

Changes to cough and cold medicines for children

Factsheet

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Therapeutic Goods Administration (TGA) advice

1 September 2012

- Cough and cold medicines should not be given to children under 6 years of age.
- Cough and cold medicines should only be given to children aged 6 to 11 years on the advice of a doctor, pharmacist or nurse practitioner.

Affected products

Type of medicine	Active ingredients
Antihistamines	Brompheniramine, chlorpheniramine, dexchlorpheniramine, diphenhydramine, doxylamine, pheniramine, promethazine, triprolidine
Antitussives	Codeine, dextromethorphan, dihydrocodeine, pentoxyverine, pholcodine
Mucolytics/ expectorants	Bromhexine, guaiphenesin, ipecacuanha, senega and ammonia
Decongestants	Phenylephrine, pseudoephedrine, oxymetazoline, xylometazoline



Other important information in the TGA review

- There are no immediate safety risks with these products.
- There is no proven benefit in using these products in children.
- There are potential risks associated with these products for children.
- Possible side effects include: allergic reactions; increased or uneven heart rate; slow and shallow breathing; drowsiness or sleeplessness; confusion or hallucinations; convulsions; nausea; constipation.
- The above side effects are rare. However, overuse of these products or overdose can lead to serious harm.
- Using these products can also sometimes delay medical advice being sought for more serious illnesses such as asthma, influenza, pneumonia, bronchitis or middle ear infection.

The labels of these products are being changed to reflect the new advice, but will take time to implement and be phased in. Existing stock with the older labelling will still be allowed to be sold for use in adults and children aged 6 years and older until it is exhausted.

For more information visit www.tga.gov.au/consumers/information-medicines-cough-cold.htm

Overview

The TGA has carried out a comprehensive review of the safety and efficacy of registered over-the-counter (OTC) cough and cold medicines for children aged 2-12 years. As a result of this review, the TGA has concluded that there are potential risks associated with these products for children and only limited benefits.

A number of changes have been recommended for the packaging and sale of these products which will have a significant impact on community pharmacies. Pharmacists and pharmacy assistants must be informed of these changes and up skilled to enable them to respond appropriately to customer queries.

PSA recommends that page 1 of this document be printed and used, if required, when counselling customers.

Responding to customer queries

SCENARIO 1

A customer presents in the pharmacy and asks for X brand children's cough and cold medicine for his 4-year-old child. The child has typical cold symptoms – fever, malaise, blocked nose and a cough.



Issues

- Age of the child.
- Administration of medicines to ill children is a complex and ingrained behaviour – parents want something to ease the symptoms of a sick child.

Options

1. Refuse the sale and give information as to why – show the customer the TGA advice page.
2. Give customer information on alternative ways to care for a child with a cough and cold e.g. control temperatures (paracetamol or ibuprofen), rest, maintain fluid intake, saline nasal solutions.
3. Refer to doctor if child's condition warrants this action.

Responses

"I know that you want what is best for your child. However there is new evidence that cough and cold medicines are of no benefit to children and may have a risk of adverse effects. The new recommendations are that cough and cold medicines should not be given to children under 6 years of age."

"Possible side effects include: allergic reactions; increased or uneven heart rate; slow and shallow breathing; drowsiness or sleeplessness; confusion or hallucinations; convulsions; nausea; constipation."

"There are concerns that treating what appears to be the symptoms of coughs and colds in children with these medicines may delay the diagnosis and treatment of more serious conditions such as asthma, pneumonia and meningococcal disease."

SCENARIO 2

A customer presents to the pharmacy with her 3-year-old daughter who has a cold. She self-selects some liquid cold and flu medicine and brings it to the counter to pay. You determine that the medicine is for the child and that she has used it before. You inform her that it is no longer recommended for children under 6 years of age.



Her response

"The label has a dosing for 2-6 year olds so why can't I have it?"

Issues

- Age of child.
- Dosing instructions still on the product label.
- Customer has used it before with no adverse effects.
- How do you refuse the sale without losing the customer?

Options

1. Refuse supply knowing that the customer may choose to no longer shop at your pharmacy.
2. Supply the product with counselling and record the sale. (Not recommended)

PDL's response to option 2:

If a pharmacist recommended cough & cold medicine for a 2-6 year old child on or after 1 September 2012, knowing that the recommendation had changed, and an adverse event occurred, this could be considered an intentional act and the claim may be declined.

Responses

As for Scenario 1.

"Cough and colds are self limiting conditions and will usually get better by themselves. Ensure your child has plenty to drink and gets enough rest to help them get better faster. Paracetamol or ibuprofen can be used to reduce your child's temperature. For children who have a blocked nose, saline nasal drops are available to help thin and clear nasal secretions."

SCENARIO 3

A customer is refused sale of cough and cold medicine for her 5-year-old. She is upset and immediately requests the same medication for her 12-year-old instead.



Issues

- Age of child; is it for the 12 year old or 5 year old?
- Are you expected to question the customer's honesty?

Options

1. Refuse supply knowing that the customer may choose to no longer shop at your pharmacy.
2. Supply the product with counselling and record the sale. Treat this as you would a *Pharmacist Only* medicine (S3). It may be wise to attach a label with the recommended dose and adding the statement "not recommended for use in children under 6 years of age."

PDL's response to option 2

If the pharmacist recommended/sold cough & cold medicine for a 12 year old child but the parents also administered the medicine to their 5 year old and an adverse event occurred, then provided the details of the claim fell within the policy terms and conditions, the claim would be covered.

If a pharmacist is suitably concerned regarding patient safety, they have options with regard to the medicine with defunct labelling. They may decide to dispose of the medicine with the defunct label and not sell it. Or they may decide to have labels produced with the amended age limit and have their staff stick these over the top of the defunct label. From both a risk management and patient health perspective this latter approach would be desirable for the continued sale of the defunct label medicine.

Responses

As for Scenario 2.

"If your child's condition deteriorates and he/she becomes very unwell, has a high temperature and/or has trouble breathing, you should seek immediate medical attention."

SCENARIO 4

A woman enters the pharmacy and appears to be in a hurry.

"Could I please have a bottle of Phenergan (promethazine) or Polaramine (dexchlorpheniramine) for my 4-year-old? We are going overseas tomorrow and I've used it with my other children when we have travelled on long flights."



Issues

- Should this be treated the same as the cold and flu scenarios?
- Can the pharmacist make the decision on whether this is appropriate?

Options

1. Treat the sale as you would any *Pharmacist Only* medicine.
2. Refuse supply knowing that the customer may choose to no longer shop at your pharmacy.

This scenario is not covered by the new TGA guidelines as the product is not for a cough and cold.

Responses

This scenario should be treated in the same way as normal as it is outside the new TGA guidelines for cough and cold use in children, however you could mention:

"There is new evidence that antihistamine medicines are of no benefit to children and may have a risk of adverse effects. There are new recommendations that cough and cold medicines which contain antihistamines should not be given to children under 6 years of age."

"Possible side effects include: allergic reactions; increased or uneven heart rate; slow and shallow breathing; drowsiness or sleeplessness; confusion or hallucinations; convulsions; nausea; constipation."

SCENARIO 5

A customer presents a prescription for their 4 year old child for X brand of cold and flu medicine.



Issues

- Is the doctor aware of the new TGA recommendations?
- Is this the pharmacist's call to supply or not?
- What is normal procedure to verify a doctor's intention on a prescription?
- Doctor – pharmacist relationship status.

Options

1. Ask the customer what the doctor has told them about the medication (it may be prescribed for an allergy or inflammatory condition rather than cough and cold).
2. Contact the doctor and inform doctor of new TGA recommendations.
3. Counsel customer regarding TGA recommendations.
4. Supply as you would any prescription. (not recommended)
5. Refuse supply knowing that the customer may choose to no longer shop at your pharmacy.

PDL's response to option 4:

A pharmacist must apply their clinical knowledge and exercise their professional judgement in deciding whether or not a prescription is appropriate to dispense to a consumer. 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. Any claim against a pharmacist arising from dispensing such a medicine could be reviewed by a health complaints panel and/or the Pharmacy Board of Australia.

Responses

As for scenario 3.

SCENARIO 6

A customer asks why they are able to purchase certain unscheduled cough and cold medicines in either other pharmacies, online or non-pharmacy retail outlets, while you are refusing the sale.



Issues

- Products available from other avenues in conflict with the TGA advice.
- Will you lose the customer to outlets less vigilant in applying the new advice than yourself?
- You have no control over other outlet's actions.

Options

1. Tell the customer to go and buy them elsewhere. (not recommended)
2. Use this as an opportunity to emphasise your concern with patient health and well being as your first priority (PSA code of Ethics 2011 Principle 1).

Responses

As for scenario 3, emphasising your concern for patient health and well being.

PDL overarching advice

Broadly, a PDL member who holds professional indemnity insurance with GIL, is covered for civil liability that arises from a breach of their professional duty as a pharmacist. However, any claim that is notified to PDL or GIL must be considered with all details in mind to determine whether the claim falls within the policy cover. Depending on the circumstances, the claim may or may not be covered. For example there are exclusions that relate to dishonest, fraudulent, criminal, malicious or intentional acts committed by the insured.

If a pharmacist is suitably concerned regarding patient safety, they have options with regard to the medicine with defunct labelling. They may decide to dispose of the medicine with the defunct label and not sell it. Or they may decide to have labels produced with the amended age limit and have their staff stick these over the top of the defunct label. From both a risk management and patient health perspective this latter approach would be desirable for the continued sale of the defunct label medicine.