

**Labelling and Packaging of Cough and Cold Medicines  
Stakeholder and Public Consultation October – December 2009  
Submission received from the National Prescribing Service Limited (NPS)**

Thank you for the opportunity to comment on the TGA's proposed changes to the labelling, packaging and scheduling of medicines for the treatment of symptoms of cough and cold in children.

The National Prescribing Service Limited (NPS) agrees that the available clinical data does not provide evidence of the efficacy of OTC cough and cold medicines in children, and there are potential risks associated with their use in children under the age of 12 years.

In light of this, the recommendations proposed by the TGA may be reasonable. However, NPS has a number of comments in relation to the proposed recommendations and these are attached for consideration by the TGA.

We would particularly like to highlight the need to carefully consider the timing and implications of the proposed changes. Adequate time should be allowed to run comprehensive public education campaigns. We encourage the TGA to review—in collaboration with stakeholders—what is feasible prior to the proposed change date of 1 July 2010, especially given this is the middle of the 2010 winter season and a period of peak usage and consumer advertising.

## TGA review of OTC cough and cold medicines for children aged 2-12 years

### Labelling and packaging of cough and cold medicines: proposed changes to requirements

The National Prescribing Service Limited (NPS) notes the TGA has proposed a number of recommended changes to the labelling, packaging and scheduling of medicines for the treatment of symptoms of cough and cold in children.

NPS provides the following comments in relation to each of the recommended changes.

#### **(a) Safety, efficacy and availability**

*It is recommended that over-the-counter cough and cold medicines should not be used for the treatment of children under 6 years of age, and they should only be administered to children aged 6-12 years on the advice of a doctor or pharmacist. To this end, it is recommended that:*

- *commencing on 1 July 2010, the labelling of over-the-counter cough and cold medicines should not include dosage instructions for children under 6 years of age;*
- *if doses are included for children aged 6-11 years, the labelling must include:*
  - a. a warning statement advising against use in children under the lowest specified age, AND*
  - b. a statement advising that the product should only be administered to children between the lowest specified age and 12 years on the advice of a doctor or pharmacist; and*
- *the labelling of all over-the-counter cough and cold medicines with dosage specified only for adults and/or for those aged 12 and above should contain a warning statement specifically advising against their use in children under 12 years of age.*

On the basis of the evidence of benefits and harms the labelling changes described above are reasonable. However, we do recommend that for ages 6-11 years, statement (b) above relating to use of these preparations only with advice from a doctor or pharmacist should also be presented as a warning statement.

Because these products are currently used in high volumes, and parents will often have experience with using particular products, it is important to note there is a risk that a product may continue to be used even though the dosage instructions for the age group do not appear on the label. Where dosage instructions do not appear on labels parents may guess the dose.

One alternative may be a staged approach, where the labelling changes occur after a significant public education campaign.

Coughs and colds are very common in the age group 2-6 years, and some parents may choose therapies other than cough and cold products which may also have poor efficacy and potential risk of harm. Quality use of medicines principles should be applied to planning and implementing changes in access and labelling. Parents will need ready access to evidence-based information about appropriate alternative treatments for the symptoms of coughs and colds, including analgesics, complementary medicines and whether antibiotics have a role. This will need to be available at all access points where cough and cold medicine have been previously supplied, including supermarkets where relevant.

It is particularly important that reduced access to cough and cold medicines do not result in increased unnecessary use of antibiotics or increased use of complementary medicines where these products have no evidence of efficacy or adequate evidence of safety.

The full extent of use of complementary medicines in children is not well described in Australia. A small study of hospital in-patients found 8% of the 120 children whose parents responded were using a herbal medicine.<sup>1</sup>

---

**(b) Packaging**

*In the interests of consistency and improved safety:*

- *It is recommended that, commencing on 1 July 2010, all over-the-counter cough and cold medicines should be marketed in containers with child-resistant closures.*

On pragmatic grounds this proposal is reasonable for quality use of medicines. Consumers are less likely to differentiate the level of the risk of poisoning with respect to their storage of medicines, so the extra safe guard for child-resistant packaging is reasonable.

Manufacturers should be consulted in relation to an appropriate timeframe for implementation if the risk of harm from poisoning is not high.

Consumers who are disadvantaged by child-resistant closures are those with impaired manual dexterity. This is likely to be of lower prevalence among parents of young children than older people.

---

**(c) Scheduling**

*The current scheduling of most cough and cold medicines as S2 (pharmacy only) medicines ensures that advice is available but does not ensure that such advice is given regarding use in children. Such advice is more likely to be given if these medicines were S3 (pharmacist only) medicines. For this reason:*

- *It is recommended that the NDPSC be asked to consider including substances used in cough and cold medicines in Schedule 3 when intended for use in children aged 6-12 years, and in Schedule 4 for use in children under 6 years of age.*

For the use of cough and cold products to be rapidly limited to the under 6 years age group, rescheduling would quickly enforce the change. However, this proposal to reschedule will pose a significant burden on community pharmacy to communicate the changes in access and provide advice to consumers on alternative management for children with symptoms. It may be inappropriate to implement a change in scheduling quickly and any change in scheduling should not occur before educational materials for consumers and health care professionals have been prepared and disseminated.

Does the evidence of harm justify the rescheduling to S4, ie prescription only, for children under 6 years of age? Maintaining products in schedule 3 may provide as sufficient a constraint on use, assuming that community pharmacy is fully supported with materials to educate the parent when

---

<sup>1</sup> (Fong DP, Fong LK. Usage of complementary medicine among children. [Aust Fam Physician](#) 2002 Apr;31(4):388-91)

each product request is made. The NDPSC should be asked to consider a range of options in scheduling which will constrain use.

Consumers will have many questions, such as is it safe to use the product stored at home, has the medicine become unsafe, etc. Confusion for the consumer can be reduced by a carefully planned information and education campaign.

---

**(d) Public awareness**

*The changes recommended above would need to be widely promoted and explained to medical practitioners, pharmacists, parents and caregivers. For this reason,*

- It is recommended that particular efforts be directed towards educating consumers, medical practitioners and pharmacists that OTC cough and cold medicines have not been shown to be effective, and are potentially harmful in children under 6 years of age. Education campaigns should be directed through the National Prescribing Service (NPS), professional associations and colleges such as the Royal Australian College of General Practitioners, Australian College of Rural and Remote Medicine and the Royal Australian College of Physicians Paediatrics and Child Health Division, Australian College of Pharmacy Practice and Management, Pharmaceutical Society of Australia, Pharmacy Guild, Consumers Health Forum and the pharmaceutical industry.*

If the proposed changes are to occur in scheduling, a sophisticated and comprehensive education program for consumers, parents, care givers, medical practitioners, pharmacists and nurses (such as child health nurses) is needed and will require funding.

It will be particularly important to support health professionals to explain alternatives for symptom relief in children with coughs and colds, and to help prevent the use of inappropriate alternatives.

Parents may have experienced satisfaction using these products, therefore may not readily accept the change in access. This presents a frequent presenting problem for community pharmacists and pharmacy assistants in the event specific product requests are made in the pharmacy. Community pharmacy will need materials and time to develop effective processes in order to deal with consumer requests, especially in the winter season of 2010.

There may also be a risk that antibiotics may be prescribed by medical practitioners if no other alternative medicines for symptom control are available.

The proposed date for changing in labelling of 2010 may not allow time for comprehensive materials to be developed. Stakeholders should be encouraged to collaborate on a staged and properly coordinated communications strategy.

All consultation and communications about this proposal should be explicit about whether the proposals apply to other products, such as topical nasal decongestants.

NPS is happy to discuss further with the TGA how we might support the development and dissemination of an education program for the audiences identified in this recommendation.

**December 2009**