March 19, 2019

Medical Device Reforms
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Re: Consultation: Proposed new medical device classification for substances introduced into the body via a body orifice or applied to the skin

Thank you for the opportunity to respond to the proposed changes to the Therapeutic Goods Advertising Code.

We believe that Personal Lubricants, which are invasive should be Class II (short term use, invasive, transient)

The reason for this is that the TGA and Australia Border Force are not policing the import of Personal Lubricants into Australia, which are NOT on the Australia Register of Therapeutic Goods (ARTG). So an increase in classification may make that happen.

Medically, personal lubricants are used invasively and consumers should have increased confidence as to the ingredients, interactions and quality of the product.

The TGA should be required in accordance with the Therapeutic Goods Act, to close down and stop the sale and advertising of Medicines and Medical Devices that are not listed on ARTG, which the TGA has been made aware of and they have not taken action on. There must be a level playing field for all businesses and especially small business. At the moment there are medical devices sold and advertised in Australia that the TGA has been aware of for over 7 years and no action has been taken as they are still for sale.

Thanking you