accord
hygiene, cosmetic & specialty products industry

OTC Medicines Regulatory Process Review
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Email: OTCBPRconsultationpaper@tga.gov.au

Dear Sir/Madam

Accord Australasia is pleased to provide the following submission to the *OTC Medicines Business Process Reform* consultation paper released in September 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 lower risk OTC medicine products are currently overregulated under the therapeutic goods regulatory regime. A lighter touch approach to regulating these products would enable the TGA to re-direct its attention more appropriately to products which present a higher risk.

Accord has long advocated for a more efficient and effective regulatory system in Australia. One of the features of such a system is applying regulatory controls that are commensurate with the identified level of risk. We are therefore pleased to note that the Consultation Paper is promoting a risk based approach to

regulating OTC medicines. However, we note that Accord's products that are low risk appear to have been missed in the risk consideration.

Our comments will focus on how we see our products better fitting in to the model of risk categorisation proposed in the Consultation Paper.

Accord also notes that the Consultation Paper does not appear to clearly articulate the range of medicines captured by the OTC Medicines Business Process Reform.

Having considered the contents of the Consultation Paper, we have assumed that the scope of the reform was limited to registrable OTC medicines. We have also assumed that sunscreens, even if they are registrable are outside the scope of this consultation as there is a significant difference in the regulatory treatment of sunscreens in Australia and in New Zealand.

Our comments are therefore based on these assumptions.

We will also provide some general comments on the proposals in the Consultation Paper under the heading 'General Comments'. In addition to this, Accord supports the views of the Australian Self Medication Industry (ASMI) in their response to the Consultation Paper.

Accord recommendations

Accord notes the risk categorisation framework in the Consultation Document, and also the products/application criteria used for application categories in different risk ratings. As stated earlier, our Members' products do not appear to fit neatly in to any of the application categories.

Many of the products represented by Accord are therapeutic only because of the low level therapeutic claims that are made e.g. toothpaste, mouthwash, some shampoos and handwashes. When considering the spectrum of risk represented by therapeutic goods regulated by the TGA, such non-ingested topical therapeutic goods are arguably the lowest risk products regulated by the TGA. If therapeutic claims were not made, these products would not require a TGA assessment, i.e. the safety and quality of these products is generally not in question.

To put this in terms of risk categorisation used in the consultation paper, the consequence or risk to patient outcome from these products is "negligible" (on a scale of "negligible" to "extreme" – page 11 of the Consultation Paper), and the likelihood of occurrence or probability of occurring is "unlikely" or "possible" (on a scale from "very unlikely" to "Almost Certain" – page 11 of the Consultation Paper). Therefore, these products probably fit between N1 and N2 categories for new medicine applications. Given this consideration, we strongly urge the TGA to consider the following recommendations to include in the OTC Medicine Business Reform Process.

Recommendation 1

Expand the scope of N1 to include new products which are identical to currently registered products except for fragrance, colour and/or flavour and associated minor changes in excipients. This will increase the number of applications that can fit into the N1 category, therefore improving the efficiency of the TGA, benefiting both the TGA and industry. These differences should not impact on the safety, efficacy or quality of products.

Recommendation 2

Include a monograph for alcohol (ethanol) based hand-rubs in the OTC Medicine Monographs. Alcohol-based hand-rubs rely on the alcohol content for efficacy and are not formulation dependent. The

formulation of these products generally only varies for aesthetic reasons, i.e. adjusting viscosity, fragrance, colour, etc.

Recommendation 3

Add a new category (perhaps N2.1), where the products in the category fit the following characterisation:

1. High volume fast moving consumer goods,
2. Except for the therapeutic claim, the products are cosmetic. These therapeutic goods maybe packaged with non-therapeutic goods, and
3. Not intended for ingestion (e.g. handwashes, toothpastes, mouthwash, acne treatment, etc).

For these products, a guideline on the types of claims that can be made would be sufficient. The sponsor of these products would be required to hold all safety, efficacy and quality data necessary and be subjected to random audits.

General Comments

Monographs

We note that currently, the TGA is proposing unique Australian monographs for a selected number of actives. While we understand that this proposal is based on the current workload of the TGA, we believe this is short-sighted. In order to ensure that 'back-logs' do not occur in the future, the TGA should be aiming to improve long-term efficiency where it is possible to do so. We believe that where there are monographs that are accepted by reputable international regulators, it would be efficient for the TGA to adopt them. This would be a similar arrangement to the current TGA practice of adopting the EU guidance documents with and without annotations as appropriate.

Two opportunities to address deficiencies in applications

While Accord is cognisant of the need to streamline the application and assessment process, we are unsure whether providing a framework where there are only two opportunities to address deficiencies would provide the best outcome for both the TGA and Sponsors.

Our members have cautiously welcomed the proposal that the TGA assessors would have to compile a single list of questions to provide to the Sponsors. We understand that the second round of questions will only relate to any deficiencies in responses to the first round of questions. There is an acknowledgement that the current process, where the assessors 'drip-feed' questions both formally and informally to Sponsors is inefficient for both the TGA and the Sponsors.

However, our Members are concerned that the formal two rounds would remove the flexibility to discuss any uncertainties in the questions being asked or clear up any misunderstandings.

We would also like to understand how genuine errors will be treated. For example, where a glaring error/deficiencies is identified by the assessor after the first round of questions, i.e. not identified in the first round of questions to the Sponsor, we are unsure how this will be addressed. If the deficiencies identified in the first round of questions by the assessor has been adequately addressed by the Sponsor, then the application should be approved. However, this is clearly not an ideal outcome. Nor is it acceptable for the application to be rejected at this point as the Sponsor has adequately responded to all deficiencies identified by the TGA.

Further where the assessor may disagree on minor issues with the application after the two rounds of questions, we believe there should be an opportunity for further discussion between the assessor and the

Sponsor. e.g. the assessor has requested amendments to the label and the Sponsor's interpretation of that request and subsequent amendments to the label does not match the expectations of the assessor.

It is our view that some flexibility is needed to accommodate such scenarios, even if we do not expect them to occur often.

Transition Period

For a successful implementation of any reform, it is important that all stakeholders are aware and prepared for the new processes. An adequate transition period would allow this to occur. We note that there is no discussion on the transition period to allow Sponsors (and the TGA) to become accustomed to the new system.

Once the new rules are established for OTC medicines, there should be a transition period where the new processes are strongly encouraged, but old processes can still be used. This time could be used by the TGA to warn sponsors that after the transition time, only the new process will be acceptable.

We believe two years from the date of implementation would be an acceptable transition time.

Conclusion

As stated earlier in this submission, Accord is pleased to note that the TGA is taking a more risk-based approach to regulating OTC medicines. However, we do not believe that the proposal in the Consultation Paper currently is truly a risk-based approach as it does not take into account the full spectrum of OTC medicines regulated by the TGA and the risks represented by these products.

Our recommendations detailed above aim to address this by providing our risk assessment of therapeutic goods represented by Accord and by fitting them into the proposed OTC medicine framework detailed in the Consultation Paper.

We look forward to continuing engagement with the TGA in this reform process. Accord and our members stand ready to provide information on cost and benefits of different implementation options to aid the TGA prepare Regulation Impact Statement and the Cost Recovery Impact Statement for this reform proposal.

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

[redacted]

Bronwyn Capanna
Executive Director

7 November 2012

Attachment 1

accord
hygiene, cosmetic & specialty products industry

Members

Consumer, Cosmetic and Personal Care

Advanced Skin Technology Pty Ltd
Amway of Australia Pty Ltd
Apisant Pty Ltd
AVON Products Pty Limited
Beautiworx Australia Pty Ltd
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
SC Johnson & Son Pty Ltd
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
Peerless JAL Pty Ltd
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

Corporate Travel Services

Unique Group Travel

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

Middletons

TressCox Lawyers

Regulatory and Technical Consultants

Archer Emery & Associates

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

Silliker Australia Pty Ltd

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