has created significant opportunities for Australian businesses that manufacture and supply innovative dental products. Australian manufacturers have relied on E-commerce to open up new overseas markets for their products, while small to medium enterprises (SME) leverage E-commerce to compete with larger multi-nationals. This is why, for Australian businesses in the dental industry, availability of affordable and reliable high-speed internet is essential for maintaining the international competitiveness, sustainable growth, and job creation capacity of the sector.

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However, E-commerce has also disrupted the integrity of Australia's borders by making them more porous, resulting in an increase in the illegal importation of dental products that are counterfeit or lack Australian Government regulatory approval. This costs businesses in Australia's dental industry, the majority of which are SMEs, millions and exposes dental patients to significant risks. Australian dental product manufacturers encounter similar problems when exporting their innovative products overseas;

The illegal global supply chain enabled by the internet undermines our capacity to enter into and maintain exclusive commercial distribution agreements with local partners in export destinations. This makes it more difficult for us to export, invest in growth, and create jobs.

Ray Cahill, Managing Director, SDI Limited – Australian dental product manufacturer in Bayswater (VIC)

To ensure that Australian patients and Australian high-tech manufacturing jobs are protected from illegal suppliers who leverage E-commerce, the Australian Government should increase funding for surveillance of illegal dental product imports at our ports. The Australian Border Force should liaise with the Therapeutic Goods Administration (TGA) to leverage the Australian Register of Therapeutic Goods (ARTG), the list of medicines and medical devices authorised for supply in Australia, to improve surveillance capabilities. ADIA would welcome the opportunity to support this work through providing data and information.

Digital Disruption and Medical Device Regulation

The majority of dental products in Australia are regulated under the *Therapeutic Goods Act 1989 (Cth)* as 'medical devices'. The TGA is the part of the Department of Health is responsible for ensuring that medical devices supplied and manufactured in Australia are high-quality, effective, and safe.

The strongest example of digital disruption in the medical device sector is innovation in 3D-printing technology, and no sector of Australia's high-tech medical device industry has more enthusiastically embraced this innovation than Australia's dental industry. Australian patients are increasingly benefiting from the introduction of medical-grade 3D-printing technology in the manufacture of custom-made dental prostheses (dental crowns, bridges, dentures, etc). While this new technology is delivering great outcomes for patients and creating new high-tech manufacturing jobs, the regulatory framework for custom-made devices has not kept up with technology.

It is in this context that ADIA has supported the TGA in reforming the custom-made medical device framework to afford adequate levels of patient protection without stifling innovation. The TGA's approach towards regulatory reform addressing digital disruption should be viewed as a model of best practice by the Australian Government.

The TGA, in developing a new regulatory framework for custom-made devices, is conducting robust consultation across industry, healthcare professionals, and patients. Further, by playing a global leadership role in chairing the International Medical Device Regulators Forum's (IMDRF) custom-made working group, the TGA is ensuring that Australian patients and industry will benefit from global regulatory harmonisation.

Though the reform consultation is still underway, ADIA is confident that the TGA will reach an outcome that will protect patients without stifling innovation. ADIA commits to supporting the TGA on this and other matters that arise from digital disruption.

Measures to Improve Business' Cyber Resilience

Just as the reliance on the digital economy by Australian businesses that supply and manufacture innovative dental products has grown, so too has the accompanying cyber risk. For Australia's dental industry, the following observation made in the Australian Government's Cyber Security Strategy holds true;

If an organisation is connected to the Internet, it is vulnerable to compromise. As people and systems become ever more interconnected, the quantity and value of information held online has increased. So have efforts to steal and exploit that information, harming our economy, privacy and safety. Cyberspace, and the dynamic opportunities it offers, is under persistent threat.

Australian Government, Australia's Cyber Security Strategy, 2016, p. 4

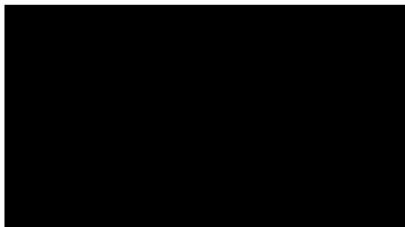
The Australian Government in 2014 estimated that the average cost of a cyber attack on a business is \$276,323 and over 33% of businesses have experienced a cyber-attack. Given this, a cyber-attack against an SME in Australia's dental industry would undoubtedly destroy jobs and potentially force a bankruptcy.

The Australian Government's Cyber Security Strategy recognises the work undertaken by large multinationals and financial institutions in bolstering their cyber resilience. However, the reality for SMEs in the dental industry, and across the Australian economy more broadly, is that they simply do not possess the requisite scale to adequately invest in their cyber resilience. ADIA recommends that the Australian Government support Australian manufacturers and SMEs through the provision of direct grants and/or tax incentives for investment in cyber resilience.

ADIA applauds the Committee on its recognition of the importance of reviewing the appropriateness of regulatory frameworks with respect to the digital economy, as well as canvassing options to strengthen Australian business' cyber resilience. In this submission, ADIA has made the following specific recommendations;

1. The Australian Government should increase funding for customs surveillance to prevent the illegal importation of unapproved and counterfeit dental products.
2. The Australian Border Force should liaise with the TGA to leverage the latter's expertise and data, including the ARTG, to improve import surveillance.
3. The Australian Government should create a grant and/or tax incentive program to support Australian manufacturers and SMEs in investing in cyber resilience.

As the Committee continues its deliberations with respect to this matter, if there is a need to seek further guidance please contact myself via email at policy@adia.org.au or by telephone on 1300 943 094.



Policy & Research Manager