accord
hygiene, cosmetic & specialty products industry

TGA Labelling and Packaging Review
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Email: labellingreview@tga.gov.au

Dear Sir/Madam

Accord Australasia provides the following submission to the *TGA Medicine Labelling and Packaging Review* Consultation paper released on 24 May 2012 (the Consultation Paper).

Introducing Accord

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 primarily in Australia and New Zealand.

The formulated hygiene, cosmetic and specialty products industry is a significant industry sector contributing to Australia's economy.

Headline statistics for our industry's economic footprint include:

- Estimated annual retail-level sales of industry products nudging the $10 billion mark.
- Collectively, Accord member companies directly contribute more than 12,000 full-time equivalent jobs.
- Nationally, more than 180 offices and more than 66 manufacturing sites are operated by Accord member companies.

Member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses. In a recent member survey, 73% of Accord members indicated that they have a relationship with the TGA. A list of Accord member companies is provided at Attachment 1.

Accord has a significant interest in this review and we are pleased to participate in the review process. Accord member products while regulated by the TGA are generally low risk, fast moving consumer goods such as commercial and hospital grade disinfectants, sunscreens, tampons, oral care products, hand washes and personal lubricants. In some cases, such as in oral care products, the reason for the treatment as therapeutic goods is purely claims dependent.

We believe many of these products are generally overregulated under the therapeutic goods regulatory regime and could just as easily be managed by the product safety and consumer protection provisions

of the Australian Consumer Law. This would enable the TGA to re-direct its attention to products which present a high risk rather than low risk.

While we are pleased to note that medical devices and other therapeutic goods are outside the scope of this review, we are disappointed that sunscreens, tooth pastes, mouth washes, personal lubricants and other therapeutic goods at the therapeutic/consumer product interface have not been excluded from the scope.

We believe that the scope of this review should be limited to orally ingested medicines and support the views of the Australian Self Medication Industry (ASMI) on labelling and packaging of these products.

Inadequate RIS process and lack of evidence to support the need to restrict competition

Accord notes that the TGA is proposing to prepare the Regulatory Impact Statement (RIS) once the consultation is finalised, and after drafting the Therapeutic Goods Order. However, a RIS is meant to be prepared with a range of options for consideration so that the most effective and efficient option can be identified prior to consultation and drafting the legislation.

The following is an excerpt from the Office of Best Practice Regulation (OBPR) *Best Practice Regulation Handbook* (with our underlining), as referenced by the Council Of Australian Governments (COAG) *Best Practice Regulation Guide.*

"Preparing the RIS

Preparing a RIS ensures that all relevant information to the decision making process is documented, and that the decision making processes are made explicit and transparent. While there is no set format for a RIS, it should generally contain seven elements, setting out:

1. *the problem or issues that give rise to the need for action*
2. *the desired objectives*
3. *a range of options (regulatory and non-regulatory, as applicable) that may constitute feasible means for achieving the desired objectives*
4. *an assessment of the impact (costs, benefits and, where relevant, levels of risk) of a range of feasible options for consumers, business, government and the community*
5. *a consultation statement*
6. *a conclusion and recommended option, and*
7. *a strategy to implement and review the preferred option.*

In addition to these seven elements:

- *where a regulatory proposal restricts competition, agencies must demonstrate in the RIS that the preferred option generates a net benefit to the community as a whole and that the only way of achieving the government's objective is to restrict competition*
- *agencies may be given direction regarding which options to analyse in a RIS for the Cabinet or a committee of the Cabinet. This would require the sponsoring minister to write to the Prime Minister or the Cabinet Secretary, copied to the Treasurer and the Minister for Finance and Deregulation*

- *where a regulatory proposal implements a specific election commitment, the RIS should focus on the commitment and the manner in which the commitment should be implemented, not on the initial regulatory decision, and*

- *new or amended cost recovery arrangements must comply with the Australian Government's Cost Recovery Guidelines and relevant Finance Circulars."*

The current consultation paper is not a RIS and does not meet the requirements of a RIS detailed above. The consultation paper does not consider a range of options - it appears simply to be a TGA preferred option. The proposal by the TGA to produce a RIS meeting the conditions detailed above after stakeholders have provided comments, and after drafting the Therapeutic Goods Order, would lead to the TGA drafting and considering further options once it has drafted the legislative instrument. This is clearly an inefficient practice at best, and at worst, may be considered a cynical exercise in avoiding due process, proper consideration of issues and meaningful consultation.

It is Accord's view that the proposed regulatory amendments are inappropriate for therapeutic goods represented by Accord, i.e. sunscreens, oral care products, personal lubricants, etc. Had a RIS been prepared as per the COAG *Best Practice Regulation Guide*, we believe that these products would have been excluded from the scope of this review.

Identification of the issue or problem and statement of desired objective

The first step in preparing a RIS is to identify the problem or issue that give rise to the need for action. We believe that this is a crucial step in the RIS process. Unless all stakeholders are clearly aware of the issues/problems to be resolved, it is not possible to consider options to resolve the issues.

As far as we are aware, the issue or the problem requiring action has been neither identified nor adequately articulated by the TGA for this review.

We note that the TGA has listed what it considers to be issues on pages eight to nine of the Consultation Paper, coupled with the objective of the review. It appears to be a list of the scope of the review rather than a list of issues. The excerpt from the Consultation paper is below:

"The objective of the review of the requirements for medicine labels and packaging is to develop appropriate regulatory solutions that effectively address the consumer safety risks posed by the following issues:

- *Information about the active ingredient(s) contained in the medicine is not always easy to find*
- *Use of the same brand name for a range of products with different active ingredients resulting in look-alike medicine branding (this is known as brand extension or trade name extension)*
- *Medicine names that look-alike and sound-alike that can lead to use of the incorrect medicine*
- *Medicine containers and packaging that looks like that of another medicine*
- *Lack of a standardised format for information included on medicines labels and packaging*
- *Dispensing stickers that cover up important information*
- *Information provided on blister strips*
- *Information included on small containers*
- *Information provided in pack inserts"*

The list above appears to speculate that there may be a problem in the area of packaging and labelling. The TGA does not appear to have even attempted to consider whether there is any evidence of increased risk to consumers and patients from any of the points raised above – the increased risk appears to have been assumed rather than demonstrated.

Any identified issue or problem should be demonstrable through evidence. For example, if the TGA had analysed adverse events data and identified a trend in accidental overdose of over-the-counter medicines, this may be a problem requiring a solution.

Without clear articulation from the TGA, we can only speculate on the issues and problems to be resolved.

If the issue/problem had been properly identified, we believe that the scope and the objective of the review would have been better targeted.

Range of options, cost, benefit and risk

It is clear from the Consultation Paper that the TGA has not considered a range of options, but rather focussed on a single option that it prefers without regard to the costs and benefit or consideration of the risks.

From our analysis of the limited detail provided, the application of the proposals to therapeutic goods that are on the therapeutic/consumer products interface does not appear to provide any tangible benefits. Take for example the proposal to increase prominence of the active ingredient on the label. The Consultation Paper cites the following reasons for this proposal:

- Assisting consumers to recognise when two different brands include the same active ingredient
- Identifying the difference between different medicines
- Identifying any ingredients that may cause allergic reactions, or interactions with other medicines
- When overseas, allowing consumers to identify alternative medicines that they can use when Australian brands are not available
- Identifying the amount of active ingredient
- Avoiding accidental overdose.

None of these reasons make much sense when applied to therapeutic products on the consumer products interface, for example sunscreens. It is more important for consumers to consider the SPF factor and water resistance of a sunscreen than it is to consider the name of the active ingredient in the product and how much of it is in the product whether the product is purchased in Australia or overseas. Further, as far as we are aware, accidental over application of sunscreens has never been raised as an issue to date.

We also note that the listing of active ingredients is not necessarily the best method for addressing allergic reactions, particularly for topically applied products. We remind the TGA that cosmetic products are required to be labelled with the full list of ingredients, not just the active substances and this is the method with which many of these products are regulated in many overseas countries.

As for concerns over look-alike and sound-alike names and look-alike packaging, products on the therapeutic-consumer product interface that look and sound alike are not likely to pose any major risks to consumers. In fact, most consumer type products with a given function such as sunscreens, tooth pastes, personal lubricants, and so on, do not look and sound similar within their own product category, and deliberately so, to allow consumers to distinguish between different brands.

Standardised information format may be workable in theory for products on the therapeutic-consumer product interface, however, we do not believe that the need for the change has been established with cost/benefit analysis, particularly given their risk profile and also their global brand nature.

Sunscreens, oral care products and personal lubricants are low risk therapeutic goods. Increasing any requirements on these products should be off-set with benefits. We have not seen any evidence from the TGA on the benefits of the proposal for these products.

Restricting competition

The proposals in the Consultation Paper appear potentially anti-competitive - they restrict the freedom of companies to market their products. For products such as toothpastes and sunscreens where the benefits of use are arguably similar or equal between different brands, companies compete for market share by product distinction through packaging design and other marketing techniques including brand recognition.

The application of equal prominence of the active ingredient as the brand name restricts these marketing opportunities and restricts competition. There has been no demonstration of net benefit for communities to support the need to restrict competition.

Trade considerations and ANZTPA

Some products that are regulated as therapeutic goods, such as sunscreens, are regulated as consumer products in most other countries. To apply unique regulatory controls in Australia for these products goes against the stated Australian Government position of reducing unnecessary barriers to trade.

This is a particularly important when we consider our closest trading partner, New Zealand. In mid-2011, the Australian and New Zealand Governments renewed their commitment to the joint Australia-New Zealand Therapeutic Products Agency (ANZTPA). Many of the products on the therapeutic-consumer products interface regulated as therapeutic goods are regulated as consumer products in New Zealand. Given the big-picture goal of the ANZTPA, we are at a loss to explain the review proposal, which appears to be moving away from Australia-New Zealand harmonisation for these types of products.

Conclusion

As stated earlier in this submission, Accord has long argued that therapeutic products at the consumer products interface are currently being over-regulated in Australia. It is our preference to have many of these products regulated as consumer products rather than therapeutic goods.

However, we understand that the scope of this review is limited to the packaging and labelling of therapeutic goods.

Accord recommends that the TGA prepare a consultation RIS as per the COAG requirements and consult stakeholders after:

- the issues/problems are identified and articulated,
- the desired objective is articulated,
- the range of options for achieving the desired objective is formulated, and
- the costs and benefits of each of the options is assessed.

The RIS process would aid the TGA to refine the scope and focus of the review. We believe that a proper RIS process would exclude Accord's Members' products from the need to change packaging and labelling.

We thank you for this opportunity to provide comments. If you have any queries, or for more information, please to not hesitate to contact our Science & Technical Manager, Catherine Oh on (02) 9281 2322, or by email coh@accord.asn.au.

Yours sincerely

Bronwyn Capanna
Executive Director

04 August 2012

Members

Consumer, Cosmetic and Personal Care

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

Hygiene and Specialty Products

Albright & Wilson (Aust) Ltd
Antaria Limited
Applied Australia Pty Ltd
BP Castrol Australia Pty Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
Castle Chemicals Pty Ltd
Chemetall (Australasia) Pty Ltd
Clariant (Australia) Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
Ecolab Pty Limited
Huntsman Corporation Australia Pty Ltd
ISM/Salkat Australia Pty Ltd
Jalco Group Pty Limited
Lab 6 Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
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Recochem Inc
Rohm and Haas Australia Pty Ltd
Solvay Interox Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited
True Blue Chemicals Pty Ltd
Univar Australia Pty Ltd
Whiteley Corporation Pty Ltd

Associate Members

Equipment and Packaging Suppliers

HydroNova Australia NZ Pty Ltd

Megara (Aust.) Pty Ltd

SCHÜTZ DSL (Australia) Pty Ltd

Graphic Design and Creative

Ident Pty Ltd

Legal and Business Management

FCB Lawyers

KPMG

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TressCox Lawyers

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Archer Emery & Associates

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