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18th February 2019

Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Submitted as an attachment to the online Consultation submission form

Dear Sir/Madam,

Consultation: Changes to a number of definitions and the scope of the medical device regulatory framework in Australia

GlaxoSmithKline Consumer Healthcare (GSK) welcomes the opportunity to comment on the above Consultation.

GlaxoSmithKline is a global research-based healthcare company operating in more than 100 countries around the world. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

In Australia, GlaxoSmithKline is represented by two businesses: GlaxoSmithKline Australia Pty Ltd which represents our prescription pharmaceuticals business and GlaxoSmithKline Consumer Healthcare Australia Pty Ltd which represents our consumer healthcare business.

This submission represents the views of the consumer healthcare business.

GSK would like to respond to the proposal to adopt the EU definition of a medical device, specifically statement regarding products that clean medical devices.

*products specifically intended for the **cleaning**, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.*

Currently, cleansers for medical devices, sold to consumers, are placed on the markets in Australia under the remit of the industrial chemicals regulator NICNAS as displayed on their website;

Oral and dental hygiene
Products for care of the teeth and the mouth (other than desensitising toothpastes/gels) including some dental bleaches/whiteners and denture cleansers and adhesives.

NICNAS does recognise cleansers for medical devices can be cosmetic products.

Recently denture adhesives were formally recognised as excluded goods. Denture adhesives are used to be in contact in the mouth, denture cleansers are not, they are used outside of the mouth. Given both denture adhesives and cleansers have been sold in the Australian market as cosmetic products for many years and human exposure is less with cleanser use compared to adhesives, it is difficult to understand what benefit the consumer will receive by reclassifying denture cleansers as medical devices.

Consideration must also be given to dual use cleansers. Toothpastes that are for use on both natural teeth and dentures. How should these products be classified?

GSK would assert that classifying denture cleansers as medical devices is unnecessary and provides no further protection to the end user than current practice.

It is requested that unless *cleansers* are removed from the proposed definition of a medical device, denture cleansers should be considered excluded goods in the same manner as denture adhesives.

Should you require further information please do not hesitate to contact me.

We request that any contact details be treated as confidential information and not be published on the TGA internet site (i.e. not be made publicly available).

Yours sincerely,

GSK Consumer Healthcare