24 August 2012

TGA Labelling and Packaging Review
PO Box 100
Woden ACT 2606

Email: labellingreview@tga.gov.au

Re: TGA Medicine Labelling and Packaging Review

Dear Sir / Madam,

Ego Pharmaceuticals (Ego) is an Australian-owned pharmaceutical company who has been developing, manufacturing and marketing quality skincare products for more than 55 years. The comprehensive range of skincare products produced by Ego is sold throughout Australia and around the world. Ego is committed to creating the best possible skin therapies for customers. Ego is also a member of the Australian Self-Medication Industry (ASMI).

Ego Pharmaceuticals appreciates the opportunity to respond to the consultation paper on the TGA Medicine Labelling and Packaging Review ('the Review').

At the outset we would like to register our disappointment with both the consultation process and the consultation paper. A detailed discussion of our issues and concerns is provided in Parts A, B and C, and we only highlight the key issues here:

- The time allowed for responding to a review of this magnitude was totally inadequate and ASMI's reasonable request for an extension was declined (A copy of ASMI's request is provided in Part B - Appendix 1). There was not enough time to explore a range of solutions to address the issues identified in the Review and to test the solutions to support an evidence-based approach to regulatory reform.

- The views of the External Reference Group, which was specifically set up to advise the TGA on the Review, have not been fully taken into account, e.g. that separate requirements for different classes of medicines should be considered. The Australian Commission on Safety and Quality in Healthcare (ACSQH) also acknowledged that issues related to naming, labelling and packaging are not identical in the prescription and non-prescription medicine industries.

- There is very little evidence of a risk-based approach to the identification of issues and the formulation of reforms to address those issues. A "one size fits all" approach has been applied to the entire spectrum of medicines. Not only has there been no differentiation drawn between non-prescription and prescription medicines, no attempt was made to differentiate between categories within the non-prescription medicines spectrum, i.e. lower risk 'listed' medicines (e.g. sunscreens and complementary medicines) and higher risk 'registered' OTC medicines.

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361
www.egopharm.com

- The regulatory approach adopted in the consultation paper demonstrated no regard for the well-established COAG Principles of Best Practice Regulation. A range of feasible options (aimed at addressing each of the issues identified) has not been put forward, no attempt was made to demonstrate that the proposed changes would generate the greatest net benefit for the community and the impact on the brands of non-prescription medicines has not been considered.

- The quality of the consultation paper is also unsatisfactory. The paper is inadequately referenced and contains numerous internal inconsistencies, ambiguities and errors which made interpretation difficult.

- No evidence was provided that the proposed reforms would achieve the stated objectives of the Review. Under the principles of performance or outcomes-based labelling 'best intentions' to construct good labels do not necessarily translate into risk reduction. Until a label has been performance (consumer) tested there is simply no way of knowing whether it will achieve the stated objectives.

However, Ego has no issue with the Review itself. We have consistently held the position that the label is the single-most important source of information about non-prescription medicines available to consumers. A well-designed label, one which is easy to read, which enables consumers to readily find essential information, which is intelligible and which translates into safe use, is a critical element in the Quality Use of Medicines (QUM).

We have put forward a range of alternative options but all these come with an important caveat. None of the proposals have been tested as the consultation timeframe was insufficient to undertake that task. The need to subject our, as well as other proposals put forward during this consultation, to rigorous testing prior to implementation cannot be overemphasised.

In the final instance, any changes will result in increased costs to both manufacturers and consumers. To ensure that reforms will be cost-effective the financial impact of any change needs to be thoroughly investigated through a Regulation Impact Statement prior to implementation.

Yours faithfully,

Kerryn Greive
Scientific Affairs Manager

Ego Pharmaceuticals Pty Ltd
21-31 Malcolm Road, Braeside, 3195, Australia
Tel: +61 3 9587 1088 Fax: +61 3 9580 7647 ask@egopharm.com
ABN 86 005 142 361