

Complementary Medicines Reform Section
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

MMDR.Consultation@tga.gov.au

E-MAILED

Dear Madam/Sir

Accord provides the following comments in response to the TGA's consultation: *Reforms to the regulatory framework for complementary medicines: Assessment pathways*. We apologise for the lateness of our comments having originally been of the view that the proposal was only pertinent to complementary medicines. Upon further reading we are concerned that there may be unintended consequences for all listed medicines if there is not clarity around the reform proposals for only one target group, i.e. complementary medicines.

Accord Australasia 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 has just over 100 member companies which range from smaller Australian-owned family businesses to the local operations of large consumer brand multinationals with 80 percent of members operating as small to medium businesses (<200 employees). A full membership list is attached.

Headline features and statistics¹ for our industry's economic footprint include:

- Estimated annual retail-level sales of industry products nudging the \$10 billion mark.
- 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.
- Approximately 75% of members' export product.

Our understanding is that the proposals will only apply to complementary medicines and as such, the majority of Accord's member products would not be affected. However, it is unclear in certain parts of the document whether the proposal will only apply to complementary medicines or to all listed products. For example, the proposal to introduce "protection for new ingredients" could have unintended consequences for other listed products such as sunscreens, toothpaste and antibacterial mouthwashes. It is unclear if this proposal will apply more broadly to all new actives and excipients in all listed products or be limited to those in complementary medicines. Will new ingredients which can be used in several product categories have to apply as "new" for each product category? Similarly, all listed medicines could inadvertently be caught up in the risk based approach for therapeutic indications.

The proposal to align the transition period for the reform with that of the transition period for Therapeutic Goods Order (TGO) 92 could also add further confusion. Accord has for a long time argued for a single, comprehensive guide to sunscreen regulatory requirements. The Australian

¹ Results from Accord Industry Size and Scale Survey 2016

Regulatory Guidelines for Sunscreens (ARGS) were originally intended to be a single reference source of sunscreen regulatory requirements. However, the ARGS does not contain all that is required such as labelling. Accord's suggestion has been to incorporate the TGO 92 changes relevant to sunscreens into the ARGS to reduce confusion. The proposal to align changes to the regulation of complementary medicines with the transition to TGO 92 will potentially further confuse Accord members, many of which only deal with the TGA on sunscreen related matters. Members have already asked for an FAQ to identify changes in TGO 92 which apply to sunscreen products only.

The reform proposals should only apply to complementary medicines and not affect the current regulatory requirements for other listed products. Without these assurances Accord member products could inadvertently be caught up in a reform process intended for a completely different product category and with a different risk profile.

Should you have any questions in relation to Accord's comments, please do not hesitate to contact Ms Dusanka Sabic, Director, Regulatory Reform on 02 9281 2322, [REDACTED] or dsabic@accord.asn.au.

We trust these comments are of use.

Yours sincerely



Bronwyn Capanna
Executive Director

31 March 2017

Members

Consumer, Cosmetic and Personal Care

Advanced Skin Technology Pty Ltd	Keune Australia
Amway of Australia Pty Ltd	Kimberly-Clark Australia
AVON Products Pty Limited	La Bioesthetique Australia
Beiersdorf Australia Ltd	La Prairie Group
BrandPoint Pty Ltd	L'OCCITANE Australia Pty Ltd
Chanel Australia	L'Oréal Australia Pty Ltd
Clarins Group/Trimex Pty Ltd	LVMH Perfumes and Cosmetics
Clorox Australia Pty Ltd	Mary Kay Cosmetics Pty Ltd
Colgate-Palmolive Pty Ltd	Muk Haircare Pty Ltd
Combe Asia-Pacific Pty Ltd	Natural Australian Kulture Pty Ltd
Cosimer Pty Ltd	Nutrimetics Australia
Coty Australia Pty Limited	NYX Pty Ltd
De Lorenzo Hair & Cosmetic Research Pty Ltd	Pacific SMM Pty Ltd
Edgewell Personal Care	Panamex Group
Elizabeth Arden Australia	Pierre Fabre Australia Pty Ltd
Emeis Cosmetics Pty Ltd	Procter & Gamble Australia Pty Ltd
Estée Lauder Australia	PZ Cussons Australia Pty Ltd
Frostbland Pty Ltd	Reckitt Benckiser
GlaxoSmithKline Consumer Healthcare	Revlon Australia
Hairjamm Pty Ltd	SC Johnson & Son Pty Ltd
Helios Health & Beauty Pty Ltd	Scental Pacific Pty Ltd
Henkel Australia Pty Ltd	Skin Health Pty Ltd
Inglot Cosmetics Pty Ltd	Syndet Works Pty Ltd
iNova Pharmaceuticals – A Valeant Company	The Heat Group Pty Ltd
Integria Healthcare (Aus) Pty Ltd	Ultraceuticals
International Beauty Supplies Pty Ltd	Unilever Australasia
International Hair Cosmetics Group Pty Ltd	Vitafive
Johnson & Johnson Pacific	Weleda Australia Pty Ltd
KAO Australia Pty Ltd	

Commercial/Hygiene & Specialty Products

A S Harrison & Co Pty Ltd	Lab 6 Pty Ltd
Albright & Wilson (Aust) Ltd	Novozymes Australia Pty Ltd
BP Castrol Australia Pty Ltd	Nowra Chemical Manufacturers Pty Ltd
Brenntag Australia Pty Ltd	Peerless JAL Pty Ltd
Castle Chemicals Pty Ltd	Recochem Inc
Clariant (Australia) Pty Ltd	Rohm and Haas Australia Pty Ltd
Crisp Solutions	Schulke Australia Pty Ltd
Deb Australia Pty Ltd	Solvay Interlox Pty Ltd
Dominant (Australia) Pty Ltd	Sopura Australia Pty Ltd
Ecolab Pty Limited	Symbio Australia Pty Ltd
E.D. Oates Pty Ltd	Tasman Chemicals Pty Ltd
Huntsman Corporation Australia Pty Ltd	Thor Specialties Pty Limited
Hypred SAS	True Blue Chemicals Pty Ltd
Ingredients Plus	Whiteley Corporation Pty Ltd

Associate Members

Corporate Travel Services

Platinum Travel Corporation

Graphic Design and Creative

Ident Pty Ltd

Legal and Business Management

DibbsBarker

FCB Lawyers

K&L Gates

KPMG

TressCox Lawyers

Logistics

Bolloré Logistics Australia Pty Ltd

Chylis Pty Ltd

Regulatory and Technical Consultants

Apitton Scientific Consulting

APPharma Pty Ltd

Clare Martin & Associates Pty Ltd

Competitive Advantage

Davoren Environmental Pty Ltd

Engel, Hellyer & Partners Pty Ltd

RFA Regulatory Affairs Pty Ltd

Seren Consulting Pty Ltd

Sue Akeroyd & Associates

Tudor Chem Pty Ltd

UL International Australia Pty Ltd

Specialist Laboratories and Testing

Dermatest Pty Ltd

D.Lab Solutions Pty Ltd

Eurofins ams Laboratories Pty Ltd

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