

Consultation Document: Proposed revisions to Chapter 10 'Sunscreens' in the Australian Regulatory Guidelines for OTC Medicine (ARGOM).

X.2.1 Therapeutic sunscreens - page 3

The distinction between a primary sunscreen and secondary sunscreen are not clear and it is further not clear how a secondary sunscreen differs from a cosmetic.

The glossary of terms and abbreviations addresses the fact that a primary sunscreen is a product whose primary function is to protect the skin from the harmful effects of UV radiation and, in the X.2.1 section of the document, a therapeutic primary sunscreen must have an SPF4 or more. Secondary sunscreen products do not require an SPF 4 or more and, according to the glossary of terms and abbreviations, protect the skin from certain harmful effects from UV radiation while fulfilling another primary function.

Cancer Council NSW is concerned that the general public may perceive that:

- A secondary product is as effective and protective as a primary product when it is regulated as 'therapeutic' as opposed to a 'cosmetic'.

- That equal weight has been given to both the 'other' primary function of a secondary product (i.e. moisturising) as to sun protection (sunscreening). The fact that a secondary product does not need to be labelled with an SPF value while being labelled as or with sunscreen, may further mislead the public as to the level of protective properties the product has.

X.4.1 General – page 9

Cancer Council NSW questions the permitted coded indication on Therapeutic sunscreens that are listable – **(SUNSC5) A broad spectrum sunscreening preparation of SPF4 or greater: can aid in the prevention of premature skin ageing**. An SPF4 is very low providing minimal protection from damaging and ageing effects of UVA and UVB radiation. The SPF value should be minimum 15, preferably 30+ in line with the other coded indications.

X.4.2 Labelling of immediate container and primary pack - page11

• **directions for use of the product**

Cancer Council NSW recommends that: Sunscreen should be reapplied at least every two hours and again after swimming or towelling to be included on the product label.

• **a statement of purpose or purposes of the product.**

1. Cancer Council NSW questions whether the purpose of a product is clear if:
 - a secondary sunscreen product includes words such as containing sunscreen or with sunscreen but does not make clear the primary purpose of the product is not sun protection.

- no SPF value is provided. That is, the level of protection the product provides may be perceived to be higher than it is.

- **required warning statements as included in the RASML**

Cancer Council NSW questions why secondary products with sunscreen and defined as therapeutic goods are not required to carry a warning statement to the effect that prolonged exposure to the sun should be avoided, and it is important to wear protective clothing, hats and eyewear. It is recommended that a further warning be provided that the product is NOT a primary sunscreen and should not be used as such. Cancer Council is concerned people may be misled as to the protective qualities of such products given it is stated on the label that they contain sunscreen and some have an SPF.

X.5 SPF testing and reproducibility of results – page 13 – para 4.

Cancer Council NSW supports that labelling claims be calculated as described in US FDA method to ensure that the mean SPF is at least equal to that on the label.

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