

Head of Regulatory Affairs
<Company Name>
<Company Address1>
<Company Address2>

03 March 2009

Dear Sir/Madam

**Re: Over-the-Counter (OTC) Cough and Cold medications
licensed for use in children under 12**

We wrote to you on 18 February 2009, setting out the CHM advice and asking for variation applications to be submitted.

That letter gave details of the amendments to the MAs which needed to be made, including (in Annex 2) standard wording which would be needed in the SmPCs of all OTC cough and cold products, containing the ingredients reviewed, which are licensed for children aged 6-12 years of age.

This wording, for children age 6-12 years, was:

[Indication as per individual product] when simple measures have failed to provide adequate relief.

We would be content for this information to be reflected in the Patient Information Leaflet (PIL) **only** – it does not need to be included in section 4.1 of the SmPC.

You are asked to undertake to incorporate into the PIL for all products licensed for use in children aged 6-12 years wording which is consistent with the following:

Treating cough and cold in children

It's normal for children to get 8 or more colds in a year. Gradually they build up immunity and get fewer colds. Most colds will get better within a few days and you may not need to do more than keep your child comfortable until they get over it. Because colds are caused by viruses, not bacteria, antibiotics don't help. Here are simple steps to help your child who has a cough or cold.

1. If they are hot/feverish : Increase the amount of fluid your child normally drinks. Lower their temperature with a paracetamol or ibuprofen medicine which has doses for children. (Paracetamol is not for children under 2 months. Ibuprofen is not for children under 3 months)

2. For coughs : Although it is distressing to hear your child cough, in fact coughing serves a purpose. It helps to clear phlegm on the chest or mucus from the nose. Give the child plenty of warm clear fluids to drink.

3. To help with breathing : Plain saline nose drops, available from your pharmacy, can help babies with blocked noses who are having trouble feeding.

As indicated in our letter of 18 February, submission of leaflet or label/leaflet mock-ups is not required at this time. An undertaking must be given that the changes will be incorporated at the next reprint or by March 2010, whichever is earlier, and that the mock-ups will be submitted in the usual manner at submission of the next regulatory change.

Please note that all other changes requested in our letter of 18 February 2009 are still required to be made in accordance with the details set out in that letter and the annexes.

For further advice on the submission of your variation please contact [text redacted S38 FOIA] for procedural advice, or [text redacted S38 FOIA] for other queries.

Yours faithfully,

[text redacted S38 FOIA]
Market Towers
Vigilance and Risk Management of Medicines
MHRA