Consultation submission cover sheet

This form accompanies a submission on:

International Harmonisation of Ingredient Names	
Name and designation	Catherine Oh, Regulatory and Technical Manager
Company/organisation name and address	Accord Australasia PO Box 290 BROADWAY NSW 2007
Contact phone number	02 9281 2322 or 0418 513 968

I would like the comments I have provided to be kept confidential and not be published: *(Please give reasons and identify specific sections of response if applicable)*	☐ Yes ☒ No
I do not object to publication of my submission, but would like my name to be removed from all documents prior to publication and for my name to not be included within the list of submissions on the TGA website.	☐ Yes ☒ No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: *(tick all that apply)*

Business in the therapeutics industry *(please tick sector):*

☐ Prescription medicines ☒ Complementary medicines ☐ OTC medicines

☐ Medical devices ☐ Blood, tissues, biological ☒ Other

☐ Sole trader ☐ Business with employees

☐ Importer ☐ Manufacturer ☐ Supplier ☒ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

☐ Consumer organisation ☐ Institution (e.g. university, hospital)

☐ Regulatory affairs consultant ☐ Laboratory professional

☐ Health professional – *please indicate type of practice*:

☐ Other - *please specify*:

If you would like to be kept informed about TGA activities, please subscribe to one of the TGA's email lists <http://www.tga.gov.au/newsroom/subscribe.htm>.

It would help in the analysis of stakeholder comments if you provide the information requested below.

Responses to General Questions in the IHIN consultation paper	
Question	Response
General questions on the proposed name changes (page13)	
1. Looking at all the lists of proposed ingredient name changes, do you foresee any specific concerns or benefits as a result of any of the proposed name changes?	Accord's comments to the questions raised are provided in the attached document.
General questions on the proposal for dual labelling (page 16)	
2. What do you think about the proposal to include both the current approved name and the proposed new name (dual labelling) for substances of high clinical significance?	
3. Is the proposed time period for using dual labelling appropriate?	
General questions on the potential impact of the proposed name changes for Implications for Consumers and healthcare professionals (page 16)	
4. Do you agree that harmonising the names of ingredients with international practice will be beneficial?	
5. Will having international naming consistency assist in clinical practice?	
General questions on the potential impact of the proposed name changes for sponsors (page 17)	
6. Do you agree that harmonising the names of ingredients with international practice will be beneficial?	
7. Specifically, will the name changes make preparing labels and other documents for the Australian market easier, in terms of international consistency?	

Responses to General Questions in the IHIN consultation paper	
General question on proposed transitional period (page 19)	
8. Do you agree that the proposed transitional period is sufficient to ensure associated costs, such as printing new labels, could be met through business-as-usual activities?	

Additional comments or areas requiring clarification in the IHIN consultation paper	
Section, page number	Comments

Responses to General Questions on the update to TGA Approved terminology for medicines (page 20)	
Question	Answer
9. Do you believe anything is missing from this document? If so, please specify.	
10. Do you agree that the updated document is more user-friendly?	
11. Will this update to the guidance assist you in proposing new ingredient names?	

Responses to General Questions on the update to TGA Approved terminology for medicines (page 20)	
12. Are there any general concerns with the updates to the structure of *TGA Approved terminology for medicines*?	

Suggested improvements, amendments, corrections and areas requiring clarification in the draft *TGA Approved Terminology for medicines* guidance document	
Section, page number	Comments

Comments and areas requiring clarification in the list of ingredient names (appendices 1 to 10 of IHIN consultation paper)	
Name and ID of Ingredient	Comments

Any other additional comments

accord
hygiene, cosmetic & specialty products industry

International Harmonisation of Ingredient Names
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Email: ihin@tga.gov.au

Dear Sir/Madam

Accord Australasia is pleased to provide the following submission to the *International Harmonisation of Ingredient Names Consultation paper* (the Consultation Paper) released in May 2013.

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.

Clarification of harmonised names

While Accord is very supportive of the TGA's efforts to provide consistent and internationally harmonised ingredient names, we believe that the currently proposed approaches will not deliver such outcomes.

Accord notes that the Consultation Paper recognises the importance of internationally harmonised ingredient names. The Consultation Paper lists the reasons for this importance as:

- ensuring that only one name is used to specify an ingredient, to avoid confusion
- each name clearly and unambiguously identifying the substance being named

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- ensuring consistency of ingredient names with international conventions
- ingredients being defined in such a way that a laboratory could determine if a substance that is used as an ingredient in a medicine meets the definition for that name
- promoting international trade (interchangeable labelling)
- providing clarity to industry on TGA requirements for naming, through updated guidance documents.

However, we note that it may not be possible to provide a name that meets all the above points.

For example, sunscreen products are regulated as therapeutic goods in Australia. In most other regions they are treated as cosmetic products. As cosmetic products, the ingredients are identified using the International Cosmetic Ingredient Dictionary (ICID) names rather than International Nonproprietary Names (INNs).

If the TGA was to move away from ICID names for these ingredients, then this would result in a perverse outcome of moving away from international harmonisation.

The harmonisation of names for sunscreen actives and excipients must take into account those which are used in New Zealand, most of South East and North East Asia and in Europe i.e. where ICID names are in common use.

Further, ICID names are in common use in Australia under cosmetic ingredient labelling administered by the ACCC.

Adapted ICID names are not supported and will lead to further confusion.

The adoption of the INN Sunscreen active name, while short in length and consistent with the US ICID, regrettably does not harmonise with EC Cosmetics Directive and the supporting Cosmetic Ingredients database (Cosing). In Australia, cosmetic sunscreens are required to use the European ICID nomenclature. New Zealand, ASEAN countries, Middle Eastern Countries and South Africa apply the EC Cosmetic Directive by reference, thereby the European ICID.

Neither provide resemblance to the current AAN name.

We do support that where an ICID name has changed, the AAN should also change to the new ICID. For example, the ICID names Octyl Methoxycinnamate and Octyl Salicylate were changed sometime between 1993 and 2004 and are now referred to as Ethylhexyl Methoxycinnamate and Ethylhexyl Salicylate. Another ingredient that changed ICID names in 2004, is Sodium Hydroxyethyl Acrylate/Acryloyldimethyl Taurate Copolymer to Hydroxyethyl Acrylate/SodiumAcroyldimethyl Taurate Copolymer.

Accord notes that there is also a proposal to change the names of a number of well-known cosmetic ingredients. These include the laureth "family" (laureth-2, laureth-3, laureth-4, etc., proposed new names are lauromacrogol 100, lauromacrogol 150, lauromacrogol 200, etc) and the oleth "family" (oleth-3, oleth-5, etc., proposed new names are olomacrogol 150, olomacrogol 250, etc.) among a number of others.

We note that these names will not be recognised internationally, as they are not used internationally.

We note that the TGA has provided in the appendices the list of proposed name changes and the old and the new reference for the names. We also note that many of the new references given have an asterisk next to it and that these asterisks are not explained anywhere within the document.

We presume that it has the same meaning as in the TGA's Approved Terminology for medicines which states that an asterisk next to a reference indicates that the name has been adapted from the title of the monograph in the reference.

This is unacceptable. An adapted name has no status and it should not be inferred that the name has been approved or that the adapted name is in wide usage.

For example, the current name oleth-10 is in the current version of the ICID. The proposed name the TGA has provided for this is olomacrogol 500, which has a new reference also to ICID with an asterisk (ICID*).

However, our reference to the ICID confirms that oleth-10 is the ICID name not olomacrogol 500. We are therefore unsure why the TGA is suggesting that the new name should be used, and why ICID is given as the reference.

The list of 472 ingredient names contains 247 ingredient names that are adapted or asterisked names. Many of these 247 ingredient names while not referenced as adapted ICID names are names that propose to move away from an ICID name to a non preferred and non harmonised adapted INN. We do not support changing any of the 247 adapted ingredient names to a name that is not in use in Australia or New Zealand or anywhere else in the world.

The TGA should either follow a hierarchy i.e. BP, INN, BAN (British approved names), USP, USAN (United States Adopted Names) BPAP (British Pharmacopoeia appendix), EP, IP (International Pharmacopeoia), BPC, MAR, MI, FCC PCF, ICID, and so on, or follow names commonly in use.

Lack of RIS

Having read through the Consultation paper, it is apparent that the TGA has not considered all the options available to it to improve international harmonisation of ingredient names. We believe that a proper Regulatory Impact Assessment would have helped the TGA identify the best option forward to improve harmonisation. We understand that this is under consideration as the next step in the consultation process.

As indicated, where there is no harmonisation internationally on the product categories i.e. whether a product is therapeutic or cosmetic, imposing an Australian interpretation of international naming conventions can have a perverse outcome of reducing international harmonisation and hindering trade.

We believe that the TGA should consider all of its options for improving harmonisation of ingredient names through a RIS process and when the information on cost and benefit is available, then conduct further stakeholder consultations.

Transition

The proposed five year transition appears acceptable, but it should align with the ANZTPA single product registration and labelling and packaging review outcomes. The outcomes must also improve international harmonisation.

We thank you for this opportunity to provide comments. We have provided some specific comments relevant to cosmetics regulated as medicines in Australia, but would also support the comments and issues raised by the Australian Self Medication Industry in their comprehensive submission.

If you have any queries, or for more information, please to not hesitate to contact our Regulatory and Technical Manager, Catherine Oh on (02) 9281 2322, or by email coh@accord.asn.au.

Yours sincerely

[redacted]

Bronwyn Capanna
Executive Director

12 July 2013

Members

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