

**MEDSAFE**NEW ZEALAND MEDICINES  
AND MEDICAL DEVICES  
SAFETY AUTHORITYA BUSINESS UNIT OF  
THE MINISTRY OF HEALTH  
[www.medsafe.govt.nz](http://www.medsafe.govt.nz)

13 November 2009

Tim Roper  
NZSMI  
PO Box 6473  
Auckland

Dear Tim

**Section 36 notice concerning the use of medicines to treat the symptoms of the common cold in children.**

Thank you for your letter dated 30 October 2009. I hope that the following response will clarify the issues you have raised.

*1. Clarification of labelling requirements for products only indicated for children older than 6 years of age*

Medsafe requested sponsors to amend the package labelling (data sheet and CMI) to include the statement: Must not be used in children under six years of age, or equivalent wording.

Medsafe expects that for products currently not indicated for use in children 6 years of age or above that the labelling will state not for use in children under (age for which product is indicated e.g. 12). For products indicated for children 12 years and above it is not necessary to add a statement to seek healthcare professional advice. Medsafe considers this to be *equivalent* wording. It was expected that for products only indicated in children older than six years that the sponsor would confirm this in their response to the Section 36 notice.

*2. Use with other medicines*

Medsafe requested sponsors to 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.

It is not intended to make this statement an additional contraindication, but rather to add some precautionary wording. The aim of this statement is to reduce the risk of accidental overdose due to use of multiple medicines containing the same substances. Therefore it is appropriate that a patient or carer seeks professional advice on whether different products should be used together. Referral to a healthcare professional may also aid identification of patients with more serious illness.

Medsafe has clarified this position with those sponsors who have already queried this requirement. Medsafe has suggested that the statement includes advice to consult a healthcare professional before using another cough and cold medicine in the warnings section of the label. Sponsors are welcome to propose wording relevant to their products.

### *3 Consumer Medicine Information*

Medsafe welcomes a proposal from sponsors on creating a standard information format for specific active ingredients and combination of active ingredients that would be readily accessible and that is understood by consumers.

### *4 Child Resistant Packaging*

The intention of this requirement was to reduce the potential for accidental overdose of medicines by children. This requirement was highlighted in the Section 36 notice as the Cough and Cold Review Group considered it was a very important method of reducing child exploratory poisonings. As detailed in the NZRGM, Part D, blister packs are already considered to be safety containers that are resistant to attempts to being opened by small children. All liquid medicines should still be provided with a child resistant cap. Medsafe recommends to parents that they purchase medicines with child resistant caps and measuring devices whenever possible.

(<http://www.medsafe.govt.nz/hot/alerts/CoughandCold/TreatColdOct2009.asp>).

### *5 Maximum Daily Dose*

Medsafe notes that many products already include this information on the package labelling. Medsafe was expecting, in the absence of other scientific information, that the sponsor include a statement/information to the effect that the maximum dose is x number of doses (or mg or ml) in 24 hours.

### *6 Improvements in dosing instructions*

Medsafe understands that this may be difficult and therefore the Section 36 notice asked only for proposals. The intention is to, for example, include weight based and age based guidelines if the sponsor has information to support this. Alternatively there may be scope for introducing a finer graduation in dosing e.g. including age range for a dose of one and a half 5ml spoonfuls rather than jumping from one to two spoonfuls.

### *7 Measuring device*

The Cough and Cold Review Group had concerns that children could be given accidental overdoses of medicine if the parent or carer does not have an accurate measuring device. Medsafe believes that responsible companies should not have any difficulties with this request. Medsafe recommends that parents purchase medicines containing a measuring device whenever possible (see point 4 above).

### *8 Approval process and cost*

Full colour mock ups of labelling will be required in order for the Clinical Risk Management Branch to assess the changes with respect to the Section 36 notice requirements. A CMN will then be required for the Product Regulation Branch to assess overall compliance of the labels in line with the relevant legislative requirements and guidelines. Medsafe assures you that the different branches of Medsafe are working very closely regarding changes to products as a result of the Section 36 notice. It is our intention that once the Section 36 notice has been adhered to, that the CMN process will be quick and straightforward. Medsafe does not believe that a guidance document is needed for these relatively straight forward labelling changes. It is not Medsafe's intention to delay this process or to dictate exact wording to sponsors.

### *9 Implementation timeline*

Medsafe has no intention to require a recall or overstickering for sponsors who comply with the Section 36 notice in a timely manner, and include clear and logical reasons for the time lines involved. Sponsors should provide justification of timelines to Medsafe.

### *10 Products under evaluation*

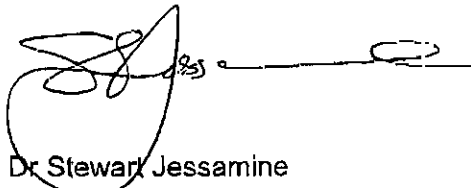
Products currently under evaluation have been included within the scope of the Section 36 notice. Where evaluation is almost complete, sponsors will be contacted and requested to comply with the Section 36 requirements. Where evaluation has not yet commenced, the Section 36 requirements will be assessed as part of the initial evaluation process. In both situations, any changes made may be incorporated into the NMA process without additional cost. Non-compliance will need to be suitably justified and accompanied by an implementation plan and timeline for how the changes will be approved prior to the 2011 cough and cold season. Post-approval changes will need to be made by a CMN, with payment of the associated fees. Medsafe expects that there are considerable cost and time benefits for both sponsors and Medsafe if the Section 36 requirements are implemented prior to approval of pending products.

### *11 Trans Tasman harmonisation*

Medsafe is prepared to consider changes required by the TGA, as part of the Section 36 notice. It is the responsibility of individual sponsors to notify Medsafe of any difficulties caused by shared packaging as part of their response to the Section 36 notice. Medsafe will consider these requests on a case by case basis.

I hope this letter has clarified your concerns, please do not hesitate to contact me if you require any further information.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Dr. Stewart Jessamine', is written over a horizontal line. The signature is stylized and somewhat cursive.

**Dr Stewart Jessamine**  
**Group Manager**  
**Medsafe**