Procter & Gamble Australia Pty. Ltd.
ABN 91 008 396 245
Level 4, 1 Innovation Road
Macquarie Park NSW 2113
PO Box 128
North Ryde NSW 1670
+61 2 8864 5000

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Device Reforms Unit
devicereforms@tga.gov.au
Therapeutic Goods Administration
P.O. Box 100
Woden ACT 2606

Procter & Gamble Australia's Submission to the Consultation on

Changes to a number of definitions and the scope of the medical device regulatory framework 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®. To help achieve our vision of touching lives, improving life, we offer Australian consumers a variety of products in the beauty, hair care, personal care and shave care categories. Specifically, our beauty and grooming offerings extend beyond the ordinary blades and razors to the more innovative personal-use epilators and intense-pulsed light (IPL) equipment for hair removal.

It is in this light that we would like to provide our comments to the proposed expansion of the scope of the medical device regulatory framework to products "without an intended medical purpose," as described in Annex XVI of the EU MD Regulations. In particular, our interest is to exclude personal-use consumer devices/products from the scope.

> *High intensity electromagnetic radiation (e.g. infra-red, visible light and ultraviolet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.*

We understand the principle behind expanding the scope of regulated medical devices to those with analogous functionality and risk profile, albeit not used for medical purposes. However, we do not believe the low safety risks associated with personal-use IPL devices warrant the additional regulatory burden imposed by medical device classification.

We propose that personal-use IPL's be exempted from this scope, and not be regulated as medical device.

We currently market two models of personal-use IPL's for hair removal under Braun Silk-expert brand. Personal-use IPL's provide consumers with an effective, safe, quick (in under 10 minutes), convenient (in the privacy of their own home), versatile (can be used on the face and body) alternative to more expensive professional treatments in hair clinics. It is also a painless method of hair removal compared to epilators, and a more effective method of hair removal compared to shavers.

In terms of technology, personal-use IPL's use significantly lower power and light intensity compared to commercial/professional IPL machines. Technology has advanced so as to build in safety features into these hand-held IPL devices to protect consumers during use. Among these features is a skin contact sensor that continuously reads the skin tone and automatically adapts the light intensity for best efficacy and safety. Another is an onboard pigmentometer which detects skin tone and help prevent burning/pain during product use. Lastly, it flashes when in full contact with the skin to provide extra precaution to consumers during use.

To substantiate the safety of personal-use IPL's, we have actual data evidence to show that in Australia, the number of health effects reported by consumers is extremely low [redacted] Globally, it is the same trend with extremely low reported health effects. The reported health effects are also not critical requiring medical treatment. We're happy to provide actual data if needed.

Personal-use IPL's are currently regulated as consumer products under the Australian Consumer Law, and as electrical equipment under the Electrical Equipment Safety Scheme (EESS). Under the EESS, from July 2019, IPLs in Australia have to comply with the IEC safety standard 60335-2-113 on "Particular requirements for cosmetic and beauty care appliances incorporating lasers and intense light sources" in line with the updated AS/NZS 4417.2:2018. This is an additional safeguard for the consumers to protect them against potential hazards.

TGA's concern that these personal-use IPL's used for cosmetic purposes poses the same harm/risks to consumers as those used for medical purposes is unjustified. This is supported by the product technology with lower power and light intensity, built-in safety features, actual consumer data confirming their safety, and safety testing requirements under the EESS. Therefore, there is no basis or need to regulate the personal-use IPL's any further.

If TGA regulates personal-use IPL's as medical devices, this will greatly impact our company in terms of regulatory obligations like listing and all related medical device requirements. All these will impact on the viability of this product offering to the Australian consumers. Without the alternative personal-use IPL's, consumers will have to incur extra time and money to visit professional hair clinics for the cosmetic purpose of hair removal or resort to the more painful method of hair removal via epilators.

In terms of timeframe, we propose that TGA stage the implementation in Australia no earlier than EU's timing to help the local industry ease into the changes, especially as some of the IPL devices are sourced from EU.

In summary, we propose that personal-use IPL's be exempted from the scope of "products without intended medical purpose," and not be regulated as medical device. We ask that IPL's remain regulated under the Australian Consumer Law and the EESS. Thank you for your consideration.

Sincerely yours,

Aimee Dy-Kam
Regulatory Affairs Manager
Procter & Gamble Australia