

30 October 2009

Dr Stewart Jessamine
Group Manager
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Dear Stewart,

Re: Section 36 Notice concerning the use of cough and cold medicines in children

Thank you for your letter dated 25 September 2009, issuing a notice under Section 36(1) of the Medicines Act 1981, contraindicating the use of cough and cold medicines in children under 6 years of age and requiring a list of further amendments to labelling of medicines for coughs and colds. The New Zealand Self Medication Industry (NZSMI) would like to thank you for the opportunity to comment on the proposal and welcomes discussion on these requirements, in particular with regard to issues outlined below.

1. Use in Children under 6 for product only indicated for Children over 12 years of age

Amend the package labelling to include the statement: 'Must not be used in children under six years of age', or equivalent wording

If the product has a data sheet, add to the 'Contraindication' section that the product is contraindicated in children under six years of age

If the product has a package insert and/or Consumer Medicine Information, include 'Must not be used in children under six years of age', or equivalent wording, and remove any dosage instructions for children under six years of age.

Currently, there are many medicines on the market for cough and colds which are indicated for children over twelve years of age. The labelling for these products include warnings such as, "Do not use for children under 12 years of age", or words of a similar meaning. However, the requirement to amend the package labelling to include reference to children under 6 on all cough and cold medicines is not relevant for cough and cold products that are only indicated for adults and children over 12 years of age. It would be potentially confusing and misleading for products indicated for children 12 years of age and over, to include the statement that these products should not be used in children under six years of age.

Similarly it would be potentially confusing and misleading for products indicated for children 12 years of age and over to have the labelling amended "*to inform parents/guardians to seek advice from a medical practitioner before using in children aged six years and over*".

Recommendation: Products not indicated for children under the age of twelve should not be required to have the aforementioned statements on the labelling. It should be sufficient that there are no dosage instructions for children under 6 and that the product is not indicated for children under 12 years of age on both packaging, CMI and datasheets.

2. Use with other medicines:

Amend the package labelling to state that Cough and Cold products should not be taken with any other medicine (including complementary medicines) intended to treat the symptoms of the common cold.

This requirement may contradict current labelling and the manner in which products are currently used and lead to confusion. A common cold is characterized by sore throat, malaise, and low-grade fever at onset. These symptoms generally resolve within a few days and are followed by nasal congestion, rhinorrhea, and cough within 24 to 48 hours after onset of the first symptoms (Simasek, M et al, 2007). Cough and cold products are currently used for symptomatic relief to alleviate a range of symptoms including fever, headache, muscle aches and pains, sore throat, nasal congestion, cough, watery eyes and sinus pain. Cough and cold medicines are sold, either as products containing single actives or in combination to treat the symptoms that most affect individuals for the duration required. Access to a range of products allows the patient to choose the treatment that most suits the patient and their symptoms. They may choose to buy a product containing single actives and use these in combination with other products when required. Patient choice is dependent on a number of factors. A patient may wish to alleviate the symptoms of a dry cough with a lozenge while they are travelling or at work, a cough liquid while at home, and treatment with paracetamol for aches and pains. Patients may wish to use a formulation containing a decongestant and paracetamol while they have symptoms of sinus congestion and use a single active paracetamol for when they don't suffer from congestion. Therefore, the requirement to include a statement on the labelling stating that a product may not be used with any other cough and cold medicines contradicts the manner in which patients use these products for the symptomatic relief of cough and colds. This requirement limits patient choice and restricts patient's autonomy to self select products that suit them.

Recommendation: We propose that the requirement for all cough and cold products to include labelling that states that the product should not be used with any other medicine be removed. For actives such as paracetamol, the labelling may include: 'Do not use if you have taken paracetamol'. A list of statements relating to other active(s) could also be developed for implementation

3. Consumer Medicine Information

Sponsors have been requested to prepare and submit Consumer Medicine Information for each Cough and Cold product for publication on the Medsafe website.

To aid patient understanding of the active ingredients used to treat the symptoms of coughs and colds, the benefits, and the risk associated with these ingredients, it may be better to include individual active ingredient information on the Medsafe website rather than product specific information. As mentioned above, the range of products offered for the symptomatic relief of coughs and colds empowers the patient to choose the product that provides the most benefit to them. This gives the patient the autonomy to choose a range of products to suit their symptoms for the duration of each symptom based on information about the active ingredients. Patients may only wish to treat one symptom or they may wish to use a combination of active ingredients to treat only the symptoms that are bothering them at the time. Therefore, it would be of greater benefit to have individual active ingredient specific information on the Medsafe website rather than consumer information sheets for products that may have a number of actives. Patients would be better informed on both the adverse effects of active ingredients as well as the indications

of the actives. The patient's autonomy in choosing the treatment that best suits them will be supported by information on the actives and help avoid any confusion on cough and cold medications. A useful example of standard information on active ingredients for medicines can be found on the Australian Self medication Industry website:

<http://www.asmi.com.au/industry/Consumer-Medicine-Information.aspx>

Recommendation: To better inform patients and avoid potential for confusion, NZSMI recommends that generic consumer medicine information on the actives used in cough and cold medications is presented on the Medsafe website instead of product specific information.

4. Child Resistant Packaging

Supply the medicine in child resistant packaging

NZSMI wishes to seek clarification on whether the requirement for child resistant closures extends to dosage forms other than oral liquids eg nasal sprays and lozenges. We also need confirmation as to whether this requirement extends to medicines labelled for adult use only; such medicines could include powder in sachets and liquids. Medicines on the market currently already comply with regulation 37 of the Medicines Regulations 1984, which requires certain products such as paracetamol and aspirin to be distributed in child resistant closures.

Recommendation: Please clarify whether the requirement for child resistant packaging extends to all dosage forms including nasal sprays and lozenges.

5. Maximum Daily Dose

Amend the package labelling to include a maximum daily dose

NZSMI seeks clarification on whether the maximum daily dose is for adults or children and whether it relates to all active ingredients. For active ingredients such as guaiphenesin and phenylephrine, where a maximum daily dose is not identified through scheduling, the NZSMI wishes to seek clarification from the Medicines Classification Committee on the maximum daily dose requirements to be included on packs. The maximum daily dose for products such as paracetamol can be easily identified; however, this is not the case for all cough and cold medicines.

Recommendation: Medsafe clarify whether the term "maximum daily dose" refers to adults or children over 6 years of age and to provide guidance on the maximum daily dose to be included on the labels where such doses are not easily determined.

6. Improvements to the dosing instructions

NZSMI seeks clarification on the request to propose improvements to dosing instructions. Products currently comply with the Medsafe Checklist on Labelling of Medicines and trans Tasman products also comply with the Therapeutic Goods Order No. 69 which outlines requirements for labels for medicines.

Recommendation: Medsafe to clarify their meaning behind the request to propose improvements to the dosing instructions.

7. Measuring device

Supply an accurate measuring device with the medicine

Recommendation: NZSMI recommends that this be an optional requirement for consideration in the longer term, and not a short term solution.

8. Process of Approval of Labelling and Cost of CMN

Please submit a full colour mock up of labelling artwork with scale identified for approval by the Clinical Risk Management Branch. Upon approval you will be requested to submit a Changed Medicine Notification.

This process is a two stage process which increases the timeline and increases the potential for complexity where two teams may not agree on the proposed artwork. Each discussion and meeting to discuss the requirements increases timeframes and delays patient access to these medicines.

Recommendation: NZSMI proposes that a guidance document on what is/is not acceptable be provided to the Evaluation team and industry to minimise any potential conflicting advice, hence making the implementation more efficient and timely.

NZSMI would also like to propose that a fee waiver be granted for these proposed CMNs to change the labelling since Industry has already in the recent past had an equivalent labelling change imposed upon them.

9. Implementation timeline

An implementation plan, including proposed timelines with justifications must be provided in your reply to this section 36. Medsafe expects that changes to the package labelling be complete by the beginning of the 2011 cough and cold season.

Recommendation: NZSMI proposes that the transition timeline of May 2011 be agreed to, as a sell-in date of compliant artwork, and stock in the trade at that time, be allowed to be sold through the trade, without the need to recall or over sticker. This proposed timeline takes into account:

- the 6 month production leadtime usually required to take a change through global channels, and
- the estimated timeline for a decision to be made by the Medicines Classification Committee (MCC) with regards to the evaluation of scheduling as recommended by the Group.

This proposed timeline ensures that sponsors are not required to make a further round of changes if the currently proposed labelling changes are implemented prior to an MCC decision. This will also minimise confusion with both the pharmacists and consumers.

Further, consideration should be taken for products requiring child resistant packaging to be adopted, and that a longer transition period should be permitted to avoid products being withdrawn from the market.

10. Products under evaluation

Further to the discussion in Item 9, NZSMI requests that products currently under evaluation do not have to comply with the Section 36 notice requirements when they are given ministerial consent, but will be brought in line (as will all marketed products) by the agreed transition date in 2011. Where a Request for Information (in line with the section 36 notice) has been received for any product under review, sponsors can defer implementation of the Section 36 requirements as agreed above, to the agreed transition date in 2011.

11. Trans Tasman Harmonisation

Further to the discussion in Item 9, the TGA are presently consulting on this same issue with the consultation closing on the 18th December 2009.

Recommendation: Since the majority of products sold in New Zealand are supplied from Australia, NZSMI proposes that details of the changes to be made not be finalised

until after the results of the TGA consultation are known. This will enable companies to make a single set of changes for both countries, thereby minimising disruptions in supply of product to the market.

Summary

In summary, to avoid possible consumer confusion and to aid better understanding of the active ingredients used to treat coughs and colds, we propose:

- That generic consumer medicine information sheets for the active ingredients be placed on the Medsafe website.
- That the requirements for labelling to include references to children under 6, and between 6 and 12 years, be removed for those products that are indicated for children over the age of 12 years.
- That the requirement to include the statement that the product 'should not be taken with any other medicine', be removed, as it may contradict the use of these products for symptomatic relief
- That Medsafe provide guidance on maximum daily doses to be included on product labelling
- That Medsafe provide guidance to both Industry and the Evaluation team on labelling requirements and possible improvement.
- That the requirement for supply of an accurate measuring device be removed.
- That Medsafe clarify the request to use child resistant packaging.
- CMNs supporting the requested label changes be granted a fee waiver.
- Implementation timeline: a sell-into trade date of May 2011 be agreed, with existing stock being allowed to flow through the trade. Consideration to be taken into account with regards to potential further changes recommended by either the MCC and/or TGA, and a longer transition period for products requiring child resistant packaging to be introduced.

I look forward to hearing from you. Because of the tight timeframes for companies to implement the s36 changes, I would be grateful if you could provide a response to the above issues by **16 November, 2009**

Kind regards

Tim Roper¹
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Auckland, New Zealand

Simasek, M. et al., Treatment of the Common Cold, Am Fam Physician 2007;75:515-20, 522

¹ Signed for and on behalf of Mr Roper who is currently out of the country