

**Weleda Comments to the consultation paper
Review of the regulation of products at the interface between
cosmetics and therapeutic goods, 5/5/05**

Submitter
Ms Bridget Crooks
Regulatory Affairs Manager, Weleda (NZ) Ltd.
P.O. Box 8132, Havelock North, NZ
Tel: +64 6 8774389; Fax: +64 6 877 4989
Email: bridgetc@weleda.co.nz

Issues relating to 4.3. Sunscreen-Containing Products, pg. 55

Proposal 1

Weleda proposes that, if a system is required for the licensing of sunscreen products to ensure that only approved sunscreen agents are used, that excipients be exempt from the licensing requirement.

Rationale

- The main aim of sunscreens is protection against the sun which is a function of the active sunscreen agents. The current system in Australia for the listing of sunscreens requires the entry of all ingredients in the sunscreen, both active sunscreen agents and excipients. Whilst there is a need for a mechanism to ensure that only safe and effective sunscreen agents are used, Weleda is concerned about the requirement to enter all of the excipients.
- Page 60 of the consultation paper notes that:
"If the product is within the Act, any excipients (inactive ingredients) must have been approved by the TGA. In considering applications for new excipients, the TGA will consider evaluation reports from other regulatory bodies (e.g. NICNAS, CIR). It is important to maintain this level of assessment because in Australia sunscreens are often used over large areas of the body surface for long periods of time."

Weleda disagrees with the conclusion that excipients must be approved because sunscreens are used over large areas of the body surface for long periods of time. Weleda does not regard this as adequate scientific substantiation to require this level of assessment. There would need to be evidence to suggest that the use of certain excipients was detrimental in products that are used in this way – this evidence was not supplied in the paper.

In fact there are a number of cosmetics, which are regularly used over large areas of the body surface for long periods of time such as body lotions and after-sun lotions. These products are not controlled by any requirement for product licensing and use of only TGA approved ingredients. If these products were considered to be fundamentally unsafe, it would be expected that a safety process to address these types of products would have been identified as a priority before now.

- The listing system in Australia is a system for medicines. Weleda suggests that the evaluation of excipients for products that, apart from the sunscreen function, are essentially cosmetics is inappropriate.
- For companies importing products from Europe and other countries this is a unique requirement that acts as a preventative to providing effective product to a market place that requires sunscreens.

Co (NZ)

- It is noted that the FDA has standards regarding active sunscreen agents but there is no mention of standards for excipients.

Proposal 2

Weleda proposes that cosmetic GMP as applied in Switzerland and other countries should be adequate to fulfill the manufacturing requirements of sunscreens, particularly along with compliance to the AS/NZS SPF standards.

Proposal 3

Weleda proposes that as well as the claims that are made for the sunscreen function, that cosmetic claims that comply to the Cosmetic Claims Guidelines be allowed for sunscreens.