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: *Changes to a number of definitions and the scope of the medical device regulatory framework in Australia* (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.

While Accord supports in-principle the TGA's decision to align the regulatory approach for certain products without an intended medical purpose to that of the EU, a proper regulation impact assessment should be undertaken to determine the costs and benefits of each proposed product group. For example, we question the necessity of including consumer products already well-regulated for consumer safety under the Australian Consumer Law (ACL). This would include intense-pulsed light (IPL) equipment for hair removal for specific non-professional consumer use.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) has been looking at IPLs for the beauty industry and conducted an impact assessment in 2015. It found that lasers used for cosmetic purposes were regulated in some jurisdictions and that IPLs are regulated in Tasmania. The main findings of ARPANSA's work was that while there was insufficient information to support a national regulatory framework, the key areas of focus should be consumer education and provider competency for the professional sector.

In conclusion, it is unclear how regulating IPL products for consumer use as medical devices will result in any benefit to the consumer when they are adequately covered by product safety and product liability requirements of the ACL. Accord recommends that IPL personal-use consumer goods already covered under the ACL not be regulated as medical devices by the TGA.

Our specific comments on Table A2 regarded proposed changes to definitions are attached.

I trust our comments are of assistance. The contact person for this matter is Ms Dusanka Sabic, Accord's Director of Regulatory Reform. Ms Sabic can be contacted on 02 9281 2322 or by email at dsabic@accord.asn.au.

Yours sincerely

Authorised for electronic submission

Bronwyn Capanna
Executive Director

18 February 2019

Regarding *Table A2 Other definitions – proposed to be reflected in the Australia legislation* Accord supports the harmonisation of definitions where possible within the Australian legislative context. While Accord supports most of the TGA proposals for amendments we have some specific questions/comments as follows:

(24) *benefit-risk determination* – it is unclear from the comments whether the TGA will accept the EU definition of benefit-risk determination or provide an alternative definition to the EU for the Australian legislation.

(36) *health institution* – the TGA should include a definition in the Act regardless that its general meaning is well-understood.

(40) *conformity assessment* - we note that the definition of conformity assessment in the EU Regulation is 3 lines compared to 30 in the Act. We believe there is some scope for simplification.

(57) *adverse event* – given that this is a term widely used by the TGA but not specifically defined in the Act but referred to through an *indirect definition*, it would be preferable for the TGA to define this in the Act.

(58) *serious adverse event* – as with our comments in relation to other terms not currently defined in the Act but well understood, a definition of serious adverse event should be included in the Act.

(62) *recall* - like our comments on adverse event and health institution, recall should be defined in the Act even though it may have a well-established meaning.