

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

Email: devicereforms@tga.gov.au

Dear Madam/Sir

Accord provides this submission to the TGA's consultation: *Proposed new medical device classification for substances introduced into the body via a body orifice or applied to the skin* (Consultation Paper).

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, cosmetic and specialty products, their raw material suppliers, and service providers. Accord member companies make and/or market fast-moving consumer and commercial goods including hygiene, cosmetics and specialty products, sunscreens, food contact sanitisers, industrial and agricultural sanitisers, household pesticides, disinfectants and specialty commercial products. Member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses with over half our members operating as SMEs (<200 employees). A list of Accord member companies is available on our website: <http://accord.asn.au/about/members>.

Accord members are in general agreement with the proposed approach as outlined in the TGA's Consultation Paper. However, the proposed change to the table on page 10 of the Consultation Paper implies that ALL Dentifrices will become Class IIa. For clarity and consistency with other similar entries in the table, we believe the following change would improve clarity for the device section concerning "Dentifrice":

Change "Proposed Classification" column

from

"Class IIa

(applied in the oral cavity as far as the pharynx and achieve their intended purpose on that cavity)"

to

"Class IIa

(applied in the oral cavity as far as the pharynx, *absorbed by or locally dispersed in the human body*, and achieve their intended purpose on that cavity.)"

I trust our comments are of assistance. Please do not hesitate to contact me on 02 9281 2322 or by email at dsabic@accord.asn.au should you have any questions in relation to our comments.

Yours sincerely

Authorised for electronic submission

Dusanka Sabic

Director Regulatory Reform

29 April 2019