

Monday, 2nd March 2009

**New MHRA advice on Children's Coughs and Colds
Medicines is Precautionary and Proportionate**

The Pharmaceutical Society of Northern Ireland has welcomed the completion of a review by the Medicines and Healthcare Regulatory Agency (MHRA) into the use of Over-the-Counter (OTC) cough and cold medicines for children under 12 years old.

The review did not identify any heightened safety issues associated with the use of such medicines for children, but did find evidence to suggest the efficacy of their use is more limited than previously considered. Therefore, in view of potential side effects, such as allergic reactions and effects on sleep or hallucinations, the MHRA are recommending that parents and carers no longer administer OTC cough and cold medicines to children under 6 years of age.

The Pharmaceutical Society of Northern Ireland has issued the following statement in response:

“The clarity of the MHRA’s advice on cough and cold medicines for children under 6 is to be welcomed. However, there is no cause for public alarm or undue concern as this is largely a precautionary move based on a review of the balance of risk – the risk has not grown, but the assessed benefit has declined.

“We advise parents and carers in Northern Ireland to always ask their pharmacist about the best ways to relieve a child’s ailments, especially cough and colds. It is essential whatever medicines are being administered to always read information leaflets enclosed within children’s medicines carefully and to store all medicines out of a child’s reach.”

Ends

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Editor's notes

1. The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacy in Northern Ireland. Its principal objective is the protection of patient safety in the provision of pharmacy services in Northern Ireland.
2. The Registrar of the Pharmaceutical Society of Northern Ireland is available for interview on the numbers given above.
3. The core advice issued by the MHRA is:
 - 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, with clearer advice on the packaging/labeling from the pharmacist
 - Cough and cold medicines for 6 to 12 year olds should have strengthened warnings on the packaging and labeling
 - Products for children of 6 to 12 years old containing the ingredients reviewed should be indicated for use "second line" to standard best care, and with the duration of use restricted to no more than five days
 - All liquid cough and cold medicines (including those for adults) should be supplied in a child resistant container
4. The active medicine ingredients reviewed were: antihistamines, nasal decongestants, expectorants and antitussives. A list of branded products affected can be found in Annex 1 of the Healthcare Professional letter attached to the MHRA press release:

<http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON038902>

5. No product recall has been deemed necessary although new products reflecting the above advice will be introduced in pharmacies later this year in time for the 2009/10 winter cough and cold season.

6. More details of the advice are available on the MHRA website below:

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON038908>