



NEWS RELEASE

Caring for Kids with Colds: Ensuring the Safe and Effective Use of Children's Cough and Cold Medicines

Ottawa, Ontario – December 18, 2008

NDMAC and the leading manufacturers of nonprescription children's cough and cold medicines have been working closely with Health Canada on measures aimed at ensuring the appropriate use of children's cough and cold medicines. In keeping with Health Canada's announcement today, industry will continue to move forward with plans to enhance the labelling and packaging of these products.

Health Canada has reviewed the safety and effectiveness of cough and cold medicines in children. While the safety of these products has been directly evaluated in children for decades, their effectiveness has historically been established through studies conducted in adults. Health Canada has determined that there is a need for new clinical trial data to directly establish the effectiveness of cough and cold medicines in children. In view of this, the labels of children's cough and cold medicines will be revised to limit their use to children six years of age and over and to include additional information supporting the safe use of these medicines in older children. All children's cough and cold medicines will be packaged in child resistant containers and will include accurate dosing devices. These changes will be phased in during the summer of 2009.

It is important to note that some products currently on store shelves intended for children six and older and/or for adults also have dosing instructions for children under the age of six. Health Canada has indicated that these products can continue to be used in children age six and older, as well as in adults, and will continue to be available on store shelves until the relabeling is completed.

When used as directed, children's cough and cold medicines have an excellent safety record, which has been established over many decades with tens of billions of doses administered. Research shows that dosing errors and unsupervised ingestions – not the safety of the ingredients themselves – are the primary causes of very rare adverse events in young children.

NDMAC and its member companies continue to have confidence in the value that these medicines have in the management of children's coughs and colds. Manufacturers are reaffirming the effectiveness of oral nonprescription pediatric cough and cold medicines through a multi-year clinical research program. The first phase of this program, pharmacokinetic studies to confirm the dosing schedules for some of these medicines, is already in the field.



“With the cough and cold season upon us, the nonprescription medicines industry, Health Canada and health professionals are all working together to help parents and caregivers treat their children’s coughs and colds,” said industry spokesperson Gerry Harrington.

Parents and caregivers are reminded that the key to ensuring the continued safe use of these products is to read and follow label directions carefully and, if any questions remain, to consult with a health care professional such as a doctor or pharmacist. Specifically, parents and caregivers should follow these rules when treating their children with cough and cold medicines:

- Always read and follow label directions carefully when giving any medicine to your child.
- Do not give cough and cold medicines to children under the age of six years.
- Never give a cough or cold medicine to your child unless it has specific dosing instructions for their age group.
- Do not use cough and cold medicines with any other medicines unless you consult your doctor or pharmacist first.
- Do not use cough and cold medicines containing antihistamines to calm children or help them get to sleep.
- When using medicines that come in liquid form, be sure to use an appropriate measuring spoon/device to administer the correct dosage. These are readily available in all pharmacies.
- Always keep all medicines out of the reach and sight of children and know the telephone number of your local poison control centre in the event that accidental ingestion of a medicine by a child does occur.
- If you are ever unsure about the appropriate use of a medicine for your child, consult a pharmacist, doctor or your provincial health information service (e.g. BC HealthGuide or Nurseline, Saskatchewan Healthline, Telehealth Ontario, Info Santé, etc.).

Finally, parents and caregivers should note that this initiative does not apply to single-ingredient children’s pain relievers and fever reducers. Those medicines have been extensively studied in children and their safety and effectiveness is not in question.

NDMAC is a 111 year-old trade association representing the self-care medicines industry, including the manufacturers of cough and cold remedies.

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