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Procter & Gamble Australia's Submission to the Consultation on

Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

P&G is a multinational consumer goods supplier of many well-known household brands in Australia, including Pantene®, Gillette®, Olay®, Oral-B® and Vicks®. We are not a medical devices company but we do have a limited number of medical devices that will be impacted by the introduction of UDI in Australia.

Our Oral-B range of toothpastes include sensitivity toothpastes that are classified as a medical device based on the definition of medical device (i.e., sensitivity being a therapeutic benefit which is effected via a physical mode of action) and are Class IIa based on the risk classification. However, we all recognize that toothpastes/dentifrice are very different from the conventional medical devices in terms of usage/administration and risk profile, which would render the UDI to be irrelevant and simply introduces unnecessary complexity, cost and resources to the company with no benefit to the consumer.

We agree with TGA that UDI is an important way of improving identification and traceability of medical devices as it provides several benefits as detailed in the TGA's consultation paper. This is true for the medium to higher-risk medical devices but for certain low-risk devices, there are no benefits to be gained out of the system, and if there are, the complexity of the UDI outweighs any potential benefits. To illustrate this, we use the sensitivity toothpastes. The same scenario can apply to relatively low risk devices like bandages, dressings.

	Expected Benefit	Sample assessment in the context of sensitivity toothpaste
a.	More efficient post market management of safety related issues	They have very low numbers of safety related issues.
b.	More robust pre-market assessment	Comprehensive STED (Summary of Technical Documentation) would still provide robust pre-market assessment.
c.	Reduction in surgical procedural errors	Not relevant, as toothpastes are used in home setting.
d.	Enhanced analysis and research with electronic health records	Due to personal use for self-diagnosed sensitivity, we don't expect to have toothpaste included in health care records and the like.
e.	Secure distribution – tackling diversion/counterfeiting	The probability of counterfeiting of toothpaste is very low.
f.	Better sharing of MD information around the world	We don't expect toothpastes to be in the important group of devices that require cross-sharing of information across the globe.

TGA has touched on the possibility of having exemptions from UDI requirements. We thank TGA for considering this. We agree that certain medical devices should be exempted from UDI requirements. In general, we see Class I (low risk) and even Class IIa devices (low to medium risk) as potential candidates for exemption. Said another way, TGA should instead be targeting the introduction of UDI to medium-to-high-risk Class IIb devices and high-risk Class III devices, based on TGA's risk-based regulatory approach to therapeutic goods. These are the group of devices that are most likely to gain all the benefits from the introduction of UDI.

We recognize that the group of Class IIa devices may be too broad and too diverse, and it may not work to exempt them all totally from the proposed UDI introduction. In this case, we propose that TGA makes provision for sponsors to seek exemption from the UDI requirements based on certain criteria like intended purpose, risk profile, duration of use, extent of usage/exposure in the healthcare system, usage setting (at home vs. surgery/clinic). This can be via an application for exemption of device type by sponsors. Under this proposed scheme, we see Class IIa devices like toothpastes, contact lenses, and hydrogel dressings to be eligible candidates for exemption. As TGA collects these data and makes appropriate assessments, TGA can slowly build a list of exempt devices to help the industry.

We believe having a more principle-based framework for imposing the UDI requirements is more appropriate as not all devices will merit from the UDI. The company will be subject to the onerous implementation burden including the additional cost and resources for no clear benefit. TGA needs to consider the benefit-cost ratio of imposing such a system.

In terms of timeframe, we propose that TGA stage the implementation in Australia at least 2 years after the EU timing to help TGA and the industry learn from the EU implementation and put in place an improved system. As UDI will impact the product labelling, a lagged timeframe after EU will help with the labels of our products which are sourced primarily from EU. The current EU implementation timing for Class IIa devices is May 2023. To help

Australian medical device industry ease into this new system and learn from EU, we propose that that implementation timing for Australia to be May 2025.

Given that the introduction of UDI will have broad impact to the company, we encourage TGA to continually engage with the industry as this evolves.

Procter & Gamble Australia