

MMDR Consultations
Enhancing sanctions and penalties
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Madam/Sir

Accord is pleased to provide this submission to the Consultation: TGA – enhancing sanctions and penalties in the *Therapeutic Goods Act 1989* (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 80 percent of members operating as SME (<200 employees). A list of Accord member companies is available on our website: <http://accord.asn.au/about/members>.

Headline statistics¹ for our industry's economic footprint include:

- Estimated annual retail-level sales of industry products nudging the \$10 billion mark.
- Accord's membership is approximately 100 companies.
- Collectively, Accord member companies directly contribute more than 15,000 full-time equivalent jobs.
- Nationally, more than 180 offices and more than 60 manufacturing sites are operated by Accord member companies.

Accord supports most of the reform proposals to the TGA's suite of enforcement and compliance tools. The proposed adoption of the standard powers of the *Regulatory Powers (Standard Provisions) Act 2014* (RPSPA) is welcomed. Accord has only two areas of concern regarding the proposed arrangements.

Accord does not support modifying the RPSPA to maintain the current power in the *Therapeutic Goods Act 1989* (the Act) to allow authorised persons on reasonable grounds to enter any premises without a warrant. The Consultation Paper states that the RPSPA represents best practice in relation to regulatory powers and includes operational safeguards while maintaining appropriate oversight to specific regulatory regimes. We believe that obtaining a warrant is a necessary and transparent action to demonstrate that reasonable grounds exist to enter premises and seize goods. There is no evidence provided in the Consultation Paper to support the continuation of the current TGA practice.

¹ Results from Accord Industry Size and Scale Survey 2016

The other area of concern is related to the proposed sanctions and penalties for advertising. The Consultation Paper correctly notes that in the 2016 consultation on reforms to advertising, concerns were raised about the proposed powers and lack of consistency with comparable regulators such as the ACCC. Accord certainly supports enhancing the TGA's ability to address serious non-compliant advertising of therapeutic goods, but the proposed new tiered offences structure appears harsh.

In our submission to the TGA last year on the advertising reforms we noted that the proposed penalties in the consultation paper did not appear consistent with other penalties in like regimes in Australia. We shared the concerns raised by ASMI regarding the sanctions and penalties and believed them to be totally unrealistic and unjustifiable. We continue to hold reservations regarding the proposed penalties for the new tiered offences and the TGA's anticipation that the level of civil penalties will act as an effective financial disincentive against non-compliance. Again, Accord would prefer to see penalties aligned with the RPSPA rather than those in the Act.

Rather than primarily relying on harsh penalties, Accord would prefer to see the TGA focus its efforts on industry and stakeholder education. Both the TGA and industry would have an ongoing role in industry and stakeholder education.

I trust this feedback is useful.

Should you have any questions in relation to our submission the contact officer is Ms Dusanka Sobic, Accord's Director Regulatory Reform who can be contacted on 02 9281 2322, 0422569222 or at dsobic@accord.asn.au.

Yours sincerely



Bronwyn Capanna
Executive Director

31 May 2017