



Royal Pharmaceutical Society of Great Britain

Law and Ethics Bulletin

Advice on the use of cough and cold products in children

This bulletin aims to provide additional information on the Medicines and Healthcare products Regulatory Agency (MHRA) advice (see www.mhra.gov.uk) on the use of cough and cold products in children under two years of age.

The MHRA reviewed the safety and efficacy of cough and cold products in children and advised that cough and cold products containing certain active ingredients will no longer be licensed for children under the age of two years.

The active ingredients involved are:

- Brompheniramine, chlorphenamine and diphenhydramine (antihistamines)
- Dextromethorphan and pholcodine (antitussives)
- Guaifenesin and ipecacuanha (expectorants)
- Phenylephrine, pseudoephedrine, ephedrine, oxymetazoline and xylometazoline (decongestants)

The Royal Pharmaceutical Society issued guidance in response to the MHRA advice (available at www.rpsgb.org/pdfs/treatmentcoughscoldschildren.pdf) and recommended that pharmacists review how these products are stored and sold.

Products with updated advice on their packaging and in the patient information leaflets should be in pharmacies and stores by October 2008. In the meantime, a leaflet for parents and carers is available with additional information concerning management of coughs and colds in children, toddlers and babies (see www.pagb.co.uk).

Non-pharmacy outlets have been informed of the situation via the British Retail Consortium.

Products directly targeted at children under two years to be removed from open display

Six products directly targeted at children under two years (ie, positioned for young babies because of their name, pictures of babies on the pack, etc) should be removed from open display until they have been repackaged with new dosage instructions and updated advice. They will still be available under the supervision of a pharmacist, for children over the age of two years.

- Asda Childrens Chesty Cough Syrup
- Boots Chesty Cough Syrup 1 yr Plus
- Boots Sore Throat and Cough Linctus 1 yr Plus
- Buttercup Infant Cough Syrup
- CalCough Chesty
- Childrens Chesty Cough (Bell's)

Products authorised for use in children up to six years of age

Single ingredient analgesic products containing paracetamol and ibuprofen are not affected. Parents can still give these to children to manage pain and fever.

The MHRA website contains a table entitled 'Products authorised for use in children up to 6 years of age which can be sold as before'. The products cited in the table should no longer be supplied for use in under-twos but, because they are not directly marketed at this age group, they do not need to be removed from open display. This list is as fully comprehensive as the MHRA could make it. However it should be noted that not all products are currently marketed and some products have more than one authorised product name and may be marketed under alternative names.

If a medicine has more than one indication but includes coughs and colds, the advice on supply to under-twos still applies even if the product is not specifically being sought for management of coughs and colds.

The advice on supply to under-twos does not apply to any products that do not have cough or colds included as part of the licensed indications.