

Management and Co-ordination Section  
Office of Product Review  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

**E-MAILED**

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Dear Madam/Sir

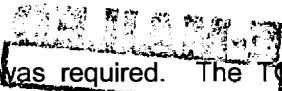
Accord welcomes the opportunity to provide preliminary comments in relation to the public consultation paper on *Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods*.

Accord Australasia, represents the manufacturers and suppliers of formulated products, including: hygiene, cosmetics and specialty products – member products relevant to this inquiry include such products as: personal insect repellants with sunscreens, hand sanitisers, oral hygiene products, sunscreens, disinfectants and specialty commercial products, tampons and devices. These products help safeguard public health and enhance our quality of life. A current members' list is provided.

Accord member products are generally characterised as low risk, fast moving consumer goods at the regulatory interface of either therapeutic and industrial chemicals (including cosmetics) or therapeutic and agricultural and veterinary products. As such, many of these products have a long history of safe use and would not particularly fall under the requirements for a new-to-market risk communication scheme for therapeutic goods.

The TGA has sought comment on four specific questions. Our suggestions are as follows:

- 1 *Whether or not you support the idea of a new-to-market risk communication scheme*  
From the information provided in the Consultation Paper, we are unsure as to the scope of the new scheme as all chemical entities could potentially be covered. This could include new chemical entities in low risk products such as sunscreens, which we do not support. There is not enough information contained in the Consultation Paper upon which to base a decision regarding support or otherwise. A detailed impact assessment should be undertaken including costs and benefits of such a scheme for industry to determine if there is support for such a scheme in the Australian context or if Australia is able to leverage off the scheme as it exists elsewhere.  
  
We would not support such a scheme applying to low risk over the counter medicines and devices. If such a proposal were to go ahead, it should only apply to high risk medicines and devices. We would therefore like more information regarding the scope of products for inclusion and exclusion of the scheme.
- 2 *The potential value and uses of a new-to-market risk communication scheme*  
As mentioned above, this would need to be developed within a proper impact analysis. There needs to be a demonstrated need, based on evidence and clearly, the benefits should far outweigh the costs. It would be helpful if the UK Black Triangle Scheme had been evaluated prior to the extension of the scheme into the EU or if the TGA has access to information which formed the basis of the decision making process prior to its introduction into the EU. This would assist industry in determining the value of such a scheme for Australia. In particular, the interactions of such a scheme with other forms of mandatory safety reporting to regulators and the costs associated with the scheme would be of great assistance.
- 3 *How a new-to-market risk management scheme might be designed, promoted and evaluated*  
From the information available on the UK Black Triangle Scheme it would appear that if such a scheme was warranted, it should be voluntary and industry run, if industry determined that such a

  
scheme was required. The TGA currently has in place a number of mechanisms to capture information regarding the safe and effective use of medicines and devices. The Consultation Paper has not established a need for a new system to add to the current requirements.

- 4 *How a new-to-market risk communication scheme will impact on you*  
If new requirements were imposed on all new chemical entities in low risk products such as sunscreens this would have a significant impact on the further supply of these products into the Australian market. It would create further unique Australian requirements adding to the costs of production, particularly for those products which are regulated as secondary therapeutic sunscreens by the TGA but recognised as cosmetics elsewhere.

On the basis of the information provided, Accord is hesitant to support the introduction of such a scheme without further data. We recommend that a detailed study including the costs and benefits of such a scheme be provided to industry to assist in the decision making process.

Please do not hesitate to contact me on 02 9281 2322, 0422 569 222 or by email at [dsabic@accord.asn.au](mailto:dsabic@accord.asn.au) should you require any further clarification on the matters raised.

Yours sincerely

  
Dusanka Sabic  
**Director, Regulatory Reform**

 June 2013

## *Members*

### **Consumer, Cosmetic and Personal Care**

Advanced Skin Technology Pty Ltd	Keune Australia
Amway of Australia Pty Ltd	Kimberly-Clark Australia
Apisant Pty Ltd	La Bioesthetique Australia
AVON Products Pty Limited	La Prairie Group
Beautiworx Australia Pty Ltd	L'Oréal Australia Pty Ltd
Beautopia Hair & Beauty Pty Ltd	LVMH Perfumes and Cosmetics
Beiersdorf Australia Ltd	Mary Kay Cosmetics Pty Ltd
BrandPoint Pty Ltd	Natural Australian Kulture Pty Ltd
Chanel Australia	Nutrimetics Australia
Clorox Australia Pty Ltd	NYX Pty Ltd
Colgate-Palmolive Pty Ltd	Panamex Group
Combe Asia-Pacific Pty Ltd	Procter & Gamble Australia Pty Ltd
Cosmax Prestige Brands Australia Pty Ltd	PZ Cussons Australia Pty Ltd
Coty Australia Pty Limited	Reckitt Benckiser
De Lorenzo Hair & Cosmetic Research Pty Ltd	Revlon Australia
Elizabeth Arden Australia	Rusk Australia
Emeis Cosmetics Pty Ltd	SC Johnson & Son Pty Ltd
Energizer Australia Pty Ltd	Scental Pacific Pty Ltd
Estée Lauder Australia	Shiseido (Australia) Pty Ltd
Frostbland Pty Ltd	The Heat Group Pty Ltd
GlaxoSmithKline Consumer Healthcare	The Purist Company Pty Ltd
Helios Health & Beauty Pty Ltd	Three Six Five Pty Ltd
iNova Pharmaceuticals – A Valeant Company	Trimex Pty Ltd
Integria Healthcare (Aus) Pty Ltd	True Solutions International Pty Limited
Johnson & Johnson Pacific	Ultraceuticals
KAO Australia Pty Ltd	Unilever Australasia
KAO Brands Australia Pty Ltd	Weleda Australia Pty Ltd

### **Hygiene and Specialty Products**

Albright & Wilson (Aust) Ltd	Lab 6 Pty Ltd
Antaria Limited	Novozymes Australia Pty Ltd
Applied Australia Pty Ltd	Nowra Chemical Manufacturers Pty Ltd
BP Castrol Australia Pty Ltd	Peerless JAL Pty Ltd
Brenntag Australia Pty Ltd	Recochem Inc
Castle Chemicals Pty Ltd	Rohm and Haas Australia Pty Ltd
Chemetall (Australasia) Pty Ltd	Solvay Interlox Pty Ltd
Clariant (Australia) Pty Ltd	Sopura Australia Pty Ltd
Deb Australia Pty Ltd	Tasman Chemicals Pty Ltd
Dominant (Australia) Pty Ltd	Thor Specialties Pty Limited
Ecolab Pty Limited	True Blue Chemicals Pty Ltd
Huntsman Corporation Australia Pty Ltd	Univar Australia Pty Ltd
Jalco Group Pty Limited	Whiteley Corporation Pty Ltd

## **Associate Members**

### **Corporate Travel Services**

Unique Group Travel

### **Equipment and Packaging Suppliers**

HydroNova Australia NZ Pty Ltd

SCHÜTZ DSL (Australia) Pty Ltd

### **Graphic Design and Creative**

Ident Pty Ltd

### **Legal and Business Management**

FCB Lawyers

K&L Gates

KPMG

TressCox Lawyers

### **Regulatory and Technical Consultants**

Clare Martin & Associates Pty Ltd

Competitive Advantage

Engel Hellyer & Partners Pty Ltd

Robert Forbes & Associates

Seren Consulting Pty Ltd

Sue Akeroyd & Associates

Toxikos Pty Ltd

### **Specialist Laboratories and Testing**

ams Laboratories

Dermatest Pty Ltd

*June 2013*