

Dear Provincial Colleague,

Health Canada has now made public its decision on the labelling of over-the-counter cough and cold medicines for children. By fall 2009, manufacturers will be required to relabel their products to indicate that they are not for use by children under the age of six. Information on the new requirements can be obtained at [www.healthcanada.gc.ca/coughandcold](http://www.healthcanada.gc.ca/coughandcold) or by calling 1-866-558-2946.

Since over-the-counter cough and cold medicines will remain on store shelves carrying dose information for children under the age of six until the relabeling is complete in fall 2009, Health Canada is leading an outreach campaign to provide information to stakeholders and the general public about use of these products during the current cough and cold season.

On our web site, you will find a variety of information, including Health Canada's Public Advisory, answers to frequently asked questions, a backgrounder, the report of Health Canada's Scientific Advisory Panel on over-the-counter cough and cold medicines for children, and awareness tools such as posters and leaflets for downloading and printing. **We hope that we can count on your collaboration to distribute this information electronically to appropriate locations.** By working together, we can provide the public with the most up-to-date information on children's cough and cold medicines.

For general information concerning this decision, please consult our Web site or call 1-866-558-2946. If you have questions about other aspects of the outreach strategy in your region, please see the list of contacts below to get in touch with Health Canada's Regional Public Involvement Officer for your area.

Yours truly,

Meena Ballentyne  
Assistant Deputy Minister  
Health Products and Food Branch

**Health Canada's Regional Public Involvement Officers:**

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# Advisory

## Health Canada Releases Decision on the Labelling of Cough and Cold Products for Children

**December 18, 2008**

**For immediate release**

**OTTAWA** – Health Canada is advising consumers of the outcome of its review of cough and cold medicines for children under the age of 12.

Health Canada is requiring manufacturers to relabel over-the-counter cough and cold medicines that have dosing information for children to indicate that these medicines should not be used in children under 6. The products affected are those containing any of the active ingredients listed below that are given orally:

**Table 1: Active Ingredients Affected by Health Canada’s Decision on Cough and Cold Products for Children**

Therapeutic Category (Purpose)	Active Ingredients
Antihistamines in cough and cold medicines (used to treat sneezing, runny nose)	brompheniramine maleate chlorpheniramine maleate clemastine hydrogen fumarate dexbrompheniramine maleate diphenhydramine hydrochloride diphenylpyraline hydrochloride doxylamine succinate pheniramine maleate phenyltoloxamine citrate promethazine hydrochloride pyrilamine maleate triprolidine hydrochloride
Antitussives (used to treat cough)	dextromethorphan dextromethorphan hydrobromide diphenhydramine hydrochloride
Expectorants (used to loosen mucus)	guaifenesin (glyceryl guaiacolate)
Decongestants (used to treat congestion)	ephedrine hydrochloride/sulphate phenylephrine hydrochloride/sulphate pseudoephedrine hydrochloride/sulphate

The relabelling of these medicines will be completed by fall 2009, in time for the next cough and cold season. [\(link to HC Notice\)](#) During the current cough and cold season, medicines

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will remain on store shelves and in homes with the current labelling, which could include dosing information for children under 6, because many of these products also have dosing information for adults and older children on the same label. As a result, for this cough and cold season, parents or caregivers should consult a pharmacist or a health care practitioner when buying or using these products. These medicines can still be used in children 6 and older, and adults.

This decision is the result of a Health Canada review of these medicines, including the input of a Scientific Advisory Panel convened in March 2008. Health Canada has concluded that while cough and cold medicines have a long history of use in children, there is limited evidence supporting the effectiveness of these products in children. In addition, reports of misuse, overdose and rare side-effects have raised concerns about the use of these medicines in children under 6. The rare but serious potential side-effects include convulsions, increased heart rate, decreased level of consciousness, abnormal heart rhythms and hallucinations. The Scientific Advisory Panel's conclusions and details of the new Health Canada recommendations are posted on the Health Canada Web site. [\(link to web page\)](#)

Health Canada previously issued advice on the use of these medicines in an October 2007 Public Advisory. [\(link to advisory\)](#) Based on a preliminary review, Health Canada at that time recommended not using over-the-counter cough and cold medicines in children under 2 years of age, unless instructed to do so by a health care practitioner. The current decision expands on those preliminary recommendations.

Until the relabelling of these products is completed, Health Canada advises parents and caregivers to follow these important guidelines:

- Do not use these over-the-counter cough and cold medicines in children under 6 years of age.
- With children older than 6, always follow all the instructions carefully, which includes the dosing and length-of-use directions, and use the dosing device if one is included.
- Do not give children medications labelled only for adults.
- Do not give more than one kind of cough and cold medicine to a child. Cough and cold medications often contain multiple ingredients. Combining products with the same ingredient(s) could cause an overdose that may result in harm to a child.
- Talk to your health care practitioner (doctor, pharmacist, nurse, etc.) if you have questions about the proper use of over-the counter cough and cold medicines.
- The common cold is a viral infection for which there is no cure. Cough and cold medicines offer only temporary relief of symptoms such as runny nose, cough, or nasal congestion. Symptoms can also be managed using a variety of non-medicinal measures such as adequate rest, increased fluid intake and a comfortable environment with adequate humidity.
- For babies and young children, it is important to rule out serious illnesses that have cold-like signs and symptoms (for example, pneumonia, ear ache or other infections). This is especially important if symptoms do not improve, or if the child's condition worsens.

- If you are concerned about the child's health (such as if symptoms worsen, last for more than a week, or are accompanied by a fever higher than 38 C or the production of thick phlegm), consult a health care practitioner for a medical evaluation.

For more information about Health Canada's decision and the use of cough and cold products in children, consult the [Health Canada](http://www.healthcanada.gc.ca/coughandcold) ( [www.healthcanada.gc.ca/coughandcold](http://www.healthcanada.gc.ca/coughandcold) ) Web site or call toll free at 1-866-558-2946.

For advice on how to properly dispose of medications, see the "It's Your Health" article entitled [The Proper Use and Disposal of Medication](http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/disposal-defaire-eng.php) ( <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/disposal-defaire-eng.php> ).

For more information on the safe use of medicines, see the "It's Your Health" article entitled [Safe Use of Medicine](http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/safe-secure-eng.php) ( <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/safe-secure-eng.php> ).

You can report any adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following three ways:

- [Report online](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) ( <http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php> ) at the [MedEffect™ Canada Web site](http://www.healthcanada.gc.ca/medeffect) ( [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect) )
- Call toll-free at 1-866-234-2345
- Complete a [Canada Vigilance Reporting Form](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php) ( [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php) ) and either:
  - Fax toll-free to 1-866-678-6789
  - Mail to: Canada Vigilance Program  
Health Canada  
AL 0701C  
Ottawa, ON K1A 0K9

To have postage pre-paid, [download the postage paid label](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/post_paid-affranchi-eng.php) ( [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/post\\_paid-affranchi-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/post_paid-affranchi-eng.php) ) from the [MedEffect™ Canada Web site](http://www.healthcanada.gc.ca/medeffect) ( [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect) ). The [Canada Vigilance Reporting Form](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php) ( [http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei\\_form-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php) ) and the adverse reaction reporting guidelines may also be obtained via this Web site.

**Media Inquiries:**  
Health Canada  
(613) 957-2983

*Également disponible en français*

**Public Inquiries:**  
(613) 957-2991  
1-866 225-0709

**New Labelling for Cough and Cold Product  
Use in Children  
FREQUENTLY ASKED QUESTIONS**

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**Document Title – Frequently Asked Questions**

- 1. What is Health Canada’s decision regarding the use of cough and cold medicines in children?**
  - 2. Which cough and cold products are involved?**
  - 3. Why has Health Canada decided that these medicines should not be used only in children under 6?**
  - 4. If there is a risk with these products for children under the age of 6, then why are they being allowed to stay on the market until fall 2009?**
  - 5. What sort of outreach is Health Canada doing to ensure that parents and caregivers of children under 6 are aware of this decision?**
  - 6. If these medicines shouldn’t be given to children under 6, what can parents and caregivers do instead to help their child with a cough or cold?**
  - 7. What about for children older than 6?**
  - 8. Is it OK to use natural health products to treat coughs and colds in children under age 6?**
  - 9. What should parents do with medications for use in children under 6 that they have already purchased or have started to use?**
  - 10. If there isn’t strong evidence of the effectiveness or safety of cough and cold medicines in children, why is Health Canada allowing them to be marketed at all to children under the age of 12?**
  - 11. Hasn’t the U.S. decided to ban the use of cough and cold medicines in children under 4? Why is Canada setting a different standard?**
  - 12. Exactly what changes will be made to products that stay on the market?**
  - 13. How did these products get approved in the first place if Health Canada is saying now that there is not sufficient evidence of safety or effectiveness?**
  - 14. Is it possible that a child may have suffered long-term harm from past use of cough and cold medicines?**
  - 15. How strong is the evidence that these medicines are safe and effective in adults? Is the labelling for adults going to change in any way?**
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- 1. What is Health Canada’s decision regarding the use of cough and cold medicines in children?**

After conducting an assessment of these medicines, Health Canada has decided to require manufacturers to relabel products that have dosing information for children under the age of 12. The new labelling will say that these medicines should not be used in children under 6. There will also be enhanced information for use in children aged 6 to under 12. The relabelling will be completed by fall 2009, in time for the next cough and cold season.

- 2. Which cough and cold products are involved?**

Health Canada’s decision affects medicines that can be purchased without a prescription (over-the-counter medications) to treat cough and cold symptoms in children under 12 years of age. The affected products contain one or more of the active ingredients listed in the chart below. These medicines are given by mouth. They fall into four broad categories: antihistamines, antitussives, expectorants and decongestants.

**Table 1: Active Ingredients Affected by Health Canada’s Decision on Cough and Cold Products for Children**

Therapeutic Category (Purpose)	Active Ingredients
Antihistamines in cough and cold medicines (used to treat sneezing, runny nose)	brompheniramine maleate chlorpheniramine maleate clemastine hydrogen fumarate dexbrompheniramine maleate diphenhydramine hydrochloride diphenylpyraline hydrochloride doxylamine succinate pheniramine maleate phenyltoloxamine citrate promethazine hydrochloride pyrilamine maleate triprolidine hydrochloride
Antitussives (used to treat cough)	dextromethorphan dextromethorphan hydrobromide diphenhydramine hydrochloride
Expectorants (used to loosen mucus)	guaifenesin (glyceryl guaiacolate)
Decongestants (used to treat congestion)	ephedrine hydrochloride/sulphate phenylephrine hydrochloride/sulphate pseudoephedrine hydrochloride/sulphate

Cough and cold medicines that do not contain any of these ingredients, that are not given by mouth, or that are only available by prescription are not affected by the decision.

**3. Why has Health Canada decided that these medicines should not be used only in children under 6?**

Over-the-counter cough and cold medicines have a long history of use in children, however, there is limited evidence supporting the effectiveness of these products in this population. In addition, reports of misuse, overdose and rare side-effects have raised concerns about the use of these medicines in children under 6. The rare but serious potential side-effects with this group of children include convulsions, increased heart rate, decreased level of consciousness, abnormal heart rhythms and hallucinations.

Other factors supporting Health Canada's decision to make age 6 the cutoff include:

- Recommendations from Canadian and international health professionals and experts that these medicines should not be used in children under 6;
- Body weight can affect how medicines work. Some children between the ages of 2 and 6 years may weigh the same as other children who are less than 2 years old, and Health Canada has previously recommended that cough and cold medicines not be used in children under the age of 2;
- Children under the age of 6 years generally have more colds compared to older children, so they are likely to be exposed more often to these medicines and therefore to any related potential health risks; and
- Younger children are less likely to be able to communicate a potential problem with a cough and cold medicine, or to ask their parents or caregivers for help in the same way a child over the age of 6 can.

Health Canada's decision also takes into account feedback received from the Scientific Advisory Panel on Nonprescription Paediatric Cough and Cold Medications convened in March 2008 by Health Canada.

**4. If there is a risk with these products for children under the age of 6, then why are they being allowed to stay on the market until fall 2009?**

Health Canada's decision to let the medicines stay on the market until the relabelling is complete takes into account the limited evidence supporting the effectiveness of these products in children, coupled with the potential risks of these products when used in children, along with the risks associated with removing these products from the market altogether while waiting for relabelling. Specifically, since many of these products also have dosing information for adults and older children on the label, immediately removing all cough and cold medicines for children under 6 would have an impact on product availability for these groups. The decision is also based on the fact that Health Canada is undertaking an outreach effort during this cough and cold season to widely share the information that these products should not be used in children under 6.

**5. What sort of outreach is Health Canada doing to ensure that parents and caregivers of children under 6 are aware of this decision?**

Health Canada has prepared a package of materials available on its Web site ([www.healthcanada.gc.ca/coughandcold](http://www.healthcanada.gc.ca/coughandcold)) to answer questions about the decision. This includes the Public Advisory, a Backgrounder, Frequently Asked Questions, and a Web video, as well as the draft labelling standard and the report of Health Canada's Scientific

Advisory Panel on cough and cold medicines. There is also a toll-free information line (1-866-558-2946) consumers can call with their questions about the labelling decision. Information on the decision has been shared with pediatricians, medical groups, pharmacists, provincial and territorial governments, industry and other stakeholders for dissemination through their various communications channels.

**6. If these medicines shouldn't be given to children under 6, what can parents and caregivers do instead to help their child with a cough or cold?**

It is important to remember that there is no cure for the common cold, and that these medicines may offer only temporary relief of cold symptoms such as cough, nasal congestion or sore throat. These symptoms typically improve on their own in 6 to 10 days.

There are different non-medicinal ways to provide temporary relief from cough and cold symptoms:

- Clear nasal passages and ensure that the child gets enough rest;
- Ensure the child gets plenty of clear fluids (e.g. diluted non-sweetened fruit juice, or clear soups). This prevents dehydration, reduces congestion and keeps the throat moist; and,
- Provide a comfortable environment with enough humidity.

If the child's symptoms do not improve within 6 to 10 days, or if the symptoms worsen, consult a health care practitioner (doctor, pharmacist, nurse, etc). You should not give a child under age 6 a cough and cold medicine intended for an older child or an adult, even at a smaller dose.

**7. What about for children older than 6?**

Parents and caregivers can try the non-medicinal measures suggested above to treat the child's symptoms. If you use an over-the-counter cough and cold medicine:

- Use only products that provide dosing instructions for the child's age group;
- Always follow dosing and length-of-use instructions carefully and use the dosing device if one is included;
- Do not give a child more than one kind of cough and cold medicine. Combining medicines with the same active ingredient(s) may cause problems, such as overdose;
- Ask a health care practitioner which ingredient is most effective for treating the symptom troubling the child;
- Check with a health care practitioner to make sure the medicine you choose won't interact with any other health products the child may be taking; and

- If symptoms do not improve within 6 to 10 days, worsen, or are accompanied by a fever higher than 38 C or the production of thick mucus (phlegm), consult a health care practitioner.

Health Canada has produced an *It's Your Health* article with tips on the safe use of all medicines ([www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/safe-secure-eng.php](http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/safe-secure-eng.php)).

## **8. Is it OK to use natural health products to treat coughs and colds in children under age 6?**

Some natural health products have been authorized by Health Canada for the treatment of coughs and colds in children. Only those containing ephedrine hydrochloride/sulfate or pseudoephedrine hydrochloride/sulphate are affected by Health Canada's decision and should not be given to children under 6 years old.

Any substance, whether natural or synthetic, that has an effect on the body can potentially be a risk to health. Children may be particularly susceptible to risk, especially with products with multiple ingredients. Parents and caregivers should discuss the use of any therapeutic health products in young children, including natural health products, with a health care practitioner.

Consumers can identify a Health Canada authorized natural health product by the eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) on the label. These products are also required to have clear labelling on appropriate use, including dosing, risk information and whether they can be used safely in children. Parents and caregivers are advised to carefully read the medicinal ingredients, labels and instructions for all health products before giving them to children.

## **9. What should parents do with medications for use in children under 6 that they have already purchased or have started to use?**

Until the relabelling is completed by fall 2009, there will be cough and cold medicines being sold and in people's homes with the current labelling. For this cough and cold season, parents or caregivers should consult a pharmacist or a health care practitioner when buying or using these products. These medicines can still be used in children 6 and over, and adults.

Health Canada has produced an *It's Your Health* article with helpful information on the safe use and disposal of medicine ([www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/disposal-defaire-eng.php](http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/disposal-defaire-eng.php)).

**10. If there isn't strong evidence of the effectiveness or safety of cough and cold medicines in children, why is Health Canada allowing them to be marketed at all to children under the age of 12?**

Although there is limited scientific evidence supporting the use of cough and cold medicines in children of any age, these products have a long history of use. Health Canada's assessment and subsequent decision take into account why these limitations still exist, and how they can be addressed without compromising the health and safety of children under the age of 12.

As mentioned in question 3, older children tend to have fewer colds than younger children, reducing their exposure to these medicines. Older children are also more likely to be able to communicate about a potential side-effect with a medicine. There have been fewer side-effects reported to Health Canada involving children in this age range as well. For these reasons, cough and cold medicines marketed to children aged 6 to under 12 years will remain on the market, but will require stronger safety labelling and packaging changes to further minimize any potential health risks. Health Canada will also be encouraging new research into the safety and effectiveness of these products in older children.

**11. Hasn't the U.S. decided to ban the use of cough and cold medicines in children under 4? Why is Canada setting a different standard?**

Health Canada decision to set the age cut-off at 6 was reached through an extensive, independent review process that considered both Canadian and international data. The relabelling of over-the-counter cough and cold medicines in the U.S. to indicate they should not be used in children under the age of 4 was a voluntary action undertaken by the makers of these products. At the time of Health Canada's decision, the U.S. Food and Drug Administration had not finished its own regulatory decision-making process related to these products.

**12. Exactly what changes will be made to products that stay on the market?**

Cough and cold medicines currently labelled for use in children may remain on the market if they change their label to ensure dosing only for children aged 6 and older. In addition, Health Canada will require that all cough and cold medicines for children have child-resistant packaging and include dosing devices, when applicable. The target for meeting these new standards has been set for fall 2009, in time for the start of next year's cough and cold season.

**13. How did these products get approved in the first place if Health Canada is saying now that there is not sufficient evidence of safety or effectiveness?**

For many years it was assumed that cough and cold medicines worked the same way in children and adults. Therefore, dosing for children was estimated using adult data. However, it is now better understood how children's bodies react differently to certain medicines, and how cold viruses affect children differently. Health Canada will be encouraging the makers of over-the-counter cough and cold products and researchers to study the dosing, safety and effectiveness of these products in children.

**14. Is it possible that a child may have suffered long-term harm from past use of cough and cold medicines?**

There is no evidence that children who have used these medicines in the past are still at risk from having taken them.

**15. How strong is the evidence that these medicines are safe and effective in adults? Is the labelling for adults going to change in any way?**

The standards for clinical trials have evolved since many of the earlier adult studies on the effectiveness of cough and cold products. However, no safety issue has been identified at this time with cough and cold products use by adults, as long as dosing instructions are followed. Labelling for products intended for adult use will not have to be changed unless the product also provides dosing information for children.