



**Royal
Pharmaceutical
Society
of Great Britain**

Good Practice in the Treatment of Coughs and Colds in Children

The Society is issuing this guidance in light of the Medicines and Healthcare products Regulatory Agency (MHRA) decision to review the sale and supply of cough and cold products to children less than 2 years of age.

The MHRA came to their decision to restrict these products after a thorough review of the evidence on both safety and efficacy. The safety concerns were linked to reported adverse effects and overdoses in the under 2's in particular. Children under 2 years old can be particularly sensitive to overdose because of their small size and different pharmacokinetics and pharmacodynamics. The evidence of efficacy of nasal decongestants and over the counter medicines for acute cough in children has recently been reviewed by the Cochrane Collaboration (1) (2). The conclusions of these reviews were that there is insufficient data to recommend the use of nasal decongestants in children under 12 and no good evidence for or against the effectiveness of OTC medicines in acute cough.

The MHRA is continuing their review of the use of these products in children over 2 years old.

It is good practice to restrict the use of over the counter products for the treatment of cough and cold symptoms in children under 2 years old to the following: -

1. Paracetamol or ibuprofen to relieve pain and lower temperature (3)
2. Simple non-pharmacological cough mixtures for the treatment of coughs (for example paediatric simple linctus or those containing glycerol or honey and lemon) (4)

3. Vapour rubs and inhalant decongestants which can be applied to children's clothing to provide relief of stuffy or blocked nose for children and infants over 3 months. Saline (Sodium Chloride 0.9%) nose drops can be helpful particularly in infants who are having difficulty feeding.

The same principles can be applied to children over 2 years old, although there are a range of other over the counter cough medicines that may be given to children over 2.

We recommend that pharmacists review how products marketed for the treatment of coughs and colds in children are stored and sold (see Appendix).

The MHRA will shortly be issuing its own advice for healthcare professionals on the sale and supply of cough and cold medicines to children.

Appendix

The following products directly targeted at children under 2 should be removed from open shelves:

- Asda Children's Chesty Cough Syrup [PL 03105/0056 – MAH: Bell's]
- Boots Chesty Cough Syrup 1 Year Plus [PL 00014/0381 – MAH: Boots]
- Boots Sore Throat and Cough Linctus 1 Year Plus [PL 00014/5152R – MAH: Boots]
- Buttercup Infant Cough Syrup [PL 02855/0022 – MAH: Chefaro]
- CalCough Chesty [PL 15513/0052 – MAH: McNeil]
- Children's Chesty Cough [PL 03105/0056 – MAH: Bell's]

- these medicines can still be supplied under the supervision of a pharmacist for older children.

Advice for healthcare professionals:

- Parents and carers should be encouraged to use the following medicines to alleviate the symptoms of coughs and colds in children: single-constituent paracetamol or ibuprofen; simple cough medicines (eg, those that contain glycerol or honey and lemon);

vapour rubs and inhalant decongestants (which can be applied to a child's clothing); and, particularly in infants, saline nasal drops

- Non-prescription cough and cold medicines that contain the following active ingredients should not be used in children younger than 2 years:

- brompheniramine, chlorphenamine, and diphenhydramine (antihistamines)

- dextrometorphan and pholcodine (antitussives)

- guaifenesin and ipecacuanha (expectorants)

- phenylephrine, pseudoephedrine, ephedrine, oxymetazoline, and xylometazoline (decongestants)

- Products that contain these active substances and that are licensed for use in children age 2–6 years will be updated to include: information on maximum daily dose; a warning not to take other cough and cold medicines at the same time; and an instruction for parents or carers to seek the advice of a pharmacist or other healthcare professional before using the medicine

- For children older than 2 years, cough and cold medicines are considered safe at the recommended doses, which should be followed carefully and not exceeded. Parents and carers should be advised not to give a child more than one cough and cold medicine because different brands may contain the same active ingredient(s)

References:

^[1] Taverner D, Latte J. Cochrane Database of Systematic Reviews 2007

² Smith SM, Schroeder K, Fahey T. Cochrane Database of Systematic Reviews 2008

³ Please note that these products may only be licensed for use in children over 2 or 3 months respectively (see packs for details)

⁴ Please note that some of these products may only be licensed for use in children over 3 months (see packs for details)