

**Australian
Competition &
Consumer
Commission**

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Our Ref: C2003/820-03
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5 May 2005

Mr Pio Cesarin
Director, Non-Prescription Medicines Branch
Therapeutic Goods Administration
PO Box 100
Woden, ACT 2606

Dear Mr Cesarin

Thank you for providing the Australian Competition and Consumer Commission (the ACCC) the opportunity to comment on the draft report entitled *Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods*. The following are issues the ACCC would like to be address before the final report is published.

Declassification of products

If products are to be declassified as therapeutic goods, they will be automatically covered by the product information standard requirements of Section 65D of the Trade Practices Act 1974 (the TPA). In this regard the ACCC would seek a fair lead time to allow suppliers to comply with the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*.

Of the dozen or so products considered for review, only two have been recommended for declassification, those being antiperspirants and sunscreens with an SPF rating of lower than 4. Antiperspirants do not look likely to raise any issues for the ACCC with regard to enforcement under the regulations. On the other hand, certain sunscreen products may raise enforcement issues where the criteria for exemption look complicated and may present us with some 'demarcation issues' regarding the coverage of Section 65D of the TPA. The ACCC, therefore, would seek very clear and uncomplicated definitions as to what products are to be covered by the regulations.

Regulatory vacuum

While industry is pushing for further declassification of therapeutic goods, they are suggesting other general consumer protection laws, such as Sections 52 and 53 of the TPA, can address outstanding concerns. These two Sections of the TPA are general provision that

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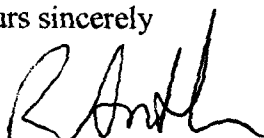
address matters related to misleading, deceptive and false conduct or representation. They do not on their own require advertisers to disclose certain specific information about their product.

Industry has also proposed that if any outstanding concerns linger with declassified goods, one option is to regulate them as mandatory safety or information standards. The ACCC has the view that it would be unusual for a product formerly regulated by a specialist agency to be picked up by a general consumer protection agency if concerns remain. In other words, if justification exists to regulate, it may follow that the responsibility for administering regulations remain with the specialist agency.

In summary, the above issues potentially impact on the operations of the ACCC. In conducting the review of the regulation of products at the interface between cosmetic goods and therapeutic goods, the ACCC requests that the above issues be addressed and any future proposals be made available for further comment.

If you have any inquiries, please contact myself on 02 62431297 or Sherif Seid on 02 6243 1351 or sherif.seid@accc.gov.au

Yours sincerely

A handwritten signature in black ink, appearing to read 'R Antich', written in a cursive style.

Robert Antich
General Manager
Policy & Liaison Branch