



Information for Pharmacy Staff

Changes to the use of cough and cold medicines in children

Frequently Asked Questions

1 Why are some brands of cough and cold medicines still labelled for use in children under 6 years of age?

While the packaging and labelling of many of the affected cough and cold medicines is now consistent with the new recommendations, there are some sponsor companies that are in the process of making the change. The TGA anticipates that all the changes will be in place for winter 2013.

Batches of affected products with the old labelling that were in the marketplace prior to 1 September 2012 are allowed to be sold until the end of their shelf life. For a period, there will be cough and cold products with the old and new labelling available from pharmacies. Pharmacists should ensure that the supply of all cough and cold medicines from their pharmacy is consistent with the new recommendations.

2 Can cough and cold medicines be supplied for use in children under 6 years of age if they are labelled for this age group?

No. Irrespective of the labelling, from 1 September 2012, cough and cold medicines should not be supplied or recommended for use in children under 6 years of age.

If a pharmacist recommends or supplies a cough and cold medicine for a child under 6 years of age on or after 1 September 2012, should an adverse event occur, the pharmacist may be subject to a complaint being lodged.

3 Can cough and cold medicines be supplied for use in children aged from 6-11 years if they still have the old labelling with directions for this age group?

Yes, but only on the advice of a pharmacist or prescriber. Although there is no change in the scheduling of cough and cold medicines, any requests for cough and cold medicines for children under 12 should be referred to the pharmacist. Irrespective of the labelling, pharmacy assistants should not supply cough and cold medicines for use in children under 12 years of age without consulting the pharmacist.

From both a risk management and consumer health perspective, when supplying a cough and cold medicine with the old labelling for children over 6 years of age, pharmacists should consider attaching a dispensing label with the directions for the relevant age group and with a warning 'Not to be used in children under 6 years of age'.



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4 What should pharmacists do if they are presented with a prescription for a cough and cold medicine for a child under 6 years of age?

A pharmacist must always apply their clinical knowledge and exercise their professional judgement in deciding whether to dispense a medicine from a prescription. Based on this knowledge, if a pharmacist does not believe it is appropriate to dispense a prescribed medicine, they should decline the request and discuss the matter with the prescriber.

While 'off-label' prescribing and dispensing is not illegal and may sometimes be clinically appropriate, there are a number of clinical, safety and ethical issues that should be considered. The 'off-label' use of medicines for children and infants is common in Australia because products are often not registered for use for this age group. However, where a government body such as the TGA has specifically recommended against use for a particular age group, should an adverse event occur following recommendation or supply for use in the specified age group, prescribers and pharmacists may have difficulty defending their actions.

The references on the TGA website cite international data that supports the view that there is insufficient evidence to justify the use of cough and cold medicines in children under 6 years of age, irrespective of whether the medicine is prescribed or not.

If a pharmacist is presented with a prescription for a cough and cold medicine for a child under 6 years of age, they should contact the prescriber and discuss the individual circumstances with consideration of alternative options. PDL members can access information about 'off-label' supply from the members section at www.pdl.org.au.

In managing such issues when dispensing a prescription, it is recommended that pharmacists document their actions and advice.

If parents or carers would like additional information on managing coughs and colds, some useful websites include:

- *NPS: Common Cold*
- *NPS: Medicines for coughs and colds*
- *Better Health Channel: Colds*
- *Better Health Channel: Coughs*

For after-hours support or advice, parents or carers can contact the after-hours GP Helpline on 1800 022 222.

5 Can antihistamines be supplied for use in young children for other conditions?

While the changes apply specifically to cough and cold medicines, pharmacists should remain aware of the risks and benefits associated with using antihistamines in young children for other conditions. As with cough and cold medicines, the risks are greater for children under 6 years of age. When supply is warranted, pharmacists should ensure that parents or carers are also informed of the risks and benefits as well as correct instructions for use.

