Labelling and Packaging of Cough and Cold Medicines
Stakeholder and Public Consultation October – December 2009
Submission received from the Novartis Consumer Health Australasia Pty Ltd

We take this opportunity to provide comments on the recommended changes to the labelling, packaging and scheduling of medicines for the treatment of symptoms of cough and cold in children, following the TGA review of the safety and efficacy of these medicines.

(a) Safety, efficacy and availability

TGA recommendations:

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.

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.

Although it is stated that the above approach will bring the regulation of cough and cold preparations in Australia into line with measures in place in the UK and Canada, it should be noted that in Canada, the above approach excludes topical cough and cold medicines such as topical nasal decongestants. Similarly in New Zealand, there is an exemption for bromhexine and topical nasal decongestants including phenylephrine, oxymetazoline and xylometazoline, to remain contraindicated for children under 2 years of age.

As many products are harmonised for supply in both Australia and New Zealand, it is important that the labelling requirements remain aligned to enable continued supply in

both countries. Should separate packaging be required for each country, the demand may result in deletion of certain products.

Further, from the available safety data, it is evident that topical nasal decongestants are of lower risk and potential for harm, compared to systemic cough and cold preparations. Therefore their use in the paediatric population should not be required to be changed, given the long history of safe use in both adults and children, when used as directed.

However to ensure that consumers continue to use these medicines appropriately, we support the requirement to include a statement to refer the consumer to their healthcare professional for advise before use in children under 12 years, or words to that effect. This slight amendment to the wording proposed by the TGA brings it in line with the warning statement required by Medsafe.

The recommended implementation date of 1 July 2010 does not allow adequate time for sponsors to take the necessary steps through the regulatory approval process, and production and supply chain which are located overseas for many sponsors. Further, if additional changes are proposed under (c) scheduling, the recommended timeline does not allow for all the required changes to be made in the same round of changes. This has the potential to cause confusion in trade and with consumers, while also creating resource and financial strain to sponsors in coordinating and managing multiple implementations for a whole portfolio of products. We therefore recommend that the implementation date be extended to the following cough cold season, that is May 2011.

Summary of recommendations:

- systemic over-the-counter systemic cough and cold medicines should not be used for the treatment of children under 6 years of age, while topical nasal decongestants such as phenylephrine, oxymetazoline and xylometazoline should remain available for use in children over 2 years of age
- for topical nasal decongestants, a statement be added to labelling advising that the consumer seek advice from a healthcare professional before use in children between 2 and 12 years
- the timeline for implementation be extended to May 2011, to allow adequate time for sponsors to incorporate all potential changes within one round of packaging and/or artwork changes, and for the changes to be affected at overseas production plants
- any non-compliant packaging/labelling at the time of implementation should be allowed to run through the supply and retail chain without the need for recall

(b) Packaging

TGA recommendations:

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

Child-resistant closures are required where there is a potential risk for accidental overdose by children, and that the toxicity of the substance contained in the medicine has the potential to cause significant harm should it be ingested by a child.

While we support the introduction of child resistant packaging for all liquid cough and cold preparations, we feel that the current exemption as outlined in subsection 7(d) of Therapeutic Goods Order 80 "Child-Resistant Packaging Requirements for Medicine" should apply. Therefore, liquid preparations for application to the eye, ear or mucous membrane (including nasal cavity), when supplied in a container with a nominal capacity of not more than 20 mL or which is fitted with a restricted flow insert should not be required to be supplied in child resistant packaging.

This brings in line with requirements in the UK, where the Medicines and Healthcare products Regulatory Agency (MHRA) excluded topical preparations, such as nasal sprays and drops and throat sprays, from the new requirements for child-resistant containers for all liquid preparations of cough and cold medications.

Separately, the recommended implementation date of 1 July 2010 does not allow adequate time for:

- the development and validation of child-resistant closures for medicines that do not currently have one, and
- sponsors to take the necessary steps through the regulatory process for the new closure to be approved, and
- the product to come through the production and supply chain

As reference, the introduction of child-resistant containers for all oral liquid preparations of cough and cold medications in the UK allowed a transition period of 19 months (notice for the introduction was issued in February 2009 and compliant packaging is required to enter the supply chain by September 2010).

Summary of recommendations:

- topical liquid preparations be exempt from the requirement for child-resistant closure, in line with decision in the UK
- current exemption in TGO80 for topical liquid preparations supplied in a container with a nominal capacity of not more than 20 mL or which is fitted with a restricted flow insert should apply
- the timeline for implementation be extended

(c) Scheduling

TGA recommendations:

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

The definition of a Pharmacy Medicine (Schedule 2) in the Standard of Uniform Scheduling of Drugs and Poisons (SUSDP): substances, the safe use of which may require

advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.

The definition of a Pharmacist Only Medicine (Schedule 3) in the Standard of Uniform Scheduling of Drugs and Poisons (SUSDP): substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.

The main difference between the two schedule is the availability of the products for self-selection by the consumer. In both instances, the advice of a pharmacist is readily available. Therefore we feel that Pharmacist Only Medicine (Schedule 3) classification should not be applied to all cough and cold medicines indicated for children between 6 and 12, as this restricts access without enhancing availability of advice from a healthcare professional.

We feel that Pharmacy Medicine (Schedule 2) classification is adequate, as it still ensures that a healthcare professional is available for advice should it be required, yet allows the flexibility for consumers to self-select if they have already received advice elsewhere.

Further, enhanced warnings and dosage instructions on labels will help encourage safe and appropriate use of these medicines.

We propose that the scheduling of all cough and cold medicines remain unchanged.

Summary of recommendations:

- the scheduling of cough and cold medicines intended for use in children aged 6-12 should remain in Schedule 2.

(d) Public awareness

TGA recommendations:

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 Services (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

It should be acknowledged that cough cold products have been used in children safely and effectively for many years. The lack of efficacy data should not be taken as an indication that the products are not effective, and if these products are used appropriately and as directed, their potential to cause harm is small.

Post-market safety data confirms that the primary usage pattern in adverse events, where case details were available, reported for infants and children under 6 years are due to medication administration error or accidental ingestion (majority between ages up to 2 years of age), and not from those who have been administered the medicine as directed.

Any communication to consumers should not raise undue harm and must be balanced. The safety profile of these medicines have not changed and safety reports from overseas markets must be interpreted in context of the Australian environment.

We support the quality use of medicines and would welcome the opportunity to help raise awareness about the appropriate use of cough and cold medicines in children.

Summary of recommendations:

- any communication to the public should be balanced and should not raise alarm
- any reference to overseas safety data must be given in context of the Australian environment

Conclusion

While we support the need to ensure cough and cold medicines continue to provide safe and effective treatment for children, we do not agree with some of the changes proposed by the TGA.

We have made some recommendations in an attempt to meet the same objectives of ensuring continued safe use of cough and cold medicines in the paediatric population. We trust that these recommendations will be considered and should further information or clarification be required, please contact us directly.