AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793
T | 61 2 6270 5400
F | 61 2 6270 5499
E | info@ama.com.au
W | www.ama.com.au
42 Macquarie St Barton ACT 2600
PO Box 6090 Kingston ACT 2604

AMA submission to the Therapeutic Goods Administration – Proposed refinements to the regulation of medical devices that are substances introduced into the human body via a body orifice or applied to the skin

devicereforms@tga.gov.au

The AMA understands that recent moves to further align Australia's medical device regulation with the European Union Framework has created a situation where some medical devices can also be considered medicines, causing regulatory confusion and overlap.

While the AMA supported aligning with the EU Framework[1], the AMA also supports the proposed amendments to medical devices that are substances introduced into the human body via a body orifice or applied to the skin. Under the amendments, these medical devices will be considered medicines instead.

The TGA's medicines regulatory framework is seen as effective and the changes proposed will not compromise current levels of oversight.

August 2021

Contact
Hannah Wigley
Senior Policy Adviser
hwigley@ama.com.au

[1] Australian Medical Association (2017) *TGA proposed alignment with European medical device regulatory framework.*