



Use of Children's Cough and Cold Medicines

MHRA has recommended that medicines containing certain ingredients specifically intended to relieve cough and cold symptoms and relieve congestion should no longer be used in children under 6 years of age and in future they will not be marketed for them. MHRA emphasises that parents using the products for children, or who have used them in the past, do not need to worry. The change is happening mainly because the clinical data which would be required for new products these days is not available for the children's cough and cold remedies which have been on the market for decades.

Most of the products containing these medicines affected by the new advice are sold only in pharmacies under the supervision of a pharmacist or a trained assistant. Products do not need to be cleared from the shelves.

This does not affect single ingredient pain relievers containing paracetamol and ibuprofen given to lower temperature in children with colds. Those medicines have been extensively studied in children and their safety and effectiveness is not in question.

The cough and cold medicines which are no longer recommended for children under 6 contain the ingredients below:

- Brompheniramine, chlorphenamine, diphenhydramine, doxylamine, promethazine and triprolidine (antihistamines)
- Dextromethorphan and pholcodine (Antitussives to suppress cough)
- Guaifenesin and ipecacuanha (Expectorants)
- Phenylephrine, pseudoephedrine, ephedrine, oxymetazoline and xylometazoline (decongestants)

Sheila Kelly, PAGB Executive Director comments "Industry is supporting the MHRA in promoting this new advice. Over the next few days a million leaflets will be sent to all pharmacies in the UK to help parents who will be asking how to treat their children's cough and colds. Companies who make children's cough and cold medicines have voluntarily agreed to change the labels on products to remove the dosage instructions for children under 6. This will take place as soon as possible



over the next cough and cold season during the winter of 2009/2010. Many products are already in child resistant containers and the rest will introduce them as soon as possible.”

“Children’s cough and cold medicines have been used over many decades with tens of billions of doses administered but they were designed at a time when it was not considered ethical to conduct clinical trials in children and the evidence of efficacy is based on studies carried out in adults.”

“PAGB and its member companies continue to have confidence in the value that these medicines have in the management of children’s coughs and colds for children over 6 years. Products continue to be available for this older age group and manufacturers are committed to developing the robust evidence base that is now required. A clinical research program has already begun in the United States.”

Parents and carers are reminded that if they have questions to consult with a health care professional such as a doctor or pharmacist. Specifically, parents and carers should follow these rules when treating their children with cough and cold medicines:

- For all children with temperatures try simple treatments with paracetamol or ibuprofen products in the first instance.
 - For children over one year a cough can be treated with a simple cough syrup containing honey and lemon.
 - Children with blocked noses can be given saline nasal drops or vapour products that you can put on their chests or clothing.
- If your child is over 6 years then many cough and cold treatments can still be given. Ask your pharmacist for advice on the best products to try.
- Never give a cough or cold medicine to your child unless it has specific dosing instructions for their age group.
- If you are ever unsure about the appropriate use of a medicine for your child, consult your pharmacist or other healthcare professional.

- ENDS -

PAGB (Proprietary Association of Great Britain) is the UK trade association representing manufacturers of over-the-counter medicines and food supplements.



A list of the products that **can still be given** to children under 6 years can be found at:

<http://www.pagb.co.uk/pressarea/releases/Productlistcanbegiven28.2.09.pdf>

A list of the products that are being relabelled to remove the doses for children under 6 years can be found at:

<http://www.pagb.co.uk/pressarea/releases/Productlistrelabelled28.2.09.pdf>

The leaflet that is being distributed to pharmacies can be downloaded from:

<http://www.pagb.co.uk/pressarea/releases/Coughcoldleaflet2009.pdf>

Contacts

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