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Directors of Pharmacy
Chief Executives, NHS Boards for information

**UPDATED ADVICE – OVER THE COUNTER COUGH AND COLD MEDICINES FOR
YOUNG CHILDREN**

Please see for urgent transmission to community pharmacists the attached information from the Paediatric Medicines Expert Advisory Group and Commission on Human Medicines (CHM) updating advice on the management of coughs and colds in children which follows a review of the safety and efficacy of over-the-counter cough and cold medicines which are licensed for use in children.

Thank you for your co-operation.

Yours sincerely



BILL SCOTT
Chief Pharmaceutical Officer

ACTION WITHIN 48 HOURS - FOR CASCADE TO COMMUNITY PHARMACISTS

26 March 2008

Dear Pharmacist

Updated advice - Over-the-counter cough and cold medicines for young children

The Paediatric Medicines Expert Advisory Group and the Commission on Human Medicines (CHM) have issued updated advice on the management of cough and colds in children, following a review of the safety and efficacy of over-the-counter cough and cold medicines which are licensed for use in children.

In summary, this advice is:

- Children suffering from a cough or cold should be treated with paracetamol or ibuprofen to lower the child's temperature, and if they have a cough to use a simple cough syrup (such as glycerol, honey or lemon);
- Non-prescription cough and cold preparations containing any of the active substances set out below* should not be used in children under 2 years;
- For children aged 2-6 years, care should be taken to adhere to the maximum daily dose; not to take with other cough and cold medicines; and the advice of a pharmacist or other healthcare professional should be sought if there are any concerns.

Further information is given in the attached article which will appear in the April edition of *Drug Safety Update*.

Products with the updated advice on their packaging, and in the Patient Information Leaflets, will be in pharmacies and stores by October 2008. In the interim, a leaflet for patients/carers will be available for additional advice – a copy is attached; it is also available on our website (www.mhra.gov.uk).

* Brompheniramine, Chlorphenamine, Dextrometorphan, Diphenhydramine, Ephedrine, Guaifenesin, Ipecacuanha, Oxymetazoline, Phenylephrine, Pholcodine, Pseudoephedrine & Xylometazoline

The following products directly targeted at children under 2 should be removed from open shelves:

- Asda Children's Chesty Cough Syrup [PL 03105/0056 – MAH: Bell's]
- Boots Chesty Cough Syrup 1 Year Plus [PL 00014/0381 – MAH: Boots]
- Boots Sore Throat and Cough Linctus 1 Year Plus [PL 00014/5152R – MAH: Boots]
- Buttercup Infant Cough Syrup [PL 02855/0022 – MAH: Chefaro]
- CalCough Chesty [PL 15513/0052 – MAH: McNeil]
- Children's Chesty Cough [PL 03105/0056 – MAH: Bell's]

- these medicines can still be supplied under the supervision of a pharmacist for older children.

A range of products will remain on general sale for use in children under 2 years old. These include simple cough medicines containing glycerol, lemon or honey.

Single-constituent paracetamol and ibuprofen products are not affected by this advice.

For any queries about the contents of this letter, please contact our Information Centre by email (info@mhra.gsi.gov.uk) or by telephone (020 7084 2000).

Primary Care Trusts are asked to bring this information to the attention of Community Pharmacists by copy of this letter, with both attachments.

Yours sincerely,

Shirley Norton
Deputy Director
Vigilance and Risk Management of Medicines

Attachments:

- *Drug Safety Update "Stop Press" article*
- *Leaflet for Parents / Carers*

Stop press

Updated advice—Over-the-counter cough and cold medicines for children

information from Professor Rosalind Smyth, Chair of the Paediatric Medicines Expert Advisory Group

For further information about the Paediatric Medicines Expert Advisory Group, see <http://www.mhra.gov.uk/mhra/drugsafety/update>

For further information about the US Food and Drug Administration safety review, see <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01778.html>

The Paediatric Medicines Expert Advisory Group and the Commission on Human Medicines have recently assessed the safety of cough and cold medicines for children. This assessment follows recent advice from the US Food and Drug Administration about the safety of these medicines in children.

The Commission noted that although UK data do not raise the same level of concern as those for the USA, five reports of deaths (the first in 1981) associated with use of cough and cold medicines in children younger than 2 years have been received via the Yellow Card scheme. Moreover, the Commission noted a lack of robust evidence for the efficacy of these medicines in children. It was noted that medication does not affect the course of the illness: it can only provide, at best, symptomatic relief.

Information for these medicines contains age-appropriate dose advice and many are sold under the supervision of a pharmacist. However, parents and carers may be unaware of the risk of overdose that results from the simultaneous use of different products that may duplicate ingredients. The small body size of children younger than 2 years increases the risk of serious adverse events from such dosing errors.

Both the Expert Advisory Group and the Commission concluded, on the basis of available evidence, that the balance of risks and benefits associated with the use of cough and cold medicines for children younger than 2 years is no longer favourable. Furthermore, the Commission advised that medicines in this therapeutic range that are suitable for children age 2–6 years should contain updated information.

Advice for healthcare professionals:

- Parents and carers should be encouraged to use the following medicines to alleviate the symptoms of coughs and colds in children: single-constituent paracetamol or ibuprofen; simple cough medicines (eg, those that contain glycerol or honey and lemon); vapour rubs and inhalant decongestants (which can be applied to a child's clothing); and, particularly in infants, saline nasal drops
- Non-prescription cough and cold medicines that contain the following active ingredients **should not be used in children younger than 2 years**:
 - brompheniramine, chlorphenamine, and diphenhydramine (antihistamines)
 - dextrometorphan and pholcodine (antitussives)
 - guaifenesin and ipecacuanha (expectorants)
 - phenylephrine, pseudoephedrine, ephedrine, oxymetazoline, and xylometazoline (decongestants)
- Products that contain these active substances and that are licensed for use in **children age 2–6 years** will be updated to include: information on maximum daily dose; a warning not to take other cough and cold medicines at the same time; and an instruction for parents or carers to seek the advice of a pharmacist or other healthcare professional before using the medicine
- For **children older than 2 years**, cough and cold medicines are considered safe at the recommended doses, which should be followed carefully and not exceeded. Parents and carers should be advised not to give a child more than one cough and cold medicine because different brands may contain the same active ingredient(s)

I hope that you find this information useful to your practice. Further information, including an information leaflet for parents and carers, is available at www.mhra.gov.uk

Rosalind Smyth

Chair of the Paediatric Medicines Expert Advisory Group and Brough Professor of Paediatric Medicine, University of Liverpool, Alder Hey Children's Hospital, Liverpool

Treating your child's cough and cold



Coughs and colds in children, toddlers and babies can be distressing for both you and your child but they will get better by themselves within a few days.

Here are three simple steps to help your baby, toddler or child who has a cough or cold:

1. Use either paracetamol or ibuprofen to relieve pain and lower your child's temperature if they are uncomfortably hot.
2. For a cough, simple cough mixtures containing glycerol, honey and lemon are best. For children over two a range of over-the-counter cough medicines are available.
3. Vapour rubs and inhalant decongestants, which can be applied to a child's clothing, can be used to provide relief from a stuffy or blocked nose. In addition, for children under two, particularly those who are having difficulty feeding, plain saline nose drops from the pharmacy can be used to help thin and clear secretions.

Remember:

- Always read the medicine label and follow the advice.
- Always stick to the recommended dose.
- Do not use more than one cough or cold medicine at the same time.

If you are concerned about your child, particularly if they are under 2 years old, or about the correct medicine to use, then speak to your pharmacist, health visitor or nurse.