ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

ACCORD is pleased to provide the following comments in relation to the Consultation Document: *Proposed revisions to Chapter 10 'Sunscreen' in the Australian Regulatory Guidelines for OTC Medicines (ARGOM*).

ACCORD welcomes the efforts of the TGA and the Sunscreen Working group in developing the Consultation Document. We are pleased to note that many of industry's comments proposed through the working group have been adopted in the Consultation Document.

As a general comment, the addition of NICNAS information regarding cosmetic regulation in the Consultation Document does not provide the clarity regarding the regulatory demarcation between therapeutic and cosmetic sunscreen products as has previous drafts. ACCORD recommends that the TGA adopt the original comments provided by industry to the working group.

ACCORD welcomes the TGA's efforts to reduce the regulatory burden to industry which results from unique Australian regulatory requirements given that these products are regulated as medicines in Australia but are regarded as cosmetic products elsewhere. The lighter regulatory touch in other jurisdictions places a heavy regulatory burden on those sponsors wishing to market products in Australia. The TGA is to be commended on its efforts to seek equivalence where possible with comparable EU, USA or other standards.

Specific comments in relation to the Consultation Document are as follows:

a) **X.3.2 Listing of therapeutic sunscreens**
Add new Para 9:
"Provided that product packs are complaint with AS/NZS2604:1998, therapeutic sunscreen products may also contain additional consumer information to aid in consumer choice. For example, sunscreen claims on international packs may contain additional UV claims. Additional sunscreen claims may include, but are not limited to the following examples:
   i) The EU symbol for UVA performance (the letters UVA in a circle).
   ii) The Japanese symbols for UVA performance PA+, PA++ and PA+++
   iii) The Boots Star ratings.
The TGA recognises that sunscreen products are part of a global market and does not want to create additional barriers to trade by seeking to remove this additional consumer information where it already exists on products.

In addition, recognising that many of these products are regulated as cosmetic products elsewhere, the TGA accepts cosmetic claims that may be included on therapeutic sunscreens such as:

i) a copy of ingredient labelling in accordance with ACCC Trade Practices regulation requirements where the ingredients are named according to ICID names and not necessarily Australian Approved Names; and

ii) generic cosmetic claims will still be permitted as exampled by "contains Vitamin E" or "contains Aloe Vera" or "moisturisation, anti-wrinkle, anti-aging, whitening of skin and antioxidant/ free radical barrier effects (ie not below the skin) against environmental aggressors such as pollution, chemical or smoke on the skin, will be allowed for listed and registered sunscreens. These claims will not need to be supported by Kinds of Evidence during a TGA audit provided they do not make a therapeutic claim of actions below the skin. The claim "can aid in the prevention of premature aging'" can be made for a cosmetic broad spectrum sunscreen and not be regarded as a therapeutic claim.

Non permissible claims include the following statements:

i) 100% protection from UV radiation (such as sunblock, or sun blocker or total protection).

ii) 100% resistance from removal in water (such as waterproof)

iii) No need to reapply the product (ie all day protection)."

b) X.4.1 Labelling of therapeutic sunscreens

The Consultation Draft is missing the following coded indication
(SPF04) Sunscreen SPF4 to (SPF30+): Sunscreen "SPF30 Plus" or "SPF 30+"

c) X.5 SPF testing and reproducibility of results

Para 5 – the paragraph on calculations for SPF test data appears overly prescriptive. ACCORD has always assumed that the USA FDA method is one acceptable method and not the only one acceptable to the TGA. We recommend that the language be amended to reflect this by changing the statement to "…the TGA suggests that an acceptable method of calculation for a label claim could be based on the US FDA method, as follows".

Para 9, (last para) line 2. Amend to: "The TGA may request results of pre market SPF, broad spectrum or water resistant testing. If requested, it is expected that this information will be provided to the TGA within 3 months from the date of such a request."

d) X.7.1 Stability test requirements

(Para 1). Suggest starting the sentence by including the word "Therapeutic".

e) X.9 Manufacturers of therapeutic sunscreens

Para 3 (last para) line 2 Delete: "and the excipients" and line 5 Amend to "active ingredient in that sunscreening product,"

As a general comment on this section, we note that reference is made to the new requirements for PICs GMP. While the PICs Code will replace the current Sunscreen GMP Code reference should be made in the ARGOM document that this is subject to a transitional arrangements of 12 to 18 months.

f) X.10 Sunscreening agents permitted as active ingredients

Industry requires a longer time frame to change their labels as a result of the changes to the AAN's. ACCORD therefore recommends that the footnote to the table be amended to:

"*Note: The AANs of the 7 substances marked with an asterisk have changed. Sponsors should amend their labels accordingly by 1 July 2014."

g) **X.12 Glossary of terms**

Cosmetic sunscreen product – the definition should also include reference to information contained in Section X.2.2.

Given that the TGA will accept equivalence for in vivo SPF testing – it may be useful to also include the equivalent definitions of SPF to that as cited in AS/NZ 2604:1998.

The reference to the SUSDP should be amended to reflect the change expected to occur on 1 July 2010 when it becomes the SUSMP.

Therapeutic sunscreen product – the definition should also include a reference to Section X.2.1.

The definition of a UV filters should be included, we have provided the definition used in the EU Cosmetic Directive: "UV-filters' means substances which are exclusively or mainly intended to protect the skin against certain UV radiation by absorbing, reflecting or scattering UV radiation".

ACCORD supports a reform programme to streamline the regulatory requirements for primary sunscreens consistent with their regulatory treatment in other comparable jurisdictions. For example, the unique Australian requirement for a medicines standard of GMP is an unnecessary cost burden to industry. Primary sunscreens could be subject to a much lighter regulatory control whilst still remaining within the jurisdiction of the TGA. We recommend that this reform initiative be adopted as a matter of priority by the TGA.

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Director, Regulatory Reform

18 June 2010