

## Children's Cough and Cold Medicines – United Kingdom – the facts

Millions of doses of cold remedies are given to children in the UK every year to safely treat their coughs and colds. All the medicines are individually assessed by the Medicines and Healthcare products Regulatory Agency (MHRA) for safety and efficacy before they are marketed. People trust these medicines and buy them time and again because they work for them to relieve their children's cold symptoms.

The safety of all medicinal products is constantly monitored while they are on the market. Manufacturers are legally obliged to actively monitor and to report to the MHRA any adverse effects reported to them by a consumer or health professional. Health professionals, parents and carers can report adverse effects directly to the MHRA.

The MHRA has just reviewed all the adverse effects reports for children's medicines sent in over the last 40 years. This confirms that there are no safety concerns about children's cough and cold medicines in the UK for children over 2. Following this review the Agency has issued a drug safety bulletin to health professionals in which the chairman of its expert group on paediatric medicines advises that parents can continue to give medicines to children over 2 according to the label directions.

The adverse effects reports showed 5 deaths in 40 years, all of them involving children under 2 and most likely due to overdose. Manufacturers have voluntarily agreed to remove the doses for under 2s from the packs and are working now to do that as soon as possible. Meanwhile, health professionals have been advised to tell parents that when children under 2 have colds they should be treated with paracetamol or ibuprofen to lower their temperature. If they have a cough a simple cough mixture based on honey or lemon or glycerol is recommended. Leaflets have been provided to get that information to the public.

Reference: Drug Safety Update (on PAGB website)

MHRA website: <http://www.mhra.gov.uk>