

29 April 2019

A/Prof John Skerritt
Deputy Secretary
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Via email: devicereforms@tga.gov.au

Dear Prof Skerritt

RE: Proposed new medical device classification for substances introduced into the body

Thank you for providing the Australian Dental Association (ADA) with the opportunity to participate in the *Consultation: Proposed new medical device classification for substances introduced into the body via a body orifice or applied to the skin*.

The ADA notes that the proposed changes are a further step towards the implementation of the Australian Government's agreed reforms to the regulatory framework for medicines and medical devices in Australia as recommended in the Report of the *Expert Panel Review of Medicines and Medical Devices Regulation* including that the regulation of medical devices, where possible and appropriate, align with the European Union (EU) framework including the classification of medical devices.

From a dental perspective, the proposed changes will impact on some toothpaste designed for patients who suffer from sensitivity and salivary stimulant lozenges.

The proposed changes will potentially mean that it will take longer for new or modified sensitive toothpaste to reach the Australian market or may be prevented from being sold in the Australian market due to manufacturers being unwilling to meet the costs of registering them as Class IIa medical devices. The costs of registering them as Class IIa product may flow on to consumers. A similar situation will occur with salivary lozenges.

Notwithstanding these issues, there may be benefits in that manufacturers will be required to provide a product which is safe and fit for purpose and those who cannot demonstrate conformity with their product will not be able to sell their product and this could potentially result in a number of ineffective products being removed from supermarket and chemist shelves.

The ADA is happy to expand on any or all the comments provided. Should you have any questions, please do not hesitate to contact Ms Eithne Irving, General Manager, Policy on [REDACTED] or [REDACTED]

Yours sincerely



Dr Carmelo Bonanno
President