



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Proposed advisory statements for medicines – cough and cold medicines for use in children



About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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Historical consultation document

Proposed advisory statement for medicines – cough and cold medicines for use in children

Invitation to comment

The TGA is seeking comments from interested parties on the proposed advisory statements for cough and cold medicines for use in children for inclusion in the RASML document when it is next updated.

Enquiries

Enquiries should be directed via email to otc.medicines@tga.gov.au or by telephone to 02 6232 8160.

Timetable

Document released for consultation on **Wednesday, 8 February 2012.**

Interested parties should respond by close of business **Wednesday, 22 February 2012.**

Feedback will be released following consideration of submissions. (See '[What will happen](#)').<link>

Background

The Therapeutic Goods Administration has carried out a comprehensive review of the safety and efficacy of over-the counter medicines containing one or more of the 22 medicine substances listed below for the treatment of symptoms of cough and cold in children

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

The review considered the data published in the medical literature, information available from the TGA's adverse drug reaction database, and other relevant information from external organizations such as Australian Poisons Information Centres, and the Australian Institute of Health and Welfare (AIHW). Sponsors of these medicines were also invited to provide literature references and information that they considered relevant and useful to the review.

The collated literature and other items of information were reviewed externally by a clinical toxicologist and a paediatrician specializing in respiratory disease. Their report and recommendations were considered by an internal panel composed of senior TGA personnel with expertise in medicine, pharmacy, toxicology, pharmacology and pharmaceutical sciences, as well as by the Medicines Evaluation Committee (MEC).

The outcomes of this review were published in October 2009 for public and stakeholder consultation. <http://www.tga.gov.au/newsroom/consult-labelling-cough-cold-091022.htm>

It has been recommended that:

1. The labelling of over-the-counter cough and cold medicines should not include dosage instructions for children under 6 years of age;

if doses are included for children aged 6-11 years, the labelling must include:

- a. a warning statement advising against use in children under the lowest specified age, AND
 - b. a statement advising that the product should only be administered to children between the lowest specified age and 12 years on the advice of a doctor or pharmacist; and
2. The labelling of all over-the-counter cough and cold medicines with dosage specified only for adults and/or for those aged 12 and above should contain a warning statement specifically advising against their use in children under 12 years of age.

Section 28 notices have been sent to sponsors who currently have products included on the ARTG. However the recommendations arising from this review of OTC cough and cold medicines apply equally to such medicines added to the ARTG in the future. To ensure that future products are labelled accordingly, the proposed advisory statements are recommended for inclusion in the RASML document.

Submissions

Please title all submissions with "Proposed advisory statements for medicines: cough and cold medicines – Response to Consultation".

Responses may be sent by mail, fax or email as shown below.

Mail: OTC Medicines Evaluation
Office of Medicines Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Fax: [REDACTED]
Email: otc.medicines@tga.gov.au

Content of submissions

Submissions may address any, or all, of the proposed advisory statements and other identified issues

In addition, submissions might include:

- Whether or not you support the wording of the advisory statement. If you do not support the wording of the statement you may make suggestions for an alternative acceptable to you.
- An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

What will happen

Submissions will be reviewed by the TGA and feedback on submissions will be provided through the TGA's Internet site. Recommendations made by the TGA following consideration of submissions from interested parties will be published on the TGA website as outcomes.

The proposed advisory statements will then be included in the next update of the RASML document.

Confidentiality

All submissions will be placed on the TGA's website unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked 'IN CONFIDENCE'. Reasons for a claim to confidentiality must be included in the space provided on the [TGA submission coversheet](#) <download>.

For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the TGA's website.

In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission coversheet.

More information

The TGA has specifically invited comment on the proposed amendments from the following organisations. You may wish to consider submitting your response to one of these organisations, for incorporation in its overall response, rather than submission direct to the TGA:

- ACCORD Australasia Limited
- Australian Self-Medication Industry Inc. (ASMI)
- Complementary Healthcare Council of Australia (CHC)
- Consumers' Health Forum (CHF)
- Generic Medicines industry Association (GMiA) of Australia
- Medicines Australia (MA)
- Pharmaceutical Society of Australia (PSA)
- Pharmacy Guild of Australia

The RASML Edition 1 including update 4 (dated September 2008) remains the current version which sponsors should continue to refer to.

Summary of proposed changes

Substance	Change type
Antihistamines	Amendment to include new advisory statements
Brompheniramine	New entry
Chlorpheniramine	New entry
Dexchlorpheniramine	New entry
Diphenhydramine	New entry
Doxylamine	New Entry
Pheniramine	New entry
Promethazine	New entry
Triprolidine	New entry
Codeine	New entry
Dextromethorphan	New entry
Dihydrocodeine	New entry
Pentoxyverine	New entry
Pholcodine	New entry
Bromhexine	New entry
Guaiphenesin	New entry
Ipecacuanha	New entry
Senega	New entry
Ammonia	New entry
Phenylephrine	New entry
Pseudoephedrine	New entry
Oxymetazoline	New entry
Xylometazoline	New entry

Details of the proposed changes are shown in the tables below. These tables show:

- the existing entry# which requires amendment or inclusion of an additional information (showing proposed amendment in red and underlined and the deletions, if any, in black ~~strikethrough~~); or
- the proposed new entry (inserted details in red and underlined);

#As per RASML Edition 1 including update 4 (dated September 2008)

Section 1 – Medicines to which advisory statements apply

1. Amendments to the existing entries

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
Antihistamines (Entry 1 of 23)	When: (a) included in a Schedule to the SUSMP; and (b) not separately specified in this Table and they are NOT any one or more of: (i) dermal, ocular, parenteral and paediatric preparations; or (ii) oral preparations of astemizole, desloratidine, fexofenadine, loratadine or terfenadine; or (iii) nasal preparations of azelastine; or (iv) preparations for short-term use in insomnia.	(46 and 49 and 47) ⁱ or (48 and 50) ^j
<u>Antihistamines, including:</u> (Entry 2 of 3) • <u>Diphenhydramine</u> • <u>Doxylamine</u> • <u>Promethazine</u>	<u>When included in Schedule 3 to the SUSMP and indicated for short-term use in insomnia.</u>	<u>15, 206, 220, 221</u>
<u>Antihistamines, including:</u> (Entry 3 of 3) • <u>Brompheniramine</u>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
<ul style="list-style-type: none"> • Chlorpheniramine • Dexchlorpheniramine • Diphenhydramine • Doxylamine • Pheniramine • Promethazine • Triprolidine 	When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years	B,C
	When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years	D,E

2. New entries

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
Ammonia <i>(Entry 1 of 3)</i>	When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years	A
Ammonia <i>(Entry 2 of 3)</i>	When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years	B,C
Ammonia <i>(Entry 3 of 3)</i>	When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years	D,E
Brompheniramine <i>(Entry 1 of 3)</i>	When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years	A
Brompheniramine <i>(Entry 2 of 3)</i>	When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years	B,C

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
<u>Brompheniramine</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Bromhexine</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Bromhexine</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Bromhexine</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Codeine</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Codeine</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Codeine</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Chlorpheniramine</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
<u>Chlorpheniramine</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	B,C
<u>Chlorpheniramine</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	D,E
<u>Dexchlorpheniramine</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	A
<u>Dexchlorpheniramine</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	B,C
<u>Dexchlorpheniramine</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	D,E
<u>Dextromethorphan</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	A
<u>Dextromethorphan</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	B,C
<u>Dextromethorphan</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	D,E

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
<u>Dihydrocodeine</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Dihydrocodeine</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Dihydrocodeine</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Diphenhydramine</u> <i>(Entry 1 of 4)</i> <i>(See also antihistamines)</i>	<u>When included in Schedule 3 to the SUSMP and indicated for short-term use in insomnia.</u>	<u>15, 206, 220, 221</u>
<u>Diphenhydramine</u> <i>(Entry 2 of 4)</i> <i>(See also antihistamines)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Diphenhydramine</u> <i>(Entry 3 of 4)</i> <i>(See also antihistamines)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Diphenhydramine</u> <i>(Entry 4 of 4)</i> <i>(See also antihistamines)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Doxylamine</u> <i>(Entry 1 of 4)</i> <i>(See also antihistamines)</i>	<u>When included in Schedule 3 to the SUSMP and indicated for short-term use in insomnia.</u>	<u>15, 206, 220, 221</u>
<u>Doxylamine</u> <i>(Entry 2 of 4)</i> <i>(See also antihistamines)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
<u>Doxylamine</u> <i>(Entry 3 of 4)</i> <i>(See also antihistamines)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Doxylamine</u> <i>(Entry 4 of 4)</i> <i>(See also antihistamines)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Guaiphenesin</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Guaiphenesin</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Guaiphenesin</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Ipecacuanha</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Ipecacuanha</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Ipecacuanha</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
<u>Oxymetazoline</u> <i>(Entry 1 of 5)</i> <i>(See also nasal decongestant preparations)</i>	<u>When in nasal preparations for topical use.</u>	<u>76j</u>
<u>Oxymetazoline</u> <i>(Entry 2 of 5)</i> <i>(See also vasoconstrictor eye drops)</i>	<u>When in topical eye preparations.</u>	<u>119, 226, 227, 228</u>
<u>Oxymetazoline</u> <i>(Entry 3 of 5)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Oxymetazoline</u> <i>(Entry 4 of 5)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Oxymetazoline</u> <i>(Entry 5 of 5)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Pentoxifyverine</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Pentoxifyverine</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Pentoxifyverine</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
<u>Pheniramine</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Pheniramine</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Pheniramine</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Phenylephrine</u> <i>(Entry 1 of 6)</i> <i>(See also nasal decongestant preparations)</i>	<u>When in nasal preparations for topical use.</u>	<u>76j</u>
<u>Phenylephrine</u> <i>(Entry 2 of 6)</i>	<u>When in oral preparations</u>	<u>208, 215</u>
<u>Phenylephrine</u> <i>(Entry 3 of 6)</i> <i>(See also vasoconstrictor eye drops)</i>	<u>When in eye preparations for topical use</u>	<u>199, 226, 227, 228</u>
<u>Phenylephrine</u> <i>(Entry 4 of 6)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Phenylephrine</u> <i>(Entry 5 of 6)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Phenylephrine</u> <i>(Entry 6 of 6)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
<u>Phocoldine</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Phocoldine</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Phocoldine</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Promethazine</u> <i>(Entry 1 of 4)</i> <i>(See also antihistamines)</i>	<u>When included in Schedule 3 to the SUSMP and indicated for short-term use in insomnia.</u>	<u>15, 206, 220, 221</u>
<u>Promethazine</u> <i>(entry 2 of 4)</i> <i>(See also antihistamines)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Promethazine</u> <i>(entry 3 of 4)</i> <i>(See also antihistamines)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Promethazine</u> <i>(entry 4 of 4)</i> <i>(See also antihistamines)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Pseudoephedrine</u> <i>(Entry 1 of 4)</i>	<u>When included in Schedule 3 to the SUSMP.</u>	<u>208, 209</u>
<u>Pseudoephedrine</u> <i>(Entry 2 of 4)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
<u>Pseudoephedrine</u> <i>(Entry 3 of 4)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Pseudoephedrine</u> <i>(Entry 4 of 4)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Senega</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Senega</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Senega</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>
<u>Tripolidine</u> <i>(Entry 1 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Tripolidine</u> <i>(Entry 2 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Tripolidine</u> <i>(Entry 3 of 3)</i>	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
<u>Xylometazoline</u> (Entry 1 of 5) (See also nasal decongestant preparations)	<u>When in nasal preparations for topical use.</u>	<u>76 j</u>
<u>Xylometazoline</u> (Entry 2 of 5) (See also vasoconstrictor eye drops)	<u>When in topical eye preparations.</u>	<u>119, 226, 227, 228</u>
<u>Xylometazoline</u> (Entry 3 of 5)	<u>When contained in oral preparations to treat cough and cold and the preparation does not include dosage instructions for children aged under 12 years</u>	<u>A</u>
<u>Xylometazoline</u> (Entry 4 of 5)	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 6 years to 11 years</u>	<u>B,C</u>
<u>Xylometazoline</u> (Entry 5 of 5)	<u>When contained in oral preparations to treat cough and cold and the preparation includes dosage instructions for children aged from 'x' years (where 'x' is 7, 8, 9 or 10 years) to 11 years</u>	<u>D,E</u>

Section 2 -- Advisory statements

1. Added new advisory statements

No	Statement Text
<u>A*</u>	<u>Do not give to children under 12 years of age</u>
<u>B*</u>	<u>Do not give to children under 6 years of age</u>
<u>C*</u>	<u>Do not give to children aged between 6-11 years, except on the advice of a doctor, pharmacist or nurse practitioner</u>
<u>D*</u>	<u>Do not give to children under 'x' years of age</u>

No	Statement Text
E*	<u>Do not give to children aged between 'x' and 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</u>

*A number will be allocated in the RASML document at the time of updating to ensure consistency with the numbering system.

Historical consultation document

Historical consultation document

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