Labelling and Packaging of Cough and Cold Medicines
Stakeholder and Public Consultation October – December 2009
Submission received from the Pharmaceutical Society of Australia (PSA)

PURPOSE

1. The Pharmaceutical Society of Australia (PSA) makes this submission in response to the consultation undertaken by the Therapeutic Goods Administration (TGA) on the proposed changes to labelling and packaging requirements of cough and cold medicines for children aged 2 – 12 years.

RECOMMENDATIONS

2. PSA provides the following recommendations to the TGA:

   a. **Safety, Efficacy and Availability.** PSA strongly believes TGA's recommendations do not appropriately reflect the external reviewers' report and suggest that the recommendations be reconsidered, particularly to better reflect the Australian context.

   b. PSA also firmly advocates a more evolutionary approach to decision-making and implementation of outcomes, given the long history of use of these medicines, the extremely low incidence of serious adverse reactions in Australia, the reasonably large number of products that could be affected by any proposed amendments, and the complexity of social issues surrounding the use of these medicines.

   c. **Bromhexine, Oxymetazoline and Xylometazoline.** PSA believes the TGA should undertake an analysis of relevant data to ascertain whether separate recommendations may apply to medicines containing only bromhexine, or intranasal decongestants (eg. oxymetazoline and xylometazoline).

   d. **Packaging.** PSA supports a requirement for all OTC oral liquid cough and cold medicines to be marketed in containers with child-resistant closures. However, PSA recommends that the pharmaceutical industry be consulted on the proposed 1 July 2010 implementation date to ensure the timeframe is achievable and will not result in serious supply issues which could disadvantage consumers.

   e. **Education Campaigns.** PSA supports the proposal to disseminate information and education to pharmacists, other health professionals, and consumers regarding the use of OTC cough and cold medicines in children. Such initiatives must be comprehensive and well-coordinated, involve multiple stakeholders, and be sustained for a reasonable period of time.

SAFETY, EFFICACY AND AVAILABILITY

3. PSA understands the TGA has undertaken an independent, external review of the safety and efficacy of cough and cold preparations for children which involved examining data available publicly as well as additional confidential information provided by sponsors. The result was provided in the *Review of cough and cold medicines in children* (21 April 2009) (the 'External Review Report').

4. PSA notes the TGA's statement that what is being proposed is in line with reviews undertaken and outcomes implemented in other countries. While we agree with the similar review being undertaken in Australia, we believe some of the issues highlighted in the External Review Report have not been appropriately considered in reaching the final TGA proposal.

5. **United States vs. Australia.** For example, the External Review Report compares the scenario between Australia and the US.

a. The US has a far greater range of products, with a greater range of 'actives' and a greater range of combination products.

b. In the US, cough and cold medicines are generally available in drug stores without any requirement for 'pharmacy only' sale or 'pharmacist advice' which is an intrinsic feature of Australian drug regulation, widely considered to be a valuable feature.

c. It appears that, in the US, safety concerns, especially deaths in very young children, have become the main driver for change.

6. PSA is concerned that, in subsequent TGA deliberations, it appears that such significant issues have not been taken into account adequately or appropriately when making recommendations for the Australian environment.

7. The TGA's conclusions state that:

a. it is likely that the risks associated with the use of cough and cold preparations in children outweigh the likely benefits for children below the age of six years; and

b. there are potential risks involved in use of these medicines in children aged six to 12 years.

8. In addition, the TGA's final recommendations are said to be based on "the current lack of evidence of efficacy" and the "historical profile of adverse drug reactions in Australia and overseas". These statements, however, appear to substantially disregard or undervalue the findings and conclusions of the External Review Report.

9. **Adverse Events.** In relation to the "historical profile of adverse drug reactions", PSA believes the TGA's recommendations are inconsistent with the following statements in the External Review Report:

a. Serious adverse events (ie. death or serious injury) from children's cough and cold medicines are "vanishingly rare".

b. Generally these medicines are very unlikely to be harmful in label dosages.

c. Overseas reports of serious poisoning including deaths from cough and cold medicines are generally not reflected in current Australian experience.

10. We believe the TGA's recommendations significantly depart from the conclusions of the External Review Report and therefore would suggest the recommendations need to be reconsidered.

11. **Evolutionary Approach.** PSA notes that during the course of this review, various issues have been raised including:

a. the complexity of issues surrounding the use of these medicines in children;

b. the long history of OTC use; and

c. the low level of harmful events observed in Australia.

12. Given these issues and being mindful of the number and range of products that will be impacted should any change be necessary, PSA strongly suggests that a more evolutionary approach (as flagged by the external reviewers, or similar) needs to be taken in making recommendations and including the implementation of outcomes.

13. **Bromhexine, Oxymetazoline and Xylometazoline.** We note that in New Zealand, a similar review of cough and cold medicines in children has concluded that the current restriction (to adults and children aged two years and over) should remain for medicines containing only bromhexine, or intranasal decongestants (eg. oxymetazoline and xylometazoline). This was based on an assessment that the lack of evidence of toxicity of bromhexine in overdose, and the small number of reported adverse reactions and enquiries to poisons centres involving topical nasal decongestants compared to oral decongestants provided a case for making a recommendation separate from that for other cough and cold medicines.

14. PSA believes a similar analysis in the Australian context would be worthwhile rather than simply taking the approach of the TGA Internal Panel which suggested that "industry could provide arguments or data to support the safety and efficacy of topical nasal decongestants in children if it considers that the recommendations should not apply to those products".

15. **Packaging.** PSA understands the widespread use of child-resistant closures and packaging in Australia has resulted in lower morbidity and near-zero mortality in young children from accidental or 'non-intentional' poisoning.

16. PSA supports the intent of TGA's recommendation relating to the requirement for cough and cold medicines to be marketed in containers with child-resistant closures. However, we believe the final wording should specify that this applies to all 'oral liquid cough and cold preparations' rather than "all OTC cough and cold medicines" as stated.

17. In addition, PSA is concerned that a 1 July 2010 implementation date may not allow manufacturers adequate time for compliance without serious supply issues which could disadvantage children and carers. We therefore recommend that the pharmaceutical industry be consulted on an achievable timeframe for implementation.

EDUCATION CAMPAIGNS

18. PSA supports the proposal to provide information and education regarding the use of OTC cough and cold medicines in children. PSA would be pleased to assist in the dissemination of information to pharmacists and, through them, to consumers, particularly parents and caregivers.

19. PSA reiterates the comments in the External Review Report that the use of cough and cold and other OTC medicines by parents for children represents a complex and very important social phenomenon and that this is not something simply to be solved by better education of parents. We suggest therefore that information and education campaigns need to be comprehensive and well-coordinated, involve multiple stakeholders, and be sustained for a reasonable period of time.

SUMMARY

20. PSA supports the TGA's approach to consider a number of recommendations to reduce any risks and promote the appropriate use of cough and cold medicines in children.

21. PSA is extremely concerned, however, that a number of issues raised in the External Review Report have not been appropriately considered or balanced in the Australian context. We have, therefore, provided alternative proposals in this submission.

22. We also strongly suggest that, given the complexity of issues surrounding the use of these medicines in children, the long history of use and low level of harm experienced, a more evolutionary approach needs to be taken in decision-making and implementation of outcomes.

23. PSA is keen to work in partnership with the TGA and other stakeholders to provide any advice on professional pharmacy practice issues and to support the communication of key messages and implementation of final outcomes.