Review of the regulation of products at the interface between cosmetics and therapeutic goods

Submission by the Pharmaceutical Society of Australia

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PO Box 21
CURTIN ACT 2605
Tel: 02 6283 4777
Fax: 02 6285 2869
www.psa.org.au
ABN: 49 008 532 072
Chief Executive Officer: Kerry Deans

The Pharmaceutical Society of Australia (PSA) is the national professional organisation representing 16,000 pharmacists in all areas of professional practice. The PSA is the leading professional organisation for pharmacists in Australia, influencing attitudes, opinions and policies through representation, networking, consultation, continuing education, practice support, standards, guidelines and a range of publications and health promotion programs and resources.

In this submission to the *Review of the regulation of products at the interface between cosmetics and therapeutic goods*, the PSA would like to submit comments in relation to the following two areas:

- *Antidandruff treatments (section 4.2)*; and
- *Sunscreen-containing products (section 4.3)*.

1. Antidandruff treatments (4.2)

The recommendation for antidandruff preparations presented on p. 53 outlines that:

> *Antidandruff shampoos, hairdressings or lotions should be classified as therapeutic products by the Joint Agency.*
>
> *If the antidandruff product is not included in any Schedule to the SUSDP,*
>
> (c) *the product should be exempted from licensing; and*
> (d) *the premises where the product is manufactured should be exempt from licensing.*

Currently some substances used for dandruff are marketed in different concentrations and those below a certain cut-off level are exempt from scheduling. Ketoconazole is one such example where dermal preparations containing 1% or less are unscheduled but the 2% strength products are included in Schedule 2 of the SUSDP.

As an outcome of the application of scheduling generally, this situation is not unusual. Another example would be benzoyl peroxide for external use where preparations containing 5% (or less) are unscheduled but 10% preparations are in Schedule 2.

The PSA has some reservation over the second part of the above recommendation, ie. if the antidandruff product is unscheduled, the product itself and the manufacturing premises are both exempt from licensing. Presumably this means there would be no regulatory controls on the products of lower strength (in this example) and an inability to detect any variation in the concentration of the product. With ketoconazole, some variation in the 1% preparation might result in a higher concentration product which would then be deemed to be a Schedule 2 product.

While the example we have provided above relates to a product where different strengths are classified under multiple schedules, our concerns may apply equally to products containing substances which only fall into the 'unscheduled' category. It is difficult to understand how an exemption from licensing could be applied to any substance or product when the basis for scheduling is the limits on the strength/concentration since there would be no mechanism to detect any departure from those limits (inadvertent or otherwise).

The PSA would like to see this concern explored further and addressed by relevant stakeholders.

2. Sunscreen-containing products (4.3)

The section of the consultation paper dealing with sunscreen-containing products is extremely complicated with a multitude of issues being outlined. However, PSA felt the majority of issues are logically handled with reasonable recommendations.

The one exception is the recommendation for *Moisturisers that contain a sunscreen as and for a secondary purpose*. For PSA the main concern relates to the proposed criteria for future regulatory controls involving "SPF". The following dot points attempt to illustrate further this concern but also outline some additional points which appear to be somewhat contradictory in the paper.

- Although the upper limit of 20 for the allowable SPF for this category may be based in part on the current upper limit seen in cosmetic products in New Zealand, the selection of this figure as the basis for the final recommendation otherwise seems somewhat arbitrary with limited discussion in the consultation paper.

- This allowable upper limit of SPF 20 leans towards the higher end of protection levels offered in commercial products in Australia which are in the range of 2–30+.

- Regardless of the actual protection factor rating, the use of SPF clearly communicates to consumers the notion of 'sun protection' even before more meaningful consideration might be given through assessment of the SPF number.

- Even if the SPF statement "does not, of itself, promise any therapeutic benefit" (pp. 65–66), it is highly possible that consumers would select a moisturiser with sunscreen over one without because of a perception that the former would have the 'double action'. We believe consumers would not necessarily equate the presence of a sunscreen as being of secondary purpose or benefit.

- A similar comparative scenario is considered in the section of the consultation paper dealing with *Antibacterial Hand Washes.* These products, even for domestic use, are currently considered to be therapeutic goods and therefore are subject to thorough evaluation for safety, quality and efficacy. The recommendation (p. 75) proposes that this level of scrutiny is appropriate and should continue under the joint regulatory scheme.

  Further, in this section, consideration is given to the appropriate handling of toiletries or cosmetic products which contain antibacterial agents (primarily as a marketing tool rather than for its antibacterial properties). The paper goes on to state (p. 74) that "...those products that are sold as toiletries but contain an antimicrobial agent are in a sense, more insidious...".

  The PSA takes note of this comment with interest as it appears to suggest that a substance which is present in a product for a secondary purpose cannot simply be regarded as providing an unstated or secondary benefit but rather it needs to be subjected to regulatory controls which are appropriate for that substance and situation. The PSA believes moisturisers containing sunscreens for a secondary purpose presents a similar scenario and therefore it is somewhat contradictory to apply a significantly more deregulated approach to such products.

In summary, the PSA believes that:

(a) the upper limit of SPF 20 for a moisturiser with sunscreen to not be classified as a therapeutic product is overly generous and somewhat arbitrary; and

(b) such an exemption seems to create a disparity in the standards expected of all sunscreen-containing products and in particular generates an unfair disadvantage for primary sunscreens in the same SPF category which are to be classed as therapeutic products with appropriate regulatory controls.

PSA suggests that part C of the recommendation for *Sunscreens* as outlined on p. 68 of the consultation paper needs further consideration and consultation by relevant stakeholders.