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ASMI would like to thank the TGA for the opportunity to participate in the drafting of this chapter for public consultation and the opportunity to coordinate comment from our member's responses to the final draft of the document.

Overall ASMI members are very pleased with the structure and content of this chapter. In particular, the way all the regulatory requirements for therapeutic sunscreens are incorporated in detail into this document for ease of understanding the requirements for therapeutic sunscreens. Inclusion of the detail defining and clarifying the definition of a therapeutic sunscreen from a cosmetic sunscreen is also helpful.

While ASMI would be in favour of this guideline being made a 'stand alone' guideline, for example entitled the *Australian Regulatory Guideline for Therapeutic Sunscreens*, purely for reasons of ease of accessibility for users unfamiliar with the Australian regulatory framework. Removal of the sunscreens chapter from the ARGOM, would require only minor rewording to reference back to the ARGOM for the requirements for application for registration of a sunscreen product or variation of a registration. However ASMI would not support a proposal to make this Guideline into a Therapeutic Goods Order (TGO). ASMI cannot see a benefit in establishing the Sunscreen Guideline as a legislative instrument. Such a move would require a major rewrite of the document and the stripping of helpful information to leave the legal requirements. While we appreciate the guidance information could be included in a 'Guidance Document to the TGO' this seems excessive. ASMI also suggest that the updating of a TGO is a more formal and involved process and would be less responsive to updates to the referenced standards. Given the ARGOM Sunscreen Chapter references *AS/NZS 2604:1998 – Sunscreen Products – Evaluation and Classification*, which is anticipated to be updated in the next year requiring a significant updating of the chapter and with the TGA undergoing structural reform, ASMI suggest we revisit this proposal again during the next review of the chapter.

ASMI comments to the draft chapter follow.

On Page 7, reference is made to the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP). ASMI suggest that this terminology may be out of date by the time this chapter is implemented by the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

During the drafting process ASMI members made comment under Section X.3.3 on page 6 with regard the wording:
"Products in this category include:"

- "products that make therapeutic claims other than sunscreening"

It was felt this should read;

- "products that make any therapeutic claims other than the sunscreening claims permitted under X.4 Labelling" of therapeutic sunscreens"

Our rationale for this proposal is on the basis that the current statement when read from the perspective of a sponsor outside Australia, implies that no sunscreening claim requires registration. The converse should therefore be true that any sunscreening claim may be made under a listing. This possible perception, must be put in the context that:

- the TGA's historical position on this issue is not available in the public domain,
- the Sunscreen chapter also recognises the equivalence of the ISO and FDA static SPF test methods.

The proposed wording provides no guidance on the acceptability of the use of sunscreening claims used in other jurisdictions.

The change of the AANs of 7 sunscreen actives under X.10 Sunscreening agents permitted as active ingredients, pages 18-21 and the associated wording for transition is the change that creates significant burden for ASMI members. ASMI began to question this change and raise our concerns to the TGA during the drafting process at the 2nd and subsequent drafts of the document. To make our case more clearly we will present not only the patient risk and technical impacts but also the financial implications of this change.

It is proposed the following AAN's be changed, and this change be implemented <u>at the next label run</u> or by July 1, 2013, whichever comes first.

1. Isoamyl methoxycinnamate to Amiloxate
2. Butyl methoxy dibenzoylmethane to Avobenzone
3. 4-Methylbenzylidene camphor to Enzacamene
4. Octyl triazone to Ethylhexyl triazone
5. Octyl methoxycinnamate to Octinoxate
6. Octyl salicylate to Octisalate
7. Triethanolamine salicylate to Trolamine salicylate

The implication of this change is twofold, firstly the risk to the public and secondly the economic impact to the sunscreen producers.

<u>Managing the Risk to Public</u>

Changing the AAN's outlined if not managed will create confusion for those consumers with allergies to those chemicals. Although the overall sensitivity rate to sunscreen actives is low, we consider it unacceptable to expose those consumers to that risk they can currently manage. If unmanaged the train of events would be:

1. consumers unable to detect the chemical they are avoiding on the label,
2. inappropriate purchase and use of a product causing allergic reaction,
3. consumer makes complaint to the Sponsor and/or visits GP/Dermatologist,
4. sponsor and/or GP file ADR report.
5. sponsor loses loyal consumer of their brand due to loss of trust,
6. HCP/Dermatologist unable to provide advice to prevent inappropriate purchase.

This type of change necessitates a two pronged education campaign:

1. to consumers – targeting those that have allergies to sunscreen actives; and
2. to Dermatologists and associated medical professionals to ensure they are able to recommend suitable options to their patients.

The management and cost of such a campaign should not be left to sponsors. It would be inappropriate to leave the full cost and responsibility of education of HCP's to that small segment of sponsors who specialise with products and employ an HCP detailing sales force to communicate to Dermatologists and other HCPs. Printed 'leave behind' or printable materials must be available to HCPs so they are able to support their patients to avoid the actives to which they are sensitive.

Although sunscreens sponsors are already challenged with achieving mandatory information on the label, some ASMI members have indicated the only sure and cost effective way for them to manage and communicate the change to their customers is to list the new AAN with the previous AAN in brackets, until consumers become familiar with the new names. *For example Trolamine salicylate (Triethanolamine salicylate)*. Those members seek permission to do this to manage the change to maintain the trust of their customers. Members discussed that while point of sale consumer communication mechanisms like shelf talkers and tear off pads may be useful to inform purchase, the information is not available at point of use.

ASMI members would like to see a more considered approach to this change.

Cost burden to industry

Along with the cost of education of consumers and HCPs, the wording proposed for the transition arrangements for the AAN changes, technically provides a very limited window for the implementation of the change.
'Sponsors should amend their labels accordingly at the next print run or by 1 July 2013 (whichever comes sooner).'

Printed materials are typically printed in time for each production run, except where production run quantities are lower than the economic order quantity for the printed material. There are always printed materials left from each run and these are consumed at the next production run, or if the artwork is amended between production runs the printed material code will change, new printing plates will be made, the old plates discarded and the existing printed materials on the old artwork code will be run out, or if still remaining after the transition period, written off and discarded. Technically therefore the current wording in the draft Chapter mandates that the changes must be implemented at the next print run which equates in a majority of cases to the next production run of the product. ASMI members hope that this is a misunderstanding of a terminology and propose that the wording be amended to allow them to minimise their costs.

The artwork process involves
1. the update of an artwork graphics file with the desired changes for approval (~$400/simple text change); before
2. the reprographics stage with the production of a photographic proof and artwork colour separations of the artwork (~$100 simple); from which
3. new printing plates are produced (~$1000/plate).

The indicative costs provided in brackets are typical costs for a simple change to the artwork creating a change in the printing process to a single colour plate eg the black plate. These costs can increase depending on the complexity of the artwork.

ASMI members have been surveyed and requested to provide the number of printed materials that will be impacted by these AAN name changes to allow an estimation of the cost of the artwork changes to our members using this indicative cost of $1500 per item. It should be noted this cost does not include business costs to brief, approve and implement the change or update the label information on the ARTG. The total cost to the 8 ASMI members who contributed to our survey was $529,500. See the confidential breakdown of the details in Attachment 1.

Given the AS:NZS 2604:1998 is currently under review and will require significant amendment to sunscreen labels due to the new testing requirements' and proposed SPF limits, it would seem reasonable to allow the transition of the implementation of the AAN's to extend to coincide with the new AS:NZS 2604. This would allow both changes to be made at once and avoid two label changes in close succession.

Unlike most labelling changes required by the TGA, there is no safety signal driving an imperative for this change and in fact the change is likely to create a blip on the safety signal radar due to the potential confusion for consumers. ASMI therefore propose the following amendment to the transition timeframe wording to reduce the burden on industry:

'Sponsors should amend their labels accordingly at the next packaging artwork amendment or by the transition date to the next update of AS/NZS 2604.'

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Regulatory & Technical Manager – OTC Medicines

Summary of Cost impact of change of AANs

ASMI Members	No. of Printed items*	Cost @$1500
Member 1	8	$12,000
Member 2	35	$52,500
Member 3	33	$49,500
Member 4	56	$84,000
Member 5	2	$3,000
Member 6	1	$1,500
Member 7	24	$36,000
Member 8^	194	$291,000
Member 9^	253	$379,500
Total		**$529,500**

*Printed items may include primary pack labels & backer cards or cartons &/or leaflets
^Member has Excluded printed items from other members listed.
2 Members were unable to contribute to the survey.