

28 February 2009

Dear Colleague

Over-the-counter cough and cold medicines for children

Issue

The Commission on Human Medicines (CHM) has advised on a package of measures to improve the safe use of cough and cold medicines for children under 12 years.

This follows a thorough review of the benefits and possible risks of over-the counter (OTC) cough and cold medicines for children under 12 years, which was recently completed by the Medicines and Healthcare products Regulatory Agency (MHRA).

New advice

Overall this comprehensive package includes changes to age ranges, introduces new advice on labelling, introduces child resistant packaging (to help prevent overdoses) and recommends research into how effective the medicines are in children over 6.

Key points are:

- Cough and cold remedies containing certain ingredients should no longer be used in children under 6 as the balance of benefits and risk has not been shown to be favourable.
- Products for children from 6 to 12 will continue to be available in pharmacies where advice can be given.
- Medicines to treat cough and colds in older children (6 to 12) can be considered after basic principles of best care have been tried.
- Some combinations which are illogical (such as cough suppressants and expectorants) are being phased out.
- All liquid products containing these ingredients will be in a child resistant container.

Products affected

OTC (non-prescription) cough and cold medicines containing the following active ingredients are affected by the advice:

- **Antitussives:** dextromethorphan and pholcodine

- **Expectorants:** guaifenesin and ipecacuanha
- **Nasal decongestants:** ephedrine, oxymetazoline, phenylephrine, pseudoephedrine and xylometazoline
- **Antihistamines:** brompheniramine, chlorphenamine, diphenhydramine, doxylamine, promethazine and triprolidine

A list of branded products is attached at Annex 1.

Timing

Newly packaged products reflecting the above advice will start to be introduced to pharmacies later this year in time for the 2009/10 winter cough and cold season. In the meantime medicines with the older labelling will continue to be available and can be supplied for use by older children and adults.

Immediate withdrawal of products with older labelling is not necessary because of their established use over many decades. This is consistent with the phased approach being taken to the introduction of the package of measures. Many products are used in adults and children and a total removal would leave gaps in the market, and would not be a proportionate response.

Products currently authorised with General Sales List (GSL) legal status may continue to be sold on open shelves and remain available through other retail outlets, such as supermarkets, until the new packaging reflecting Pharmacy (P) legal status becomes available.

We expect the change to be complete by March 2010.

Background

Colds and coughs occur frequently in children but they are self-limiting and rarely harmful if left untreated. Coughs have a physiological function of clearing mucus secretions from the airways.

Many medicines given to children have not been properly studied in this population. Specific paediatric studies are needed because of differences between adults and children in drug handling or drug effects, which may lead to different dose requirements. The MHRA is working hard to improve the availability of high-quality, ethically researched and properly authorised [medicines for children](#).

Furthermore, OTC cold and cough remedies, which have been in use for a very long time, were introduced when the requirement to demonstrate safety and efficacy was less robust compared to today's standards. However, over the years, the products have raised no special concern about safety.

The MHRA review examined both the safety and efficacy of children's cough and cold medicines containing the above ingredients; CHM concluded that:

- There is no robust evidence that cold and cough medicines containing the above ingredients work. Given that there have been some reports of harm with these ingredients, the risks of cough and cold medicines containing them outweigh the benefits;
- For children aged over 6 years, the risk from these ingredients is reduced because: they suffer from cough and cold less frequently and consequently require medicines less often; with increased age and size, they tolerate the medicines better; and they can say if the medicine is working. For these reasons cold and cough medicines containing the above ingredients can continue to be available for these older children, but only through pharmacies;
- Further research is required on how effective these products are in children over 6 years.

Advice on treating cough and cold in children

Helpful advice for parents and carers on the basic principles of best care for children with coughs and colds of all ages can be found in the Department of Health book "Birth to 5" and an extract is attached at Annex 2. Key aspects of this advice will be reflected in new Patient Information Leaflets accompanying all licensed products containing the active substances included in the review.

In addition, the industry trade association the Proprietary Association of Great Britain (PAGB) is arranging the distribution of a leaflet that will be available in pharmacies and is also available through the website links.

Further Information

For further information on this advice please contact the MHRA Information Centre on 020 7084 2000, email info@mhra.gsi.gov.uk, web address www.mhra.gov.uk

Yours sincerely

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Annex 1

Children's cough and cold medicines – Lists of products

An updated list of products is available on our website at:

http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON038907&RevisionSelectionMethod=LatestReleased

Annex 2

Extract from “Birth to Five” - Department of Health 2007

COLDS

It may seem that your child always has a cold or upper respiratory tract infection. In fact it is normal for a child to have a cold eight or more times a year. This is because there are hundreds of different viruses and young children are meeting each one of them for the first time. Gradually they build up immunity and get fewer colds. Here are some suggestions on how to treat colds.

- Because colds are caused by viruses, not bacteria, antibiotics don't help. It is also best for antibiotics to be used only for more serious illnesses.
- Most colds will get better in five to seven days.
- Cough and cold medicines have not been shown to work and may produce side-effects in young children. They may also cause poisoning if your child accidentally swallows more than the right dose.
- Stuffiness may be made worse by nasal decongestants; if these are necessary they should only be used for two to three days.
- Saline nose drops may help to loosen dried nasal secretions or a stuffy nose – ask your pharmacist, GP or health visitor about these.
- Tickling the nose with a teased cotton bud causes sneezing and is helpful for clearing the nose before feeding.
- Increase the amount of fluid your child normally drinks.
- A pillow or blanket put under the baby's mattress to raise the head may help snuffly babies breathe more easily.
- Fever and pain can be treated with the correct dose of paracetamol for your child's age or with junior ibuprofen. Don't use adult products/doses for children.
- Encourage all the family to wash their hands to prevent the spread of colds from infected secretions.

COUGHS

Children may also cough when they have a cold because of mucus trickling down the back of the throat. If your child is feeding, eating and breathing normally and there is no wheezing, a cough is not usually anything to worry about. But if your child has a bad cough that won't go away, see your GP. If your child has a temperature and cough and/or is breathless, this may indicate an infection on the chest. If the cause is bacteria and not a virus, your GP will prescribe antibiotics to treat this – although it won't soothe or stop the cough straight away.

- If a cough continues for a long time, especially if it is more troublesome at night or is brought on by your child running about, it might be a sign of asthma. Some children with asthma also have a wheeze or some breathlessness. If your child has any of these symptoms, he or she should be seen by your GP. If your child seems to be having trouble breathing, contact your GP, even in the middle of the night.
- Although it is distressing to hear your child cough, in fact coughing serves a purpose. When there is phlegm on the chest, or mucus from the nose runs down the back of the throat, coughing clears it away. Most doctors believe cough mixtures do not work and are a waste of money. To ease your child's cough, give him or her plenty of warm, clear fluids to drink. If your child is over the age of one, try a warm drink of lemon and honey. There is no need to try to stop the cough completely.