



**Royal
Pharmaceutical
Society**
of Great Britain

Law and Ethics Bulletin

Updated advice on the use of cough and cold products in children under 12

This bulletin aims to provide additional information on the Medicines and Healthcare products Regulatory Agency (MHRA) new advice (see www.mhra.gov.uk) on the use of cough and cold products for children under 12 years of age.¹

Following a thorough review of the use of cough and cold medicines in children under 12, the MHRA announced (28th February 2008) a 'package of measures' to improve their safe use. A 'Healthcare Professional' letter was circulated by the MHRA and contained lists by brand-name of products affected by the new MHRA advice. Following feedback from the national pharmacy bodies Lists 2 and 3 in the MHRA letter have been consolidated into a single list of those products which can still be given to children over 6 years of age (see <http://www.rpsgb.org/worldofpharmacy/useofmedicines/>).

MHRA advice

- Cough and cold medicines containing the ingredients reviewed should not be used in children under 6.
- Cough and cold medicines for 6 to 12 year olds containing the ingredients reviewed will continue to be available in pharmacies where advice can be given.
- Products for children of 6 to 12 years containing the ingredients reviewed should be indicated for use "second line" to standard best care, and with duration of use restricted to no more than five days.
- Cough and cold medicines for 6 to 12 year olds should have strengthened warnings on the packaging and labelling.
- Some combination products for children under 12 years are being phased out.
- All liquid cough and cold medicines (including those for adults) should be supplied in a child resistant container. This will be implemented in the longer term.

Products affected

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

¹ This bulletin supplements previous advice (1 April 2008) concerning the use of cough and cold products in children under 2 years of age (<http://www.rpsgb.org/pdfs/LEBcoughcoldprodchildren.pdf>).

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

The RPSGB website contains the following lists² by brand-name of products affected:

List 1: Which products can I still give to my child under 6 years of age?

List 2: Children's cough and cold products which can still be given to children over 6 years of age

The MHRA (on advice from the Commission on Human Medicines)³ has advised healthcare professionals that if a product is cited in list 2 it should only be used to treat children over 6 years of age. The list is not exhaustive. If a particular OTC cough and cold medicine is not included check the ingredient(s) and follow the MHRA advice set out above if the product contains one or more of the ingredients reviewed.

The packaging of these products will be changed over time to reflect these changes. Products with updated advice on the packaging will start to appear in pharmacies later this year in time for the 2009/10 winter cough and cold season. The change is expected to be completed by March 2010. In the meantime medicines with the older labelling will continue to be available and can be supplied for use by older children and adults.

The MHRA has stated that immediate withdrawal of products is not necessary because of their established use over many decades and as many of these products are used by older children and adults a total removal would leave gaps in the market and would not be a proportionate response based on the possible risks.

Products currently classified as General Sales List (GSL) medicines may continue to be sold on open shelves in the pharmacy and also remain available through other non-pharmacy retail outlets, until the new packaging reflecting Pharmacy (P) legal status becomes available. Pharmacists stocking these products are advised to follow the MHRA advice and not supply these products for children under 6. Pharmacists should review their standard operating procedures and ensure that their staff are fully aware of these changes.

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

The Society recognises that this is a complex message for parents and pharmacists alike. There will in effect be a period of time when the packaging of products will be out of line with the advice provided from healthcare professionals.

² The 'Healthcare Professional' letter circulated by the MHRA on the 28th February 2009 contained 3 lists of brand-name products affected by the new MHRA advice. Lists 2 and 3 from the MHRA website have been consolidated into a single list covering products suitable for children over 6 years of age, See www.rpsgb.org. Some products on the revised list will be relabelled to remove the doses for children under 6 years (a few will also have the doses for under 12 years removed).

³ Until the changes to the Marketing Authorisations of the products are made it will not be illegal to supply these products, however the RPSGB advises that pharmacists follow the MHRA advice.

More research is being done by industry on how well these medicines work in children aged 6-12 years.