Guild Position

The Pharmacy Guild of Australia (Guild) appreciates the invitation to respond to the changes proposed for cough and cold medicines for children aged 2-12 years. The Guild recognises the concerns raised by the Therapeutic Goods Administration (TGA) relating to the efficacy and safety of cough and cold medicines for children and the extensive investigation that has ensued, with particular consideration to actions taken in countries with similar standards to Australia. However, **the Guild does not support the proposed changes**. We believe that the changes proposed are premature and excessive. Put in colloquial terms, the proposed changes are like 'trying to crack a nut with a sledgehammer.'

We do not believe sufficient justification has been provided to propose taking such rigid action based strictly on quantitative evidence and will discuss this as part of this submission. Of the three possible courses of action proposed in the paper titled 'Review of cough and cold medicines in children – 21 April 2009', the Guild believes that the third option is more appropriate, 'taking a more evolutionary approach with immediate actions where justified and a more considered approach otherwise'. This would allow the opportunity for greater engagement of the TGA with manufacturer representatives such as the Australian Self Medicines Industry (ASMI) and health professional organisations such as the Guild. It would also allow for engagement with consumer groups as well as individual health professionals and consumers.

The Guild believes that adopting the third option would allow more consideration for:

1. developing a list of acceptable drugs that can be used in registered over-the-counter (OTC) children's medicines by indication and age group
2. assessing each drug on an individual basis rather than as a disparate group
3. assessing the efficacy and safety of products with single active ingredients versus multiple
4. the merit of dose instructions by weight rather than age
5. developing guidelines for product promotion through label claims or advertising.

Background

A large number of cough and cold medicines are available in Australia for children aged 2 to 12 years. Many of these products have been available for many years for indications that were accepted with much lower levels of evidence than that now required. These products have not previously been required to demonstrate their efficacy for registration on the Australian Register of Therapeutic Goods (ARTG) due to their grandfathering onto the register.

Cough and cold products for children are available in a variety of formulations such as oral liquids (mixtures or syrups), nasal sprays or throat lozenges. There have previously been products available in the form of dispersible sachets and soluble or chewable tablets. Generally speaking though it is the oral liquids which are the most common form of cough and cold medicines for children.

There is significant demand for these products from the community because of parents natural concern for their children and a desire to provide treatment when available. The conditions are often usually self-limiting and not serious in nature and capable of management by a parent, particularly with access to a health professional such as a community pharmacist.

Australia has one of the most effective scheduling systems for medicines in the world, having two OTC schedules that either requires intervention with a pharmacist (Pharmacist Only/Schedule 3) or the opportunity to consult a pharmacist (Pharmacy Medicine/Schedule 2). The majority of cough and cold medicines for children are either Schedule 2 (S2) or Schedule 3 (S3) in Australia, although there are some which are Prescription Only (S4) requiring prescribing by a doctor, or unscheduled and available from general retail outlets without any opportunity for health professional intervention. The Guild has reviewed the MIMS Online database[1] to prepare a table of cough and cold medicines for children aged 2 to 12 years which is included as *Attachment A*. This table lists the product, active ingredients, formulation, current schedule as advised within the MIMS' Abbreviated Product Information and children's dosage. It should be noted that this table is not necessarily a complete list of all relevant products.

As can be seen from *Attachment A*, cough and cold medicines for children aged 2 to 12 years may include a single active ingredient or multiple active ingredients. All the children's doses in this table are based on age, and although some products have a greater number of incremental doses (e.g. Paedamin Decongestant & Antihistamine Syrup for children), the majority of products have two dose increments according to age, usually in the range of 2 to 6 years and from 6 to 12 years.

Comments

1. **International Trends**

   The Guild has concerns that the current proposal appears to have an agenda of harmonising with overseas markets rather than evaluating the local situation based on local supply provisions with schedules and access to pharmacists.

   Although efficacy and safety are paramount for all population groups, it is important that consideration is given to the exceptional safety system we have in Australia (and New Zealand) with the range of medicine schedules. This system is not emulated in the comparator countries for this consultation and can have a significant impact in assessing risk-benefit profiles for OTC medicines.

   The table below demonstrates the arrangements in the comparator countries:

Australia	New Zealand (NZ)	United Kingdom (UK)	United States of America (USA)	Canada
Unscheduled	GSM – General Sales Medicines	GSL – General Sale Line	OTC General Sale	OTC – Unscheduled
S2 – Pharmacy Medicine	Pharmacy-Only Medicine	Pharmacy Medicine		Schedule III – Pharmacy Only
S3 – Pharmacist Only	Restricted Medicine			Schedule II – Pharmacist Only
S4 – Prescription Only	Prescription Medicine	Prescription Only Medicine	Prescription Only Medicine	Schedule I – Prescription Only

[1] www.mims.com.au

	Available only through pharmacy with opportunity to consult pharmacist
	Available only on prescription

It can be seen from this table that the supply of OTC cough and cold medicines for children in the USA can be through outlets such as grocery stores or service stations. There is no requirement for health professional intervention and therefore their solution for addressing this issue is in response to their largely unregulated system. By contrast, both Australia and New Zealand (NZ) have robust safety mechanisms in place for supply of non-prescription scheduled medicines, either requiring or providing the opportunity for pharmacist intervention.

Looking at the list of cough and cold medicines for children in *Attachment A*, it can be seen that there are still a number of products available that are unscheduled and available in Australia without requiring or providing the opportunity for access to pharmacist intervention. The Guild believes that all cough and cold products for children should be restricted to facilitate intervention by a health professional. However, in determining the level of intervention required against the risk-benefit profile of the medicine concerned, whilst it is beneficial to consider actions taken in other countries, Australia has the benefit of having a more rigorous scheduling system with more options to balance patient access with professional intervention. Such decisions though should be based on robust evidence of which there is very little with regards to these particular drugs.

2. Product Evaluation

The Guild believes robust evidence should be required to support the registration of all medicines in Australia, but that each drug should be assessed on an individual basis rather than as a disparate group.

As part of the evaluation of a medicine for efficacy and safety, it is also important to assess and consider the societal impact and any qualitative data of which little information has been provided. Quotes from two or three individual health professionals cannot be taken as representational. Nor has any information been provided regarding consumer opinion or beliefs. Consumer perceptions are important. Why do parents buy these products and what would they do if access to cough and cold medicines for their children became much more restricted? Much can be surmised, but it would be more appropriate to gather some convincing qualitative information to assist in making a final determination.

With regards to qualitative evaluation, we note that in the Extract of Minutes from the Medicines Evaluation Committee meeting of 30 July 2009, consideration was given to educating parents about non-drug approaches to relieving coughs and colds in children, or other simple measures such as lemon and honey. It would be an interesting exercise to canvas highly health literate health professionals, such as pharmacists and doctors, who have (or have had) young children, and assess how they prefer to manage their children when they have a cough or cold. We would expect the majority would support the use of cough and cold medicines.

Throughout the consultation papers, there appears be a general consensus that the evidence to date is not sufficiently compelling to demonstrate the safety or efficacy of cough and cold medicines for any age group. **A lack of evidence does not equate to evidence of lack of efficacy.** The Guild does not believe that the evidence referenced in the consultation papers justifies the need for such drastic measures as that proposed, irrespective of what is happening overseas. We note that research is being conducted in the USA regarding the safety and efficacy for eight cough and cold ingredients but the results will be some time away. The Guild would support taking action for drugs of immediate concern where there is a robust evidence base indicating serious concerns regarding safety and efficacy. At the same time, the Guild supports implementing interim, but less drastic changes for the remainder, whilst awaiting the results of these trials and any other evidence that can be supplied by manufacturers or other appropriate bodies.

The Guild believes that there would be merit in the TGA maintaining a list of cough and cold drugs suitable for use in children of various age groups and that such a list could include:

- specific indications for which it can be used
- dosing directions by weight rather than age
- indication of the level of evidence currently available and
- limitations on how it can be promoted on label or through advertising.

We are aware that the following matters have been considered, but we believe they warrant further consideration.

Multiple active ingredients
Products with multiple active ingredients can have confounding actions, therapeutic dosing levels and adverse drug reaction (ADR) profiles. We would support further investigation of the pharmacological appropriateness and safety and efficacy profile of products with multiple active ingredients versus those with single active ingredients. Outcomes from such investigation could mean different management strategies and restriction requirements.

Dosing by weight
The consultation papers correctly highlight the disparity that can result from dosing instructions applying to a wide age group, such as 2-6 years or 6-12 years. The Guild would support requiring dosing instructions to be based on a weight range rather than an age range, believing that this practice should be encouraged for all drugs with paediatric dosing. This is not uncommon practice, and reference to the clinical monographs in the Australian Pharmaceutical Formulary[2] shows that many of the listed drugs with paediatric doses are by weight rather than age. Still, several of the drugs listed in the formulary have paediatric dosing by age and we support refining existing or developing new reference tools to support health professionals in determining appropriate paediatric dose instructions by weight.

[2] APF21 – Australian Pharmaceutical Formulary and Handbook; 21st Edition; 2009

3. **Efficacy**

The Guild agrees that product efficacy is imperative to justify supply within Australia. However, the consultation papers state that there has been little effective evaluation done on the efficacy of the drugs being considered and many of the trials have not been well designed or have been too small in nature to be of use. The consultation papers also highlight that in otherwise well-designed studies, the failure to demonstrate efficacy may be due to low dosage or inappropriate dosing frequency. This may be particularly so for products with multiple active ingredients where the dose of one drug within the product may be within the safe therapeutic range whilst other active ingredients may be either over or under.

It is the Guild's view that the proposed changes are not justified by the information presented. Many of the trials listed are very old in nature (some are over 20 or 30 years old). It is questionable whether the drugs trialled or doses used are relevant to today's consultation.

With the first reference[3] in the 'Tabulated summaries of clinical trials', one trial testing two paediatric cough syrups showed a 'satisfactory response' in 46% and 56% of children compared to 21% in the placebo group. Yet the questionable conclusion to this trial is that there is inadequate evidence. It would be interesting to know what satisfactory response rate was expected to demonstrate efficacy.

Much of the more damning data presented relates to drugs with little clinical significance for OTC products in Australia (e.g. ipecac and codeine). In addition, a significant number of other trials were presented in the 'Tabulated summaries of clinical trials' concerned studies in adults for which there is questionable relevance for this particular issue. References to effectiveness of oral decongestants in common cold treatments seem to deal with improvements after one single dose rather than assessing outcomes over successive doses within a recommended dosage regimen.

Of the drugs profiled in the 'Review of cough and cold medicines in children', it would appear that some trials suggest efficacy with dextromethorphan and that there have been limited or no trials for products such as pholcodine, ammonium chloride, bromhexine and guaiphenesin and therefore it is inappropriate to make such momentous changes based on so little information.

Many, if not all of the ingredients that are affected are off patent. Without incentive, it is unlikely that a single sponsor will invest the capital to conduct the necessary research to address this issue. Such incentives may include a more considered approach to the proposed changes. The Guild also believes that in evaluating efficacy of a particular drug, it should be encouraged that studies be conducted on products with single active ingredients to support determining appropriate safe therapeutic doses.

4. **Safety**

The Guild agrees that should a medicine or class of medicine show evidence of serious patient misadventure, it is appropriate to consider restricting access. However, the Guild believes that the evidence provided in these consultation

[3] Smith et al 2008

papers have done little to justify such a severe class action as that proposed and we are concerned that rather than improve the safety profile of these medicines, it may in fact increase the risk of misadventure within a particularly vulnerable population group.

With many of these products being available for decades in Australia for which there has been strong demand, it would be reasonable to assume that sales of these products would be in millions of units. With such sales volume, the consultation papers advise of 99 adverse drug reactions (ADRs). Of these 99 ADRs, it is reported that 14 are serious of which only 1 is probable and the remainder are only possible or unclear. It is not unreasonable to assume that ADRs may be underreported, but decisions should be based on facts, not assumptions.

Safety in children is a serious issue, but decisions should be based on proper evidence. Two deaths are reported of which one is for a one year old administered oxymetazoline and morphine and the other relates to the administration of ipecacuanha but it is unclear whether this was from a cough mixture or an emetic preparation. Although these events are serious, unless they relate to the products or age groups being considered, they have little or no relevance. It is also unclear whether the ADR reports are all from the administration of children's products. Some may be from the inappropriate use of adult products, which, if so, would again be irrelevant to this consultation.

Before any decisions are made, it would be better to assess the relevance of the reports against the issue being considered. It would also be appropriate to assess whether the proposed amendments would have actually prevented the ADRs or would the situation remain largely unchanged. The Guild is concerned that without having easy access to appropriate dosage instructions, parents will use adult preparations and guess the dose for their children. Alternatively, they may resort to using complementary products that do not facilitate pharmacist intervention. This could result in more serious complications not being detected and referred to the doctor. Consumer health literacy has been identified within the recent Health Reform Reports[4] to be a serious issue. Without facilitating intervention by a pharmacist or other health professional to support them when required, parents may be misguidingly putting their children at risk.

With regards to safety, there is not a new adverse drug reaction pattern emerging, nor could it be argued that pharmacists require further understanding of the adverse reaction profile of these medicines. The Guild believes that rather than addressing safety concerns, the proposed changes would increase the risk of misadventure.

Additional safety measures

One of the proposed changes is that all OTC cough and cold medicines are marketed in containers with child-resistant closures. The Guild supports this proposal, with the exception of topical preparations such as nasal sprays as we believe this to be unjustified and unwarranted.

[4] National Health and Hospitals Reform Commission, The National Primary Health Care Strategy and the Preventative Health Strategy

We also note that New Zealand, Canada and the USA have either recommended or implemented the mandatory inclusion of accurate measuring devices in liquid preparations. This safety measure would be worth considering in Australia and would be supported by the Guild.

5. Impact on Pharmacy, the Health System and the Public

Pharmacists are highly trained health professionals, capable of triaging, assessing and treating minor ailments for all population groups, with referral to the doctor for complications outside of their scope of practice.

Given pharmacy's long history in effectively and safely supplying these medicines in Australia, and the relative inexperience of many family doctors in providing dosing information for these products, we feel that pharmacists are better placed to assess the appropriate supply of cough and cold medicines for children, and to provide the necessary dosing instructions.

In the recent Health Reform Reports, the burden on general practice in coping with primary care has been recognised with recommendations to better utilise the support of other health professionals. A July 2009 Report[5] from the Australian Institute of Health and Welfare (AIHW) states that there is a shortage of doctors and a decrease in the child attendance rate. The cause of the latter has not been determined and may partly reflect access difficulties. Consideration must be given to the impact the proposed changes to cough and cold medicines for children may have on general practice, such as:

- The capacity of general practice to treat children under 6 in a timely manner – particularly in rural and remote areas.
- Potential delays in the treatment of children because of long waiting lists to see a doctor.
- There will be a significant impost on the Medical Benefits Scheme (MBS) as parents of children under 6 will need to see a doctor.
- There will be an increased need for parents to take carer's leave so that they can take their child to the doctor.
- Potential delays of treating patients with more serious health complaints and chronic conditions as waiting lists grow due to demand for treating minor cough and cold ailments in children.
- The onus on doctors to prescribe efficacious medicines – Medical Boards hold doctors accountable for what they prescribe and doctors would (and should) expect that registered medicines restricted to prescription only have supporting evidence for quality, safety and efficacy.
- Pressure on doctors to provide a prescription – this may result in inappropriate prescribing of antibiotics or bronchodilators. A report[5] of GP prescribing habits for upper respiratory tract infections(URTIs) indicated that whilst antibiotic prescriptions for children has fallen, one in five children still receive an antibiotic for an URTI.
- Delays and costs associated with additional pathology tests for URTIs.

[5] AIHW: General practice in Australia, health priorities and policies 1998-2008; July 2009

If the proposed changes proceed, the Guild has identified considerable impact on community pharmacy, including:

- Confusion on the schedule status of the medicines affecting labelling, supply and storage requirements – having identical therapeutic agents in different schedules based on age is a largely unknown concept in Australia and the proposed changes could see the same product as S2, S3 or S4 according to the indicated aged group.
- Pressure to dispense – consumers feel that a doctor's prescription validates the quality, efficacy and safety of the medicine prescribed and pharmacists may feel pressured to supply; Pharmacy Boards consider pharmacists equally accountable if an inappropriate product is supplied, regardless of whether a prescription is involved.
- Concern that parents may provide misleading information about their child in order to obtain the medicine they want. We have concerns regarding child safety that in such cases, parents and carers may extrapolate and guess doses for younger children. This may result in many childhood overdoses which is counter to the intent of the proposed changes.
- Concern that parents may resort to requesting inappropriate products as an alternative (e.g. promethazine syrup).
- Capacity of community pharmacy to professionally manage the significant increase in S3 medicines – pharmacist intervention with S3 medicines is particularly meritorious in promoting the quality use of medicines, but it is important that arrangements are in place to ensure pharmacists are supported and prepared for changes which may impact significantly on the pharmacy workflow.

And the following possible impacts on the public should also be considered:

- Parents of children under 6 years would be subject to additional costs to see a doctor as well as additional dispensing fees if a cough and cold medicine is prescribed. These products will not be covered by the Pharmaceutical Benefits Scheme (PBS) and would be dispensed as a private prescription item, incurring a mark-up plus a dispensing fee which could be up to $10.21[6].
- In an effort to avoid these extra costs, parents may resort to purchasing OTC products indicated for older children or adults and guessing doses for the age groups not included on the container. Pharmacists will not be able to provide dosing instructions for children under 6, even if parents have the product at home having had it recommended for an adult or older child.
- For most of these products, parents currently have access to pharmacist advice if needed. Parents may resort to purchasing herbal or homeopathic remedies to treat their children, which may have questionable efficacy or safety issues. These products however do not facilitate interaction with a pharmacist and therefore there is a much greater risk of misadventure or of complicated cases not being referred.

[6] Based on the maximum allowed for under co-payment PBS items which includes a dispensing fee of $6.42 + $3.79 additional allowance.

6. **Labelling**
The Guild has concerns with the proposal to include a dogmatic warning against use in children under 6 because, irrespective of the final outcome of scheduling for products in this age group, if the product is recommended or prescribed by the appropriate health professional, the labelling advice will contradict the health professional recommendation. This could affect the trust that the parent has in that particular health professional and have a negative impact on the family's long term health support, particularly in rural and remote areas.

We suggest a better alternative would be to include a warning such as 'Do not use in children under 6 years of age [or lowest specified age] except on the advice of your pharmacist or doctor [according to the schedule of the product].'

7. **Scheduling**
In this submission we will not be addressing the proposed scheduling changes as this will be more appropriately dealt with by the NDPSC process if a proposal is put to the NDPSC following this consultation. Suffice to say that the Guild does not support the inclusion of any of the cough and cold medicines for children aged 2 to 12 years within Schedule 4. We believe that pharmacists are the best placed and most cost-effective health professional to manage the treatment of minor ailments such as uncomplicated coughs and colds for all age groups and the Australian scheduling system provides for greater pharmacist intervention without the need to restrict products to prescription only.

In saying this, the Guild is concerned that the changes proposed within this consultation will affect a wide range of medicines, including nasal sprays. The Guild believes that decongestant nasal sprays should be restricted to facilitate access to a pharmacist to monitor and manage any risk of rebound congestion, but that they should be excluded from any proposed restriction for children aged 2 to 6 years. The Guild does not believe that any evidence has been provided within the consultation papers to justify concern for nasal sprays and we understand that New Zealand has specifically excluded nasal sprays from any proposed changes.

Although the use of schedules to address safety concerns is appropriate, the Guild does not believe that the use of schedules is appropriate to address efficacy concerns. We believe that this matter is better dealt with as part of the product registration process. Pharmacists and doctors, as well as the public, have an expectation that scheduled products are efficacious for the indication/s for which they are registered. If anything, this expectation is higher if a product is S3 or S4. When a medicine is recommended by a pharmacist or prescribed by a doctor, the public have a greater trust that the particular medicine will be effective and safe for them to use.

Summary

We wish to reiterate the efficacy and cost-effectiveness of community pharmacy in managing uncomplicated coughs and colds in children to date and that we believe the most appropriate outcome from this consultation is to recognise the contribution of community pharmacy and better utilising its capacity, expertise and experience.

Efficacy and safety of medicines for children are extremely important, but it is imperative that decisions are made based on cogent evidence with consideration of the local situation. Australia has a robust and highly effective scheduling system for medicines to safeguard the public and pharmacy's long term experience with OTC cough and cold medicines has demonstrated that pharmacists are well positioned to provide appropriate dosing and treatment advice to parents regarding these products, with referral as appropriate.

The Guild does not believe that justification has been provided for the changes as proposed and that it would be more appropriate to:

- further investigate efficacy and safety of affected drugs on an individual basis
- further investigate the efficacy and safety of cough and cold products available in Australia on an individual basis
- not contraindicate cough and cold medicines for children under 6 until more evidence is available
- retain OTC accessibility to appropriate cough and cold products for children aged 2 to 12 years with pack warnings that the medicine should only be given on the advice of a doctor or pharmacist
- implement immediate changes for individual drugs or products that have been identified as having serious safety concerns e.g. diphenhydramine
- require dosing instructions for children by weight rather than age
- require cough and cold liquid medicines to have child resistant packaging
- consider whether Schedule 3 would be more appropriate for cough and cold medicines for children aged 2 to 12 years
- support the development of strategies and tools to assist health professionals in managing the changes and support the quality use of these medicines.

The Guild will be pleased to work with the TGA and other stakeholders to ensure that community pharmacy is prepared for and supported with any changes and that consumers continue to access and experience professional pharmacy intervention to support the quality use of medicines.

ATTACHMENT A

List of products affected by the proposed changes

This table is based on information available from the Abbreviated Product Information available from MIMS On-line and is not necessarily complete.

Children's Cough and Cold Products affected by proposed TGA amendments

Product	Active Ingredient/s	Formulation	Current Schedule	Dose (PRN) for children 2-5 years	Dose (PRN) for children 6-12 years	ARTG Rego
Benadryl range						
Benadryl Family Chesty Cough & Nasal Congestion	**Per 5ml:** Guaifenesin 100mg; pseudoephedirine 30mg	Mixture 100ml	S3	2.5ml q4-6h (Maximum 4 doses/day)	5ml Q4-6H (Maximum 4 doses/day)	yes
Benadryl Family Chesty Forte	**Per 5ml:** Bromhexine 3mg; Guaiphenesin 100mg	Mixture 100ml; 200ml	S2	2.5-5ml Q6H	5-7.5ml Q6H	yes
Benadryl Family Dry Forte	**Per 5ml:**Dextromethorphan 15mg/5ml	Mixture 100ml; 200ml	S2	2.5ml Q6-8H	5ml Q6-8H	yes
Benadryl Family Dry Cough & Nasal Congestion	**Per 5ml:** Dextromethorphan 10mg; Pseudoephedrine 30mg	Mixture 100ml	S3	2.5ml Q6H	5ml Q6H	yes
Benadryl Family Nightime	**Per 5ml:** Dextromethorphan 10mg; Diphenhydramine 12.5mg	Mixture 100ml; 200ml	S3	2.5ml Q4H (Maximum 4 doses/day)	5ml Q4H (Maximum 4 doses/day)	yes
Benadryl Family Original	**Per 5ml:** Diphenhydramine 12.5mg; Ammonium chloride 125mg; Sodium citrate 50mg	Mixture 100ml; 200ml; 500ml	S3	2.5ml Q4H	5ml Q4H	yes
Bisolvon range						
Bisolvon Sinus liquid	**Per 5ml:** Bromhexine 4mg; Pseudoephedrine 20mg	Mixture 200ml	S3	2.5ml tds	5ml tds	yes
Bisolvon Chesty Liquid	**Per 5ml:** Bromhexine 4mg; Pseudoephedrine 20mg	Mixture 250ml	S2	1-3yrs: 5ml tds	>3yrs: 10ml tds	yes
Bisolvon Chesty Forte Liquid	**Per 5ml:** Bromhexine 8mg	Mixture 200ml	S2	1-3yrs: 2.5ml tds	>3yrs: 5ml tds	yes
Bisolvon Dry Liquid	**Per 5ml:** Dextromethorphan 10mg/5ml	Mixture 125ml; 200ml	S2	1.25-3.75ml Q4-6H (Maximum 4 doses/day)	2.5-7.5ml Q4-6H (Maximum 4 doses/day)	yes
Bisolvon Chesty Tablets	**Per tablet:** Bromhexine 8mg	Tablets 50; 100	S2	use liquid	1 tablet tds	yes

Children's Cough and Cold Products affected by proposed TGA amendments

Product	Active Ingredient/s	Formulation	Current Schedule	Dose (PRN) for children 2-5 years	Dose (PRN) for children 6-12 years	ARTG Rego
Chemist Own range						
CO Chesty Mucous Cough Mixture	**Per 5ml:** Bromhexine 4mg; Guaphenesin 100mg	Mixture 200ml	S2	2.5ml q4-6h (Maximum 4 doses/day)	5ml Q4-6H (Maximum 4 doses/day)	yes
CO Chesty Cough Mixture	Per 5ml: Bromhexine 4mg; Pseudoephedrine 30mg; Guaifenesis 50mg	Mixture 100ml	S3	2.5ml q4-6h (Maximum 4 doses/day)	5ml Q4-6H (Maximum 4 doses/day)	yes
CO Expectalix Cough Mixture	**Per 5ml:** Ammonium chloride 100mg; Codeine7.5mg; Guaifenesin 30mg; Phenylephrine 2.5mg; Pseodoephedrine 22.5mg	Mixture 200ml	S4	4-7yrs: 5ml Q3-4H	8-12yrs: 8ml Q3-4H	yes
CO Dry Cough Mixture	**Per 5ml:** Codeine 8.6mg; Pseudoephedrine 30mg	Mixture 200ml	S4	2.5ml q4-6h (Maximum 4 doses/day)	5ml Q4-6H (Maximum 4 doses/day)	yes
CO Difenicol Cough Mixture	**Per 5ml:** Ammonium chloride 125mg; Diphenhydramine 12.5mg; Sodium citrate 50mg	Mixture 200ml	S3	2.5ml Q4H	5ml Q4H	yes
CO Kiddicol Children's Cough Mixture	**Per 5ml:** Ammonium chloride 25mg; Chlorpheniramine 1mg; Phenylephrine 1.25mg; Pholcodine 1.5mg	Mixture 200ml	S2	5ml q4h (Maximum 4 doses/day)	10ml Q4H (Maximum 4 doses/day)	yes
CO Dry Raspy Cough Mixture	**Per 5ml:** Chlorpheniramine 2ml; Dextromethorphan 10mg; Pseudoephedrine 30mg	Mixture 200ml	S4	2.5ml q4-6h (Maximum 4 doses/day)	5ml Q4-6H (Maximum 4 doses/day)	yes
CO Children's Cold & Allergy Mixture	**Per 5ml:** Chlorpheniramine 1.25mg; Phenylephrine 2.5mg	Mixture 100ml; 200ml	S2	2-4yrs: 4-6ml Q6-8H 4-6yrs: 6-8ml Q6-8H	8-15ml Q6-8H	yes
Demazin range						
Demazin Cough and Cold Syrup	**Per 5ml:** Chlorpheniramine 2mg; Pholcodine 5mg; Pseudoephedrine 20mg	Mixture 100ml; 200ml	S3	2-5ml tds	5-7ml tds	yes
Demazin Cold Relief Syrup	**Per 5ml:** Chlorpheniramine 1.25mg; Phenylephrine 2.5mg	Mixture 100ml; 200ml	S2	2-4yrs: 4-6ml Q6H 4-6yrs: 6ml Q6H	8-15ml Q6H	yes
Demazin Cough & Cold Relief Elixir	**Per 5ml:** Brompheniramine 2mg; Dextromethorphan 10mg; Phenylephrine 5mg	Mixture 100ml; 200ml	S2	2.5ml Q4H	5ml Q4H	yes

Children's Cough and Cold Products affected by proposed TGA amendments

Product	Active Ingredient/s	Formulation	Current Schedule	Dose (PRN) for children 2-5 years	Dose (PRN) for children 6-12 years	ARTG Rego
Dimetapp range						
Dimetapp Chest Congestion Paediatric Drops	**Per 5ml:** Guaifenesin 100mg	Mixture 50ml	Unscheduled	2-4yrs:2.5-3.5ml Q4H 4-6yrs: 3.5-5ml Q4H	8-15ml Q6H	yes
Dimetapp Chesty Cough Elixir	**Per 5ml:** Bromhexine 4mg; Guaphenesin 100mg	Mixture 100ml; 200ml	S2	2.5ml Q8H	5ml Q8H	yes
Dimetapp Elixir	**Per 5ml:** Brompheniramine 2mg; Phenylephrine 5mg	Mixture 100ml; 200ml	S2	2-4yrs:4ml Q6-8H 4-6yrs: 5ml Q6-8H	7.5ml Q6-8H	yes
Dimetapp DM Elixir	**Per 5ml:** Brompheniramine 2mg; Dextromethorphan 10mg; Phenylephrine 5mg	Mixture 100ml; 200ml	S2	2.5ml q4h	5ml Q4H	yes
Duro-Tuss range						
Durotuss Chesty Cough + Nasal Decongestant	**Per 5ml:** Bromhexine 4mg; Pseudoephedrine 20mg	Mixture 100ml; 200ml	S3	2-5ml tds	5-10ml tds	yes
Durotuss Chesty Cough Regular	**Per 5ml:** Bromhexine 4mg	Mixture 100ml; 200ml	S2	2-5ml tds	5-10ml tds	yes
Durotuss Cough Liquid Expectorant	**Per 5ml:** Bromhexine 4mg; Pholcodine 5mg	Mixture 100ml; 200ml	S2	2.5-5ml QID	5-10ml QID	yes
Durotuss Chesty Cough Forte	**Per 5ml:** Bromhexine 4mg; Guaiphenesin 100mg	Mixture 100ml; 200ml	S2	2.5ml q4-6h (Maximum 4 doses/day)	5ml Q4-6H (Maximum 4 doses/day)	yes
Durotuss Dry Cough Liquid Forte	**Per 5ml:** Pholcodine 15mg	Mixture 100ml; 200ml	S2	1ml QID	2-3ml QID	yes
Durotuss Dry Cough Liquid + Nasal Decongestant	**Per 5ml:** Pholcodine 5mg; Pseuodephedrine 20mg	Mixture 100ml; 200ml	S3	2-5-5ml QID	5-10ml QID	yes
Durotuss Dry Cough Liquid Regular	**Per 5ml:** Pholcodine 5mg	Mixture 100ml; 200ml	S2	2-5-5ml QID	5-10ml QID	yes
Durotuss PE Dry Cough + Nsal Decongestant	**Per 5ml:** Phenylephrine 3.33mg; Pholcodine 5mg	Mixture 100ml; 200ml	S2	2-5-5ml QID	5-10ml QID	yes

Children's Cough and Cold Products affected by proposed TGA amendments

Product	Active Ingredient/s	Formulation	Current Schedule	Dose (PRN) for children 2-5 years	Dose (PRN) for children 6-12 years	ARTG Rego
Gold Cross range						
GC Senaga and Ammonia Mixture APF14	Ammonium Bicarbonate; Camphor; Senega	Mixture 200ml	Unscheduled	2.5ml Q4H	5ml Q4h	yes
GC Ipecacuanha and Tolu Mixture APF	**Per 5ml:** Camphor Co.Spir. 0.5ml; Ipecacuanha Tinct 0.125mg; Tolu Syr 0.5ml	Mixture 200ml	Unscheduled	2.5ml Q4H	5ml Q4h	yes
GC Cough Mixture	**Per 5ml:** Ammonium chloride 125mg; Diphenhydramine 12.5mg; Menthol 0.5mg; Sodium citrate 50mg	Mixture 200ml	S3	2.5ml Q4H	5ml Q4h	yes
Nyal range						
Nyal Cold and Flu Medicine	**Per 5ml:** Phenylephrine 5mg	Mixture 200ml	Unscheduled	2.5-5ml Q4H	5ml Q4H	yes
Nyal Decongestant Mixture	**Per 5ml:** Phenylephrine 5mg	Mixture 200ml	Unscheduled	2.5-5ml Q4H	5ml Q4H	yes
Nyal Sinus Relief Elixir	**Per 5ml:** Phenylephrine 5mg	Mixture 200ml	Unscheduled	2.5-5ml Q4H	5ml Q4H	yes
Nyal Night-Time Cough Mixture	Glycyrrhiza glabra root; Melissa officinalis; Senega; Squill	Mixture 200ml	Unscheduled	2.5ml HS	5ml HS	yes
Nyal Chesty Cough Mixture	**Per 5ml:** Glucose 3g; Guaiphenesin 100mg; Treacle 1.25g	Mixture 200ml	Unscheduled	2.5-5ml Q4H	5-10ml Q4H	yes
Nyal Bronchitis Cough Medicine	**Per 5ml:** Ammonium chloride 55mg	Mixture 100ml; 200ml	Unscheduled	5-8yrs: 5ml Q4H	8-12yrs: 7.5ml Q4H	yes
Nyal Dry Cough Mixture	**Per 5ml:** Pentoxyverine 7.5mg	Mixture 200ml	Unscheduled	4-6yrs: 2-5ml Q6-8H	5ml Q6-8H	yes
Paedamin range						
Paedamin Decongestant & Antihistamine Syrup for children	**Per 5ml:** Diphenhydramine 12.5mg; phenylephrine 2.5mg	Mixture 200ml	S2	2-4yrs (12-16kg): 4-5.5ml Q6-8H 4-6yrs (16-20kg): 5.5-7ml Q6-8H	6-8yrs (20-23kg): 7-8ml Q6-8H 8-10yrs (23-28kg): 8-10ml Q6-8H 10-12yrs (28-41kg): 10-15ml Q6-8H	yes

Children's Cough and Cold Products affected by proposed TGA amendments

Product	Active Ingredient/s	Formulation	Current Schedule	Dose (PRN) for children 2-5 years	Dose (PRN) for children 6-12 years
Robitussin range					
Robitussin EX Syrup	**Per 5ml:** Guaiphenesin 100mg	Mixture 100ml; 200ml	Unscheduled	2.5-5ml Q4H	5-10ml Q4H
Robitussin EX Paediatric Drops	**Per 5ml:** Guaiphenesin 100mg	Mixture 50ml	Unscheduled	2-4yrs: 2.5-3.5ml Q4H 4-6yrs: 3.5-5ml Q4H	
Robitussin PS Syrip	**Per 5ml:** Guaiphenesin 100mg; Pseudoephedrine 30mg	Mixture 100ml	S3	2.5ml Q4-6H	5ml Q4-6H
Robitussin ME Chesty Cough Forte	**Per 5ml:** Bromhexine 4mg; Guaphenesin 100mg	Mixture 100ml; 200ml	S2	2.5ml Q8H	5ml Q8H
Robitussin DX Dry Cough Forte	**Per 5ml:** Dextromethorphan 15mg	Mixture 100ml; 200ml	S2	2.5ml Q6-8H	5ml Q6-8H
Robitussin DM	**Per 5ml:** Dextromethorphan 15mg; Guaiphenesin 100mg	Mixture 100ml; 200ml	S2	2.5ml Q6-8H	5ml Q6-8H
Non-specific ranges					
Lemsip Chesty Cough Mixture	**Per 5ml:** Guaiphenesin 50mg	Mixture 100ml	Unscheduled	5ml Q6-8H	10ml Q6-8H
Nucosef syrup	**Per 5ml:** Codeine 7.45mg; Pseudoephedrine 30mg	Mixture 100ml	S3	N/A	5ml Q4-6H (Maxium 4 doses/day)
Rikodeine	**Per 5ml:** Dihydrocodeine 9.5mg	Mixture 100ml; 200ml	S3	4-5yrs: 2-2.5ml Q4-6H	2.5-5ml Q4-6H
Tixylix Nightime Linctus	**Per 5ml:** Pholcodine 1.5mg; promethazine 1.5mg	Mixture 100ml; 200ml	S3	5ml Q8-12H	5-10ml Q8-12H
Vicks Chesty Cough Syrup	**Per 5ml:** Guaiphenesin 66.7mg	Mixture 200ml	Unscheduled	5ml q4h (Maximum 4 doses/day)	10ml Q4H (Maximum 4 doses/day)
Lozenges					
Cepacol Cough plus	**Per lozenge:** Benzocaine 1mg; Cetylpyridium 1.3mg; Dextromethorphan 5mg; Menthol 5.2mg	Lozenges - 16 pack	S2	N/A	1 Q3h
Difflam Anti-inflammatory Cough	**Per lozenge:** Benzydamine 1.5mg; Cetylpyridium 133mg; Pholcodine 5.5mg	Lozenges - 24 pack	S2	N/A	1 Q3H
Durotuss Cough	**Per lozenge:** Cetylpyridium 1.33mg; Pholcodine 5.5mg	Lozenges - 24 pack	S2	N/A	1 Q3H (Maximum 6/day)
Strepsils Cough relief	**Per lozenge:** Dextromethorphan 5mg	Lozenges - 24 pack	S2	N/A	1 Q2-3H

Children's Cough and Cold Products affected by proposed TGA amendments

Product	Active Ingredient/s	Formulation	Current Schedule	Dose (PRN) for children 2-5 years	Dose (PRN) for children 6-12 years	ARTG Rego
Nasal sprays						
Chemists' Own Decongestant N/S	**Per ml:** Oxymetazoline 500mcg	Nasal Spray	S2	N/A	1-2 sprays/nostril Q8-12H	yes
Dimetapp 12 Hour N/S	**Per ml:** Oxymetazoline 500mcg	Nasal Spray	S2	N/A	1-3 sprays/nostril bd (Max 3 days)	yes
Drixine N/S	**Per ml:** Oxymetazoline 500mcg	Nasal Spray	S2	N/A	2-3 sprays/nostril Q8-12H	yes
Drixine Paediatric Drops	**Per ml:** Oxymetazoline 250mcg	Nasal Drops	S2	2-3 drops/nostril Q8-12H	N/A	yes
Extra-life Nasex Decongestant N/S	**Per ml:** Oxymetazoline 500mcg; Cineole 0.02%; Menthol).012%	Nasal Spray	S2	N/A	1-2 sprays/nostril Q8-12H	yes
Logicin Rapid relief N/S	**Per ml:** Oxymetazoline 500mcg	Nasal Spray	S2	N/A	1-2 sprays/nostril Q8-12H	yes
Nyal Decongestant N/S	**Per ml:** Phenylephrine 5mg	Nasal Spray	Unscheduled	Not specified - listed as caution	Not specified - listed as caution	yes
Otivin Nasal Mist Junior	**Per ml:** Xylometazoline 500mcg	Nasal Spray	S2	6mths-6yrs: 1 spray/nostril Q6-12H (Max of 5 days)	2-3 sprays/nostril Q6-12H (Max of 5 days)	yes
Otivin Nasal Drops Junior	**Per ml:** Xylometazoline 500mcg	Nasal Drops	S2	<6yrs: 1 drop/nostril up to TDS (max of 5 days)	2-3 drops/nostril up to TDS (max of 5 days)	yes
Vicks Sinex N/S	**Per ml:** Oxymetazoline 500mcg	Nasal Spray	S2	N/A	1-2 sprays/nostril Q8-12H	yes