

**Labelling and Packaging of Cough and Cold Medicines**  
**Stakeholder and Public Consultation October – December 2009**  
**Submission received from the Pharmaceutical Council of Western Australia**

The Pharmaceutical Council of Western Australia (the Council) has considered the proposals put forward by the Therapeutic Goods Administration (the TGA) and the external *Review of cough and cold medicines in children*. The following comments are provided in response to the proposed changes to the availability, scheduling, packaging and labelling of cough and cold medicines for children aged 2 to 12 years.

**1. Safety, efficacy and availability**

The Council supports the principles of evidence-based medicine and agrees with the philosophy that the benefits derived from any medicine should, overall, outweigh the risks associated with its use. The Council notes that the proposals put forward by the TGA largely mirror the actions taken by equivalent bodies in other countries

Having studied the external reviewers' report in depth the Council feels that the proposals put forward are somewhat excessive, particularly in light of the following comments made by the reviewers

- *Far more drugs and drug combinations are used in cough and cold medicines in other countries, and this increases the difficulty in interpreting the literature on the subject, especially side effects of combination products.*
- *The US has a far greater range of products, with a greater range of 'actives' and a greater range of combination products.*
- *Information based on former decades is now being used to suggest excess mortality from cough and cold medicines, and this information may not altogether reflect the current situation in the US, and even less the situation in Australia...However, it does appear to reflect Australian experience, which is that death or serious injury from children's cough and cold medicines is vanishingly rare.*

The extremely low incidence of adverse drug reactions (ADRs) to these medicines is highlighted by the ADRAC data contained in the *TGA internal panel report* which documents only 99 ADRs over the 28 year period from 1981 to 2009. Of these only 14 were classified as serious, at an average frequency of one serious ADR every two years. The Council acknowledges that the greatest risk seems to exist in children aged 2 to 5 years. Furthermore, the Council noted that the reviewers found varying degrees of research into the efficacy and safety of the various drugs covered by the review, and whilst some drugs showed significant potential for harm others seemed not to.

The Council accepts that there is little documented evidence of efficacy for many of the drugs considered in the review in children aged 2 to 12 years, but feels that sufficient weight has not been given to the regulatory framework under which these products are supplied in Australia.

The restriction on the sale of these medicines to the pharmacy setting, and consequent availability of pharmacist advice with the product, has no doubt contributed to the long history of the safe use of these medicines in children in Australia.

Accordingly, the Council feels it would be more appropriate to

- Restrict the use of those particular drugs proven to pose a risk to children aged 2 to 5 years, and
- Allow those drugs not proven to pose a risk to children aged 2 to 5 years to remain on the market until such time as definitive studies can be conducted into their safety profile.

## **2. Timing**

The date for implementation of the TGA's proposals is 1 July 2010. This date falls in the middle of winter which, obviously, is the period of peak demand for children's cough and cold products.

The Council considers this timing to be ill-considered and will create the greatest degree of inconvenience for parents, pharmacists and, as a flow on effect, general practitioners and hospitals.

It could be argued that, in the existence of firm evidence that these medicines do harm, swift action would be appropriate. However, as noted above, the external reviewers found the Australian experience is that "*death or serious injury from children's cough and cold medicines is vanishingly rare.*"

The Council believes that the implementation date of any significant change to the availability of children's cough and cold medicines should occur at the time of lowest seasonal demand, and suggests that 1 January 2011 would be a more appropriate date.

## **3. Packaging**

The Council believes that the extensive use of child-resistant packaging for cough and cold medicines has contributed to the low incidence of accidental poisoning in children with these medicines in Australia.

The Council supports the proposal that all over-the-counter cough and cold medicines should be marketed in containers with child-resistant closures, but believes that manufacturers' and sponsors' opinions should be sought as to whether the proposed date of 1 July 2010 is achievable.

Furthermore, the Council seeks clarification as to whether stock held by pharmacies that does not comply with any new labelling and packaging requirements may continue to be sold after the implementation date.

The majority of stock that will be held by pharmacies on 1 July 2010 has probably already been manufactured and distributed to wholesalers. An implementation date of 1 January 2011 may be more manageable as it will give manufacturers' increased time to produce stock that satisfies the new requirements and minimise the volume of non-compliant stock held by pharmacies.

## **4. Scheduling**

The Council supports the proposal that those cough and cold medicines labelled with doses for the treatment of children that currently fall in Schedule 2 should be moved to Schedule 3. This will ensure that pharmacist advice is provided with each sale of a children's cough and cold medicine rather than simply being available.

As described in point 1 above, the Council does not support the proposal to move all of the drugs subject to the review to Schedule 4 when labelled for the treatment of children aged 2 to 5 years.

The Council supports this action, at this point in time, only for those particular drugs proven to pose a risk to children aged 2 to 5 years.

**Most importantly, the Council is firmly of the opinion that any labelling and scheduling changes should reflect each other and take effect simultaneously.**

The interval between the changes to the TGA labelling requirements for cough and cold medicines in children under 2 years of age (in early 2008) and the scheduling of the sedating antihistamines (on 1 September 2008) resulted in significant confusion amongst both consumers and pharmacists.

This resulted in a period of almost 6 months where certain products could legally be sold even though their use was no longer recommended by the TGA. Several complaints were received by the Council from disgruntled pharmacy customers who received inconsistent advice regarding the status of cough and cold medicines for use in children less than 2 years of age during this period of time.

Given the time required for the NDPSC to consider scheduling issues, and the subsequent time required for their decisions to come in to effect, the Council suggests that any scheduling changes should take effect from 1 January 2011, and as per point 2 above any labelling changes should also take effect from this date.

## **5. Public awareness**

The Council agrees that a widespread campaign will be required to inform health consumers and health professionals regarding any changes made to the availability of cough and cold medicines for children.

The Council also agrees with the reviewers' opinion that the administration of medicines to ill children is a complex and ingrained social phenomenon.

Accordingly, the Council is of the opinion that education of both parents and pharmacists will be a relatively slow process and require a comprehensive, well designed and prolonged campaign. The Council urges the TGA to utilise the expertise of the Pharmaceutical Society of Australia in developing educational materials relating to this issue.