

Press release

Date: 28 February 2009

Time: 17:15

Subject: Children's over-the-counter cough and cold medicines

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Better medicines for children's coughs and colds

The Medicines and Healthcare products Regulatory Agency (MHRA) has announced today a comprehensive package of measures to promote the safer use of over-the-counter (OTC) cough and cold medicines for children under 12 years old. This follows the MHRA's thorough review of the benefits and risks of these medicines.

On advice from the Commission on Human Medicines (CHM), the new package represents a proportionate move to improving the balance of risks and benefits for these medicines. People using these products for children, or have used them in the past, do not need to worry. Neither do shelves need to be cleared.

The MHRA review did not identify in this age-group the safety issues of the kind which prompted our action in under-2s in March 2008. But the review found no robust evidence that these medicines work and they can cause side effects, such as allergic reactions, effects on sleep or hallucinations.

Parents and carers should no longer use OTC cough and cold medicines containing the ingredients reviewed in children under 6. They should follow advice to relieve symptoms as outlined in the Department of Health's 2007 guidance 'Birth to Five'. For 6 to 12 year olds these medicines will continue to be available but will only be sold in pharmacies, with clearer advice on the packaging and from the pharmacist. This is because the risks of side effects is reduced in older children because they weigh more, get fewer colds and can say if the medicine is doing any good. More research is being done by industry on how well these medicines work in children aged 6-12 years.

MHRA Director of Vigilance and Risk Management of Medicines, Dr June Raine said, "Coughs and colds can be distressing for both you and your child but they will get better by themselves within a few days. Using simple measures to ease symptoms is likely to be most effective.

"Over-the-counter medicines used to treat coughs and colds have been used for many years. However they came into use when clinical trials were not required to demonstrate that they worked in children. This means they were not specially designed for children.

“It is not right to assume safety and efficacy based on children being ‘small adults’. Children should have access to medicines that are acceptably safe and designed for their use.”

The MHRA is working with industry and healthcare professionals to encourage ‘best practice’ and implement these measures. Industry has agreed to implement changes over a period of time. They will make the necessary labelling changes to state that these medicines should not be used in children under 6, introduce updated labelling, and to change the legal status of medicines authorised for children aged 6 – 12 years from general sale (GSL) to pharmacy (P). Newly labelled products will start to appear for the 2009 cough and cold season. Medicines with the old labelling will not be cleared off shelves. This is because many of these products are used in adults and children, and so cannot be withdrawn, creating a shortage of these medicines. Withdrawing these medicines would not be proportionate compared to the risk of side effects. These changes should be completed by March 2010.

Ends

Notes to editors:

1. Following the MHRA’s review, the findings were passed to The Commission on Human Medicines (CHM) - the Government’s independent expert advisors – for advice. It is this advice that forms the package of measures announced today:
 - 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/labelling and from the pharmacist.
 - 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.
 - All liquid cough and cold medicines (including those for adults) should be supplied in a child resistant container.

2. The move towards ensuring all liquid cough and cold medicines (including those for adults) are supplied in a child resistant container will be implemented longer-term.
3. As there are no specific safety concerns with these medicines, companies will be allowed to “sell through” their products. In the meantime these medicines can still be used but it is preferable that people follow the ‘best practice’ advice.
4. A link to the Department of Health’s 2007 guidance ‘Birth to Five’ can be found at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/dh_074924
5. The MHRA provided preliminary advice in March 2008 for the treatment of cough and colds in children under 2 stating that these medicines should not be used (as well as stronger warnings to seek advice from a healthcare professional for children aged 2 to 6 years).
6. The MHRA takes the safety of medicines for children very seriously. That is why we led in Europe on pushing through important changes to the way children’s medicines are currently developed and used. Further information can be found at:
<http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesforchildren/index.htm>
7. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. We encourage everyone –the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action.
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