

**Labelling and Packaging of Cough and Cold Medicines
Stakeholder and Public Consultation October – December 2009
Submission received from the Schering-Plough Pty Limited**

The Therapeutic Goods Administration (TGA) reviewed the safety and efficacy of registered over-the-counter (OTC) cough and cold medicines for children aged 2 - 12 years considering the availability, labelling, packaging and scheduling of these medicines for use in children.

This review was published on the TGA website on 22 October 2009. As result of this review, the TGA and the Medicines Evaluation Committee concluded that the available clinical data did not provide evidence of efficacy of these medicines in children, and their use was not without attendant risks.

Schering-Plough Pty Limited appreciates the opportunity to respond to the proposed changes by the TGA, and would like to submit the response to the TGA recommendations.

Proposals

Schering-Plough proposes that:

- For cough and cold medicines for children under 6 years, the actions taken in Australia should be aligned with the regulatory actions in similar countries such as in Canada, New Zealand and the UK: Bromhexine and topical decongestants for under 6 years should be excluded from the restrictions on cough and cold products for children
- For cough and cold medicines for children aged 6 - 11 years, the labelling should state *“Consult with a health care professional before use in children aged 6-11 years”*
- Cough and cold medicines for children aged 6 to 11 years should remain in Schedule 2; they should not be transferred to Schedule 3
- Child resistant closures are not be required for topical nasal decongestants
- Changes to labelling should take effect in May 2011

The justifications for our proposal are details below as part of responding to the TGA recommendations

(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,

Schering-Plough accepts for children under 6 years old that the actions taken in Australia should be aligned with the regulatory actions in similar jurisdictions.

We propose that, in line with UK, Canada and NZ, bromhexine and topical nasal decongestants are not restricted for children under 6 years.

and they should only be administered to children aged 6 - 12 years on the advice of a doctor or pharmacist.

Schering-Plough proposes for cough and cold products containing the affected substances for children 6 – 11 years old that the TGA should require strengthened

warnings: The labelling should state *“Consult with a health care professional before use in children aged 6-12 years”*

This means that the product remains in Schedule 2 and are not transferred to schedule 3. This proposal is in line with those UK, Canada and New Zealand.

**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;**

Schering-Plough agrees that, if over-the-counter cough and cold medicines are not indicated for children under 6 years of age, they should not include dosage instructions for children under 6 years old.

Schering-Plough does not agree with the proposed timeline. The timeline will be addressed separately below

**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,**

Schering-Plough agrees.

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;

Schering-Plough agrees that for cough and cold products containing the affected substances for children 6 – 11 years old, the warnings should be strengthened, but is opposed to changing the current scheduling.

Schering-Plough proposes for cough and cold products containing the affected substances for children 6 – 11 years old that the TGA should require strengthened warnings: The labelling should state *“Consult with a health care professional before use in children aged 6 - 11 years”*.

This means that the product remains in Schedule 2 and are not transferred to schedule 3.

This is in line with the UK, Canada and New Zealand.

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.

Schering-Plough agrees.

This approach would bring the regulation of cough and cold preparations in Australia into line with measures in place in the UK and Canada.

Schering-Plough does not concur that the proposal for cough and cold preparations is in line with the MHRA in the UK, Health Canada and Medsafe in NZ. The UK, Canada

and NZ do not include, for example, bromhexine and other mucolytics in their reviews, while proposals for topical nasal decongestants differ.

The need for such limitations on use in children should be reviewed if and when robust efficacy data becomes available.

(b) Packaging

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.

Schering-Plough does not agree with the proposed timeline. The timeline will be addressed separately below

This requirement would bring the packaging of cough and cold preparations in Australia into line with measures in place in the UK and with recommendations made by the regulators in the USA.

Schering-Plough proposes that, in line with TGO 80, nasal decongestants in small volumes should be excluded from the requirements for child-resistant containers.

The TGA proposals differ from those of the UKMHRA and the USFDA; those authorities excluded nasal decongestants from the requirements for child-resistant containers.

(c) Scheduling

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,

Schering Plough opposed to the further restriction in availability of cough and cold preparations for children 6 – 12 years old.

Schering Plough proposes strengthened warnings for cough and cold products for children 6 to 12 years. We consider that a strengthened warning such as “*consult with a healthcare professional before use in children 6 – 12 years*” would provide sufficient additional warning.

and in Schedule 4 for use in children under 6 years of age.

Schering Plough proposes that for children under 6 years old that the actions taken in Australia should be aligned with the regulatory actions in similar jurisdictions

Schering-Plough proposes that if the Schedule 4 is required, this should be treated by the TGA as an up-scheduling application, not a re-registration as a prescription medicine.

(d) Public awareness

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.

Schering Plough supports the quality use of medicines and the communication of clear, consistent messages to consumers and health care professionals to assist in their appropriate use.

Assessment of impact

Availability of product

If cough and cold products for children under 6 years old are only available on prescription from a doctor, the added cost to the carers of seeking medical attention and obtaining a prescription plus paying the dispensing fees etc would limit the volume being sold to the point when for most products commercial viability is not possible.

If cough and cold products for children between 6 and 12 years old are to be moved to Schedule 3, the added cost to the company of labelling small numbers of products, to the amount that pharmacists would be able to stock in the dispensary, to the carers of obtaining the product etc, would limit the volume being sold to the point when commercial viability may not be possible.

Schering-Plough proposes that the scheduling of over-the-counter cough and cold medicines in Australia needs to be aligned with the classification in NZ. For companies which manufactured harmonized packs for Australia, and New Zealand, this increases the possibility of commercial viability.

Timelines

Schering-Plough is opposed to the TGA require manufacturers to introduce one set of label changes after the TGA's initial decision is communicated in July 2010 and then a second set of label changes if the NDPSC determined that rescheduling should occur. The second change may not occur until 2011.

This would cause confusion to wholesalers, pharmacies and consumers. In addition, two sets of labelling changes would have significantly financial impact to the company, and could interfere with supply.

Any labelling changes required may take 9 months or more to introduce to the market, from a final decision being communicated to manufacturers until the manufacture and distribution of finished product with the new labels. This will depend on when the change is communicated relative to the cough, cold and flu season.

If the earliest time for a TGA decision is February 2010, it would not be possible for products with the new labels to be distributed to pharmacy in time for the 2010 cough and cold season.

In addition, if the TGA proceeds with its current intention to ask NDPSC to consider the rescheduling of cough and cold medicines in children under 12 years of age, the time frame would be even further extended.

Schering-Plough proposes that the changes be implemented in a reasonable fashion, given that there is no evidence of patterns of misuse, either intentional or accidental, or serious injury to children in Australia caused by current use of cough and cold medicines.

Schering-Plough propose that the changes should take effect for the cough, cold and flu season beginning in May 2011, and should be coordinated with the Australian and New Zealand markets.