

May 22, 2018

Advertising Compliance Unit
Regulatory Practice, Education and Compliance Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Re: Consultation: Complaints Handling

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

Before any changes to the Complaints Handling Process are implemented, 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 5 years and there appears to be no action taken.

At present the Complaints handling process penalises Sponsors and Small Business who do the right thing and list products on the ARTG and follow the Advertising Code, whereas Companies who distribute, sell and advertise medical devices who are not listed on the ARTG (and should be) can make any claims they like about their products and no action can be taken as they are not listed on the ARTG. The ACCC does not take action either.

This needs to be fixed before any new Advertising Code or Complaints handling process is implemented, so as to create a fair environment and consumer confidence.

Following the TGA's action in this critical area, the proposed complaints process looks fine.

Thanking you

Name & Company Withheld