

Malta, 02 March 2009  
Circular No. P06/2009

## Re: Use of over-the-counter cough and cold medicines in children - Update

The Medicines and Healthcare Products Regulatory Agency (MHRA), UK has recently announced a package of measures to promote the safe use of over-the-counter (OTC) cough and cold medicines for children under 12 years. This follows a thorough review of the benefits and risks of these medicines.<sup>1</sup>

The new package represents a move towards improving the balance of benefits and risks for these medicines. The Medicines Authority is in agreement with the MHRA's position in relation to the recommended treatment measures to be adopted with this class of medicines and is, therefore, issuing this circular to provide relevant information and advice to healthcare professionals and patients.

The review has found no robust evidence that these medicines are effective. The products can, however, cause side-effects such as allergic reactions, effects on sleep or hallucinations.

OTC cough and cold medicines containing the reviewed ingredients should, therefore, no longer be administered to children under 6 years of age unless otherwise prescribed by a physician. In Malta, these medicines are available only in pharmacies and as such they will no longer be dispensed over the counter for children under the age of 6. For 6 to 12 year olds these medicines will continue to be available over the counter since the risks of side effects in this age group are reduced. Use of these products in 6 to 12 year olds should nevertheless be adopted as 'second line' care to simple treatment measures (refer below) and duration of use should be restricted to no more than 5 days. More research is currently underway to determine the effectiveness of these medicines in children aged 6-12 years.

It is important to point out that coughs and colds will many times get better by themselves and within a few days. It is also important to keep in mind that medicines which may be safe and effective in adults may not necessarily be suitable for use in children on the assumption that they are 'small adults'. Simple measures to ease symptoms are therefore recommended in such circumstances. Such measures include increased fluid intake (especially warm clear fluids), use of saline nose drops, slight elevation of the child's head while sleeping to ease breathing, use of simple paracetamol preparations in case of fever and pain, and regular washing of hands to prevent further spread of colds.<sup>2</sup>

Industry has agreed to implement the above-mentioned changes to cough and cold product labelling to reflect the new prescribing recommendations. Newly labelled products supplied in child-resistant containers are expected for the 2009/2010 winter cough and cold season.

Medicines with the old labelling will not be cleared off the shelves since there are no specific safety concerns and many of these products are currently in use by adults and older children.

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<sup>1</sup> The review was carried out on medicines containing the following active ingredients:

- Brompheniramine, chlorpheniramine, diphenhydramine, doxylamine, promethazine and triprolidine (antihistamines);
- Dextromethorphan and pholcodine (antitussives);
- Guaifenesin and ipecacuanha (expectorants);
- Phenylephrine, pseudoephedrine, ephedrine, oxymetazoline and xylometazoline (nasal decongestants).

<sup>2</sup> Medical attention should, however, be sought immediately, if the cough persists for a long time, especially if it is more troublesome at night, or if it is accompanied by breathlessness, or if it is brought on by the child running about.