

Q & A for children's cough and cold medicines

1. What was the outcome of the MHRA review?

Following the MHRA review of all available evidence, the Commission on Human Medicines (CHM) has advised on a comprehensive package of measures to improve the safe use of cough and cold medicines in children under 12. The Commission advised that over-the-counter (OTC) cough and cold products should no longer be used in children under 6 years, because the balance of benefits and risks has not been shown to be favourable. The Commission also advised that those OTC cough and cold medicines which can continue to be available for 6 to 12 year olds will only be sold in pharmacies, with clearer advice on the packaging and from the pharmacist.

2. Which cough and cold remedies for children are affected?

OTC cough and cold remedies (including oral preparations and nasal drops) containing the following ingredients; nasal decongestants (pseudoephedrine, ephedrine, phenylephrine, oxymetazoline and xylometazoline), antihistamines (diphenhydramine, chlorphenamine bromopheniramine, promethazine, triprolidine and doxylamine), antitussives (dextromethorphan and pholcodine), and expectorants (guaifenesin and ipecacuanha).

3. Don't cough and cold medicines for children work?

There is no robust evidence that they work. At the time that many of these products were authorised it was assumed that medicines worked the same way in adults and children and dosing in children was estimated from that in adults; and clinical trials were not routinely done in children. However, we better understand now that children are not 'little adults'. Although some of the products have been available for many years, we are now working towards medicines properly designed and tested for children. The CHM has advised that research is needed on how effective the medicines are in children over 6.

4. Why should these products not be used only in children under 6

Despite the fact that these medicines have been used for many years in children there is no robust evidence that they work, and very rarely they can cause side effects, such as allergic reactions, effects on sleep or hallucinations. The risks of these effects reduces in older children because they weigh more, they get fewer colds and can say if the medicine is doing any good. Body weight can affect how medicines work, and some children between 2 and 6 years may weigh the same as other children who are less than 2 years. On reviewing all the evidence available, the CHM has advised that the balance of risks and benefits is unfavourable in children under 6.

5. Hasn't the MHRA already given advice on this?

In March 2008 the CHM gave advice based on a preliminary review that children under 2 may be at particular risk from any side effects of these medicines, especially if given in overdose, because of their small size, and that these medicines should not be used in under 2s. We took action to change the label and remove the dosage for under 2s. The latest announcement is a result of a review of all the available data, including data from available studies in children under 12 years.

6. If there is a problem why are these products not being recalled?

Recalling these products would not be proportionate compared to the very small risk of side effects. Many products are licensed for adults and older children and so cannot simply be withdrawn. New products with updated labelling will be phased in and will be accompanied by an educational material regarding best treatment for cough and cold in children. Advice for parents and carers on treating a cough and cold can be found in the Department of Health book "Birth to 5" and a summary of this will be in the leaflets provided with these medicines.

7. Do I need to worry if I have just given one of these medicines to my child?

Provided that the child has been given the dose as recommended on the bottle, you do not need to worry; but if you have concerns about the condition of your child, you should contact a health professional - for example, by calling NHS Direct on **0845 46 47**. You should review the medicines which you have, to see whether there are any which you no longer need: these can be taken to any pharmacy for disposal.

8. So what should we do when a child has a cough/cold?

Cough and colds are self limiting conditions and will usually get better by themselves. Simple measures such as ensuring your child has plenty to drink and gets enough rest will help. Paracetamol or ibuprofen can also be used to reduce your child's temperature. For young babies, particularly those who are having difficulty feeding, nasal saline drops are available to help thin and clear nasal secretions. If your child is over the age of one, a warm drink of lemon and honey may help to ease a cough. If your child is not getting better after 5 days, ask a health professional for advice.

9. Are these products safe and effective for adults? Should adults still use them?

Standards for clinical trials have become much stricter since many of the early studies on cough and cold products. However, there is not a safety concern

with the use of these products in adults as long as dosage instructions are followed.