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24 August 2012

TGA Labelling and Packaging Review
PO Box 100
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Email: labellingreview@tga.gov.au

Re: TGA Medicine Labelling and Packaging Review

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. Further information about ASMI and ASMI members is available on our website (www.asmi.com.au). ASMI is a strong advocate of the National Medicines Policy (NMP) and has consistently encouraged its members to align all aspects of their operations with the four arms of the NMP.

ASMI 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 at Appendices 1 and 2 and we only highlight the key issues here:

- The time allowed for responding to a review of this magnitude was totally inadequate and our reasonable request for an extension was declined (A copy of our request is provided at Appendix 2). There was not enough time for ASMI 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.

- 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, ASMI 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).

QUM, an objective of the National Medicines Policy, has been fundamental to the work of ASMI and its members over many years. A brief overview of ASMI's role in improving non-prescription medicine labelling is provided in a letter to ACSQH at Appendix 3. Our work is acknowledged in the ACSQH *Report on the National Roundtable on Safer Naming, Labelling and Packaging of Medicines 24 May 2011* (attached at Appendix 4):

> *"It is also acknowledged that there have been considerable efforts made in the self medication industry to improve the quality of medicines labelling. An industry-wide move to outcome or performance based labelling (whereby label effectiveness is assessed against the ability of consumers to interpret the information presented on the label), supported through the development of guidelines and an education program has been a move toward improved labelling".(at page 37)*

ASMI has always welcomed opportunities to work with stakeholders on ways to improve labelling and packaging to bring about quality use of non-prescription medicines. We view this Review in a similar light, but given the magnitude of the potential impact on industry, it would be critical to "get it right", i.e. to ensure that the proposed reforms will achieve the stated objectives. A robust evidence-based and cost-effective approach is therefore of the essence.

ASMI believes this can only be achieved through appropriate consumer testing. This view is also supported by the Consumers Health Forum (CHF). In their report, *"Achieving Best Practice in the Packaging and Labelling of Medicines: A Consumer Information and Discussion Paper"* (refer Appendix 5) it is asserted that:

> *"Undertaking a user test to ensure the maximum clarity of the critical information is desirable and recognised as best practice." (at page 11)*

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.

We remain committed to work with consumers, Government, the TGA and other stakeholders to develop and implement reforms that will achieve the stated objectives.

Yours faithfully,

Steven Scarff
Regulatory and Scientific Affairs Director

This submission is comprised of the following parts:

Cover Letter	
Submission Part A	Summary of Issues and Alternative Proposals
Submission Part B	Discussion of the specific issues
Appendix 1	Issues with the consultation process and paper
Appendix 2	ASMI Letter to Dr John Skerritt (12 July 2012)
Appendix 3	ASMI Letter to ACSQHC (29 September 2010)
Appendix 4	Australian Commission on Safety and Quality in Health Care 2011, *Report on the National Round Table on Safer Naming, Labelling and Packaging of Medicines*, ACSQHC, Sydney.
Appendix 5	Consumers Health Forum Australia 2010, *Community Quality Use of Medicines and Diagnostics Project: Achieving Best Practice in the Packaging and Labelling of Medicines: A consumer information and discussion paper*, CHF, Canberra.
Appendix 6	Case Studies in relation to blister strips
Appendix 7	Answers to the questions raised