

# FURTHER PUBLIC SUBMISSIONS ON THE PROPOSED AMENDMENTS TO THE POISONS STANDARD

## Regulation 42ZCZL, Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary of the Department of Health and Ageing publishes herein all valid public submissions made in response to the invitation for public submission on the proposed amendments to the Poisons Standard. These submissions were considered by the Advisory Committee on Chemicals Scheduling (ACCS) #8, the Advisory Committee on Medicines Scheduling (ACMS) #9 and the joint ACCS-ACMS #6 (July 2013 meetings).

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had confidential information removed.

Material claimed to be commercial-in-confidence was considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework (SPF), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible at [www.tga.gov.au/industry/scheduling-spf.htm](http://www.tga.gov.au/industry/scheduling-spf.htm).

Discrete submissions have been grouped by substance. Two submitters provided submissions that related to multiple substances and these has been separately grouped.

## LIST OF SUBMISSIONS

Substance	Total number of public submissions
1,2 benzenediol (catechol)	1 submission under 'submissions on multiple substances'
Cocoyl glycinate	1 submission under 'submissions on multiple substances'
3-iodo-2-propynyl butyl carbamate (iodocarb)	1 submission under 'submissions on multiple substances'
Hexyloxyethanol	1 submission under 'submissions on multiple substances'
Hydroquinone and monobenzone	1 submission under 'submissions on multiple substances'
Loratadine	3 (1 submission under 'submissions on multiple substances')
Vortioxetine hydrobromide	1 (under 'submissions on multiple substances')

## SUBMISSION ON MULTIPLE SUBSTANCES

One submission was on loratadine and vortioxetine hydrobromide;

One submission was on catechol, iodocarb, cocoyl glycinate and hexyloxyethanol;

One submission was on hydroquinone and monobenzone.



The Secretary  
Scheduling Secretariat  
GPO Box 9848  
CANBERRA ACT 2601

Email: [SMP@health.gov.au](mailto:SMP@health.gov.au)

Dear Sir/Madam

**Public Comment Submission to the July 2013 meeting of the  
Advisory Committee on Chemicals Scheduling (ACCS) and  
the joint meeting of the ACCS and the Advisory Committee on Medicines Scheduling  
(ACMS)**

We refer to the notice published on 13 June 2013 inviting public submissions, with respect to certain substances, addressing a matter raised in s.52E of the *Therapeutic Goods Act 1989*.

Accord Australasia Limited is the peak national industry association that represents the hygiene, cosmetic & specialty chemicals industry.

Accord wishes to provide information on **catechol**, **iodicarb**, **cocoyl glycinate** and **hexyloxyethanol** for consideration at the July 2013 meeting of the ACCS, and **hydroquinone** and **monobenzene** for consideration at the July 2013 joint-meeting of the ACCS and ACMS.

Please see attached submission for details.

Accord is an interested party and stakeholder with regard to the nominated substances and would appreciate being advised of the Committees' considerations and the Delegate's interim decision, with the opportunity for further submission, if appropriate.

We look forward to further advice from the ACCS, ACMS and the Delegate. Should the Committees or the Delegate require any additional information from Accord at this stage please do not hesitate to contact me [REDACTED].

Yours faithfully

[unsigned for electronic submission]

[REDACTED]

11 July 2013

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*Products for healthy living and a quality lifestyle*

## **ACCS meeting: July 2013**

### **1,2-Benzenediol (catechol)**

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To date, our Members have not indicated that they are using catechol in any of their products. Accord will make further submissions if any additional information comes to light between this submission and the Delegate's Final Decision.

In principle, Accord supports risk management of catechol which reflects international practice.

## ACCS meeting: July 2013

### 3-iodo-2-propynyl butyl carbamate (iodocarb)

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Accord welcomes the opportunity to clarify the current restrictions on iodocarb in the Poisons Standard. The distinction between aqueous and non-aqueous preparations containing iodocarb has caused some confusion for industry, particularly for the cosmetics industry where many of the formulations are emulsions and cannot be clearly said to be either aqueous or non-aqueous. We understand that this distinction was originally made when considering the substance in the agvet use only, and not in cosmetic use.

We note the EU restrictions on iodocarb in cosmetic products and the US Cosmetic Ingredient Review report which considered iodocarb safe for use in cosmetics in concentrations equal to or less than 0.1%. While the Poisons Standard had not set a lower limit for the specific use of iodocarb in cosmetics, it is our understanding that the products currently available in Australia would contain less than or equal to 0.1% iodocarb in formulation as a preservative.

Given that there have been no concerns raised in Australia with the use of iodocarb as a preservative in cosmetic products, we do not believe that there is as yet an established case to restrict this use. However, as it is our current understanding that the products currently available in Australia contain less than or equal to 0.1% iodocarb, if deemed necessary, and consistent with international approaches, there may be no objection to restricting the use of iodocarb in cosmetics to that level i.e. 0.1% or less.

## ACCS meeting: July 2013

### Cocoyl glycinate

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Potassium and sodium cocoyl glycinates are surfactants and hair and skin conditioning agents commonly found in cosmetics. They are used in both rinse-off (cleaning lotions, cleansing creams, shampoos and conditioners) and leave-on applications (moisturisers).

Both sodium and potassium cocoyl glycinates are freely available without restrictions for use in cosmetics in the USA, the EU, New Zealand and ASEAN economies with cosmetic regulations based on the EU Cosmetics Directive.

Accord notes that while both sodium and potassium cocoyl glycinates have been assessed and reassessed numerous times by NICNAS in the last few years, we understand that no new safety data was considered since the first assessment of cocoyl glycinate and no additional safety concerns other than skin and eye irritation potential were raised. While the NICNAS report suggests that cocoyl glycinate is corrosive, this appears to be an assumption made by NICNAS without any evidence – surfactants that are shown to be irritating at 5% cannot be assumed to be corrosive at 100%.

We also note that the reassessments considered higher concentrations of cocoyl glycinates in final formulation of the product, and each time, the higher concentrations were considered acceptable.

Accord notes that almost all surfactants are irritating to skin and eyes to varying degrees.

Companies have been working towards use of milder surfactants to reduce any potential for skin and eye irritation, while delivering the important hygiene outcome. Cocoyl glycinate is one of the new classes of milder surfactants that minimises the damage to *stratum corneum* (see <http://www.jcadonline.com/a-novel-glycinate-based-body-wash-clinical-investigation-into-ultra-mildness-effective-conditioning-and-improved-consumer-benefits/>). The mildness is benchmarked against sodium lauryl sulphate (SLS), a surfactant that is widely and freely used in cosmetics and other applications including in foods, and could be considered one of the harsher surfactants available on the market.

In 2010 and 2011, the Scheduling Committees considered the current use of SLS in cosmetics and other applications and believed that there were no concerns with the current use pattern of SLS. The final scheduling decision reflected this, whereby the Scheduling concentration cut-off was set to ensure that products currently available on the market were not affected.

While some stakeholders would not be unhappy with the decision to mirror the scheduling entry of SLS for cocoyl glycinate, we do not believe that the need for the scheduling restriction for cocoyl glycinate has been established. These ingredients are freely available for use in cosmetics with no restrictions in all other major markets and there have been no concerns over safety in any of these markets.

Given that the cocoyl glycinates are a relatively milder class of surfactant than SLS, Accord would prefer to see cocoyl glycinates added to Appendix B of the Poisons Schedule in leave-on and rinse-off preparations.

## **ACCS meeting: July 2013**

### **Hexyloxyethanol**

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To date, our Members have not indicated that they are using hexyloxyethanol in any of their products. Accord will make further submissions if any additional information comes to light between this submission and the Delegate's Final Decision.

In principle, Accord supports risk management of hexyloxyethanol which reflects international practice.

Accord notes that hexyloxyethanol is currently scheduled as ethylene glycol monoalkyl ether. In our submission to the Scheduling Review, Accord raised concerns about categories of chemicals with significantly different toxicological profiles being grouped together because of their chemical relationships, such as ethylene glycol monoalkyl ethers. We hope that this will be addressed once the Scheduling Review is completed.

Accord therefore respectfully suggests that as an efficiency measure, the consideration of hexyloxyethanol and other chemicals that fall into this category be dealt with once the Scheduling Review is finalised.

## ACCS/ACMS Joint-meeting: July 2013

### Hydroquinone and monobenzene

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Accord is pleased to note the consideration of scheduling exemption for hydroquinone and monobenzene (and their derivatives) from scheduling when used as polymerisation inhibitors in nail polish. We are particularly interested in the use of p-hydroxyanisole as a polymerisation inhibitor in light activated gel nail polish products.

Accord notes that the scheduling consideration of hydroquinone and monobenzene has previously focussed on the skin whitening potential of these chemicals and the associated concerns and impacts of their use. However, any risk posed when used as a polymerisation inhibitor in nail polish, will be significantly different.

Firstly, when used as a polymerisation inhibitor, the concentration of hydroquinone or its derivatives in contact with the skin is likely to be very low and transient.

Secondly, because its function is simply to “mop-up” any cleaved monomers, polymerisation inhibitors are only required in very small quantities. Generally speaking, no more than 200 ppm of the polymerisation inhibitor is required in the product.

While there may be a very small area of skin in contact with the product i.e. potentially the skin around the nails, this contact is expected to be very brief. Once the product is applied to the nail and exposed to UV/LED light, the polymerisation inhibitor is consumed in the polymerisation process.

Polymerisation inhibitors are necessary in products containing monomers (such as nail polish and paints) to ensure that unwanted polymerisation does not occur. As indicated above, they work by binding to cleaved monomer to stop further reaction with other monomers. Without polymerisation inhibitors, the nail polish would harden in the bottle and the product would become useless.

Given these considerations, we respectfully recommend that hydroquinone, monobenzene and their derivatives be excluded from scheduling when used as polymerisation inhibitors in nail polish. We propose the following amendment to the existing Schedule entries. The amended wording has been underlined.

#### Schedule 2

HYDROQUINONE (excluding monobenzene and other alkyl ethers of hydroquinone included in or excluded from Schedule 4) in preparations for human external therapeutic or cosmetic use containing 2 per cent or less of hydroquinone **except**:

(a) in hair preparations containing 0.3 per cent or less of hydroquinone; or

(b) when present in nail polish preparations as a polymerisation inhibitor at 0.02 per cent or less.

#### Schedule 4

HYDROQUINONE (other than its alkyl ethers separately specified in this Schedule) in preparations for human therapeutic use or cosmetic use **except** when included in or excluded from Schedule 2.

MONOBENZENE and other alkyl ethers of hydroquinone for human therapeutic use or cosmetics use, except when used as polymerisation inhibitors in nail polishes at 0.02 per cent or less.

# Submission

*July 2013 meeting of the Advisory Committee on Medicines Scheduling*

MAY  
2013

## Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission in relation to items referred by the Delegate for scheduling advice to the July 2013 meeting of the Advisory Committee on Medicines Scheduling.

## Recommendations

**Loratadine.** *PSA does not support the proposal to reschedule loratadine from Schedule 2 to unscheduled in oral preparations containing 10mg or less in packs containing not more than 5 daily doses for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over with recommended daily dose warning labels.*

**Vortioxetine.** *PSA is unable to comment on the proposal to include vortioxetine in Appendix L but would be pleased to consider any relevant information that could be made available.*

## Specific comments

### Loratadine

*Proposal to reschedule from Schedule 2 to unscheduled in oral preparations containing 10mg or less in packs containing not more than 5 daily doses for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over, with warning labels recommending a daily dose not exceeding 10mg for adults and children with body weight over 30kg, or recommended daily dose not exceeding 5mg for children with body weight 30kg and under.*

### Use and scheduling of loratadine

Loratadine is a second-generation long-acting histamine (H<sub>1</sub>) receptor antagonist. It has been used widely in Australia since 1992 when it was included in Schedule 4 and subsequently was down-scheduled over several years.

Seasonal allergic rhinitis (SAR) is a condition which can be recognised and self-managed by consumers. The safety and efficacy of loratadine in children have been established through studies against placebo, cetirizine, desloratadine and also compared with other second-generation antihistamines. Side effects are generally mild (eg. abdominal pain, diarrhoea) and hypersensitivity reactions such as rash, urticaria and pruritus are rare.

Inhaled nasal corticosteroids remain first-line treatment where allergic rhinitis symptoms are moderate to severe or co-exist with asthma. With oral antihistamines the second-generation, less sedating antihistamines are preferred to more sedating antihistamines and are appropriate as first-line therapy for children and adults with milder allergic rhinitis.<sup>1</sup>

Oral preparations of loratadine were in Schedule 2 for many years prior to the small packs of solid (divided) dose preparations for SAR becoming exempt from scheduling in 2012. However, implementation was delayed as we understand an editorial amendment to the Poisons Standard was required to correct an unintended change which had inadvertently included liquid preparations in Schedule 4.

Thus, PSA notes that loratadine is currently exempt from scheduling in:

*Divided preparations for oral use for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:*

- *in a primary pack containing 5 dosage units or less; and*
- *labelled with a recommended daily dose not exceeding 10 mg of loratadine.*

## **Proposed rescheduling**

When solid oral dose preparations of loratadine were under consideration for exemption from scheduling in early 2012, PSA did not support the proposal and expressed concerns around the availability of the product from a retail outlet without the opportunity for professional advice or intervention.

We noted that the evaluator also expressed several concerns and did not support the proposal to exempt loratadine 10 mg from scheduling.<sup>2</sup>

Despite this, exemption from scheduling of loratadine (for SAR treatment) was approved. The decision, in part, was regarded to be consistent with the exemption granted to a similar substance (fexofenadine for SAR treatment) in 2011. The 2012 proposal for loratadine did not however seek exemption from scheduling of liquid preparations or solid dose preparations for children under 12 years of age.

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<sup>1</sup> National Asthma Council Australia. Allergic rhinitis and asthma. At: [www.nationalasthma.org.au/handbook/asthma-and-allergy/allergic-rhinitis-and-asthma](http://www.nationalasthma.org.au/handbook/asthma-and-allergy/allergic-rhinitis-and-asthma)

<sup>2</sup> Final decisions and reasons for decisions by delegates of the Secretary to the Department of Health and Ageing. May 2012. At: [www.tga.gov.au/pdf/scheduling/scheduling-decisions-1205-final-accsacms.pdf](http://www.tga.gov.au/pdf/scheduling/scheduling-decisions-1205-final-accsacms.pdf)

PSA notes the wording of the current proposal for amendment to the schedule of loratadine:

- does not refer to “divided” preparations;
- includes children from six years of age and over; and
- suggests warning labels which base recommended daily doses on body weight.

Therefore our initial assessment is that the rescheduling proposal, with recommended maximum daily doses based on body weight, will have the effect of:

- extending the current scheduling exemption for small packs of divided preparations of loratadine for the treatment of SAR to include children 6–11 years of age; and
- rescheduling from Schedule 2 to unscheduled, liquid (undivided) preparations containing 10 mg or less of loratadine and not more than 5 daily doses.

### **Concerns over possible outcomes**

Following on from the previous section, further reading of the proposal has led PSA to a view that the wording of the proposed amendments is in fact not clear cut and has the potential to result in an undesirable outcome. The following is provided to illustrate an example.

The proposed amendments would exempt from scheduling, a pack of 5 dosage units containing 10 mg loratadine per dosage unit with warning labels. It is not clear however if the warning labels for the different recommended daily dose (based on body weight) could both be included on this pack. This could effectively result in a 10-dose pack for children with body weight 30 kg and under. Such a scenario could arise due to the somewhat awkward wording of the proposed amendment.

### **Optimal use of loratadine supported by professional advice**

In applying the cascading principle to scheduling, PSA would highlight that downscheduling from Schedule 2 to unscheduled is a significant step down and results in a substantially less restricted manner of supply which raises significant concerns for the pharmacy profession. Further, we have limited means to monitor the impact on consumers following a rescheduling decision.

Some parents may certainly welcome wider access of loratadine preparations for the younger age group of children. However, PSA does not believe there is substantial benefit to do so, particularly in a climate where recent changes to the recommendations on cough and cold preparations for children caused a level of confusion for some parents.

The messages issued by the TGA last year on cough and cold medicines for children were unprecedented in that they were on a wide scale and the advice was firm regarding the unsuitability of these products based on their risk-benefit profile. While loratadine does not fall in this category of medicines, the key underlying message and associated outcome of that scenario was that pharmacist advice and appropriate intervention was necessary and warranted in many cases. As the products continued to also be available through non-pharmacy outlets, many parents who did not purchase the product in a pharmacy still required and obtained pharmacist advice.

In the US where similar actions were taken by the FDA several years ago, it has been reported<sup>3</sup> that some consumers do not read or are not aware of the safety warnings and continue to purchase cough and cold medicines for very young children. The report also highlighted that, since doses for young children are no longer on the pack, many parents indicated they would administer the incorrect dose (by incorrectly extrapolating from the stated doses for older children or by making up their own dose). This confirms our view that not all consumers do or can follow instructions on the pack and supply through general retailers (where advice is not available) can be problematic.

For optimal symptom control and better health outcomes particularly for younger children it is sensible to promote an environment where health professional intervention is readily available to help avoid adverse events and further costs to the health care system.<sup>4</sup> It is possible for SAR to be confused with other conditions and it can also coexist with conditions such as asthma. It has certainly been observed that allergic rhinitis in children can go unrecognised or remain inadequately treated and lead to significant negative health consequences.<sup>5</sup> Therefore pharmacist advice on strategies for the management of symptoms of SAR may be beneficial particularly for parents of younger children.

With regards to the use of liquid oral dose preparations, there is also a concern around the not insignificant errors in medication administration by parents. It has been reported<sup>6</sup> that parents require support and education and pharmacists can assist through strategies which address accurate use of dosing instruments as well as health literacy. The 5 mg chewable tablet could be an alternative providing better dosing control.

Professional intervention in a pharmacy setting may also include, for example:

- the provision of appropriately tailored medicine information and other non-pharmacological options to parents or carers at the time of supply of a product;
- advice on follow-up when original symptoms have not improved or resolved after an appropriate period of time; and
- prompt referral to a medical practitioner when other causes (eg. an infection or more acute illness) may be suspected, or for any other reason when this is warranted.

## Summary

In summary, PSA does not support the proposed amendments for loratadine as we believe it is contrary to the principles of quality use of medicines and in particular, as it has the potential to

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<sup>3</sup> Mathews AW. Missed warnings on cold medicine for children. The Wall Street Journal 2013; May 14. p. D1.

<sup>4</sup> Williams KA et al. Non-prescription medicines and Australian community pharmacy interventions: rates and clinical significance. Int J Pharm Pract (2011). Doi: 10.1111/j.2042-7174.2010.00091.x

<sup>5</sup> Berger WE. Allergic rhinitis in children: diagnosis and management strategies. Pediatr Drugs 2004; 6(4):233–50.

<sup>6</sup> Yin HS et al. Parents' medication administration errors: role of dosing instruments and health literacy. Arch Pediatr Adolesc Med 2010; 164(2):181–6.

adversely impact on the health of children. We support the retention of current scheduling arrangements for loratadine to provide adequate levels of safeguards for consumers.

## **Vortioxetine hydrobromide**

### ***Proposal for new Appendix L entry.***

Vortioxetine is a bimodal oral antidepressant which is thought to work through a combination of reuptake inhibition of serotonin and modulation of serotonin receptor activity.<sup>7</sup> It has yet to be registered in Australia, while the European Medicines Agency and the United States Food and Drug Administration are reportedly in the process of reviewing applications for marketing approval.<sup>8</sup> Therefore access to data about this new substance is limited.

We note that in several reported human clinical studies of vortioxetine, female patients of childbearing potential who were not using effective contraception, or those who were already pregnant, were excluded from the study.<sup>9,10</sup> However, further information to clarify or determine whether the inclusion of vortioxetine in Appendix L would be warranted could not be readily accessed.

In the absence of further detail, PSA is not able to support or oppose this proposal. We would be pleased to provide further comment on this issue if additional information is released for consideration.

### ***Submitted by:***

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### ***Contacts:***

Liesel Wett, Chief Executive Officer

Kay Sorimachi, Director Policy and Regulatory Affairs  
[REDACTED]

30 May 2013

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<sup>7</sup> National Institute for Health and Clinical Excellence. Draft scope for the proposed appraisal of vortioxetine for the treatment of major depressive disorder. Sep 2012. At: [www.nice.org.uk/nicemedia/live/14144/63469/63469.pdf](http://www.nice.org.uk/nicemedia/live/14144/63469/63469.pdf)

<sup>8</sup> UK Medicines Information. New Drugs Online report for vortioxetine. At: [www.ukmi.nhs.uk/applications/ndo/record\\_view\\_open.asp?newDrugID=4797](http://www.ukmi.nhs.uk/applications/ndo/record_view_open.asp?newDrugID=4797)

<sup>9</sup> U.S. National Institutes of Health. Efficacy and safety of Lu AA21004 in acute treatment of major depressive disorder. NCT00839423. At: <http://clinicaltrials.gov/ct2/show/NCT00839423>

<sup>10</sup> U.S. National Institutes of Health. Pharmacokinetic properties of Lu AA21004 (vortioxetine) in healthy young Chinese men and women. NCT01676571. At: <http://clinicaltrials.gov/ct2/show/NCT01676571>



Unscheduled of Loratidine - ACSM July 2013 [SEC=No Protective Marking]

[REDACTED]

to:

SMP

15/05/2013 09:08

Hide Details

From: [REDACTED]

To: <SMP@health.gov.au>,

Dear Sir/Madam,

I am a member of the ACNM and have read the proposal to unscheduled loratidine in a small package size and limited dose schedule.

I would be happy to support this proposal as I do not perceive any problems likely to arise from such a move. The benefit to older children and adults would be justified.

Yours sincerely,

Dr Maureen Mitchell



The Pharmacy  
Guild of Australia

# Advisory Committee for Medicines Scheduling Meeting of 23 July 2013

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**Comments by the Pharmacy Guild of Australia to the  
proposed amendments referred by the delegate for  
scheduling advice**

**Closing date for submission – 30 May 2013**

**National Secretariat**

PO Box 7036, Canberra Business Centre, ACT 2610 Australia

Email: [guild.nat@guild.org.au](mailto:guild.nat@guild.org.au) · Internet: [www.guild.org.au](http://www.guild.org.au)

## **Background**

The Pharmacy Guild of Australia (Guild) welcomes the opportunity to comment on proposed amendments to the Standard for the Uniform Scheduling of Medicines and poisons (SUSMP) being considered by the Advisory Committee on Medicines Scheduling (ACMS) at its meeting of 23 July 2013.

The Guild is an employers' organisation servicing the needs of independent community pharmacies. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

## **Quality Use of Medicines**

Quality Use of Medicines (QUM) is one of the central objectives of Australia's National Medicines Policy<sup>1</sup>. The Guild believes that QUM is best supported by the supply of medicines through a pharmacy where there is access to professional support and advice from a pharmacist, with assistance provided from trained pharmacy assistants.

It should be noted that community pharmacy maintains a high standard of patient care with the Quality Care Pharmacy Program (QCPP) which is recognised as the Australian Standard<sup>2</sup> for service provision within the community pharmacy sector. By contrast, there are no controls or quality assurance processes in place for the supply of medicines outside of the pharmacy sector.

The QCPP is a quality assurance program aimed at raising the standards of pharmacy services, ensuring community pharmacies provide a uniformed approach when delivering professional services and customer care. QCPP accreditation has been shown to support continuous improvement in the supply of medicines.<sup>3</sup>

As of 30 June 2011, approximately 98% of Australian community pharmacies are registered with QCPP and approximately 93% are accredited or in the process of becoming accredited. As part of QCPP, it is a requirement that all pharmacy assistants involved in the supply of non-prescription medicines must be appropriately trained by an external training provider. This training includes initial and refresher training in supplying non-prescription medicines and teaches the use of protocols such as 'Ask, Assess, Advise'<sup>4</sup> in order to triage patient requests and refer to the pharmacist when appropriate.

Through the QCPP, the Guild conducts a Standards Maintenance Assessment (SMA) program, commonly referred to as the 'Mystery Shopper' program. Since its inception, the objectives of the SMA program have been aligned with the National Medicines Policy. As part of the SMA program, QCPP accredited pharmacies are assessed to measure the pharmacy's performance in the supply of non-prescription medicines, specifically Schedule 2 (Pharmacy Medicines) and Schedule 3 (Pharmacist Only Medicines). They are provided with feedback and benchmarked as part of a continuous improvement process. Analyses of SMA data to date have demonstrated continued improvement in the supply of non-prescription medicines through the pharmacy sector.<sup>5</sup>

## Consumer access and advice

Medicines are not normal products of commerce, having the potential to do significant harm if used incorrectly or inappropriately. Consumers need and want advice on the correct and proper use of medicines and this is best achieved with supply through the pharmacy sector.

The use of and access to medicines in Australia is changing, with the population ageing and consumers contributing more and more to the cost of medicines.<sup>6</sup> It is essential to protect the most vulnerable consumer groups, particularly children, the elderly, those from poorer socio-economic backgrounds or those who do not speak or understand English well. Providing consumer access to information via hand-outs or labelling is not enough. Facilitating access to professional advice for the prescribing and supply of medicines is the best way to maintain safe and cost-effective access to medicines.

The high incidence of polypharmacy warrants health professional advice on the use of medicines. A recent random cross-sectional survey of Australians aged 50 years and over reports that 87% of the respondents used a medicine in the previous 24 hours, with a mean of 4.6 medicines per participant. Over 43% of participants reported use of five or more medicines in the previous 24 hours and almost 11% reported using 10 or more medicines.<sup>7</sup>

With regards to non-prescription medicines, a research project<sup>8</sup> from the Fourth Community Pharmacy Agreement demonstrated that 80% of the interviewed consumers wanted advice to always be available at the time of purchase and the majority of people do not have issues with accessing non-prescription medicines from community pharmacies.

## Comments on Proposed Amendments

The Guild has considered the proposed amendments to the SUSMP of relevance to community pharmacy, with particular reference to Section 52E(1) of the Therapeutic Goods Act 1989. We provide comments for the following proposed amendments in line with the rationale for our position provided above:

- 1. Loratadine- Proposal to reschedule loratadine from Schedule 2 to unclassified in oral preparations containing 10mg or less in packs containing not more than 5 daily doses for the treatment of seasonal allergic rhinitis in adults and children 6 years of age and over, with a warning labels recommending a daily dose not exceeding 10mg loratadine for adults and children with body weight over 30kg, or recommended daily dose not exceeding 5mg loratadine for children with body weight 30kg and under.**

In our submission to the February 2012 ACMS meeting, the Guild did not support the proposal to exempt loratadine from scheduling in oral preparations containing 10 mg or less in packs containing not more than 5 daily doses in adults and children 12 years of age and over. The Guild notes despite our opposition to the proposal, this change came into effect in September 2012. The Guild does not support any further changes to the scheduling exemption for loratadine.

Irrespective of loratadine's reasonable safety profile, there are still public risks associated with its use. For children under 12 years of age, issues of receptor selectivity and the potential for CNS adverse effects still remain and further studies are warranted.<sup>9</sup> Although marketed as a 'non-sedating' antihistamine, it is questionable whether any antihistamine is truly non-sedating. Although psychomotor and sleep studies in healthy subjects in the laboratory may predict that an antihistamine does not cause drowsiness, the safety margin can be narrow enough to cause a central sedating effect during actual treatment. This might result from a patient's individual sensitivity, disease-induced sedation, or dosages that are for various reasons relatively or absolutely larger (patient's weight, poor response, reduced clearance, interactions)<sup>10</sup>.

Allergic rhinitis tends to run in families. If one or both parents have allergic rhinitis, there is a high likelihood that their children will also have the condition. People with allergic rhinitis have an increased risk of developing asthma and other allergies. They are also at risk for developing sinusitis, sleep disorders (including snoring and sleep apnea), nasal polyps, and ear infections.<sup>11</sup> Chronic uncontrolled allergic rhinitis can worsen asthma attacks and eczema.

If rhinitis symptoms are caused by non-allergic conditions, particularly if there are accompanying symptoms indicating a serious problem, a health professional should investigate and treat any underlying disorders. If rhinitis is caused by medications, such as decongestants, the patient may need to stop taking them or find alternatives.

A variety of factors must be considered in selecting a treatment approach. These include:

- Severity of the symptoms
- Frequency (seasonal versus all year, episodes in a given week)
- Age of patient
- Presence of other related illnesses such as asthma, atopic eczema, sinusitis, or polyps
- Type of allergens<sup>12</sup>

With loratadine being available from general stores such as supermarkets, it reduces the likelihood of clinical assessments being undertaken by healthcare professionals such as pharmacists that would likely identify underlying causes of rhinitis, advising patients regarding the potential development of other associated chronic conditions and determining the most effective treatment plan. This could result in underlying causes of rhinitis going untreated. One of the main reasons it was decided the guidelines for cough and cold supply for children should be changed was that a child may appear to have a cold but actually be suffering from a more serious illness. The Guild also notes the TGA advises 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.<sup>13</sup> The same advice should also apply to loratadine. Lack of professional oversight increases the risk of patients developing associated respiratory conditions. The Guild believes promoting access to pharmacist advice is particularly important for children in the 6-11 age group so as to minimise the risk of these related complications occurring.

Children frequently lack the ability to verbalise their symptoms, with the result that a parent may be unable to correctly diagnose their child's condition.<sup>14</sup> Consequently, there is a potential financial impact for consumers who may purchase medicines from the

grocery sector that are not suitable for their child's particular conditions, e.g. selecting loratadine for the treatment of cold symptoms. While not a significant safety concern if the medicine is taken at the recommended dose, these people may have additional out-of-pocket expenses from having to subsequently purchase more suitable and effective medicine/s from a pharmacy. While there may still be a risk that people self-select Schedule 2 medicines inappropriately within a pharmacy setting, this risk is mitigated by service from trained pharmacy assistants and access to a pharmacist if needed.

The Guild notes the proposal is accompanied with warning statements related to maximum daily dosage based on a child's weight. We have repeatedly stated that risks cannot be addressed by labeling requirements. A survey of 1000 people conducted in Northern Ireland identified only 80% of participants always or often read the instructions on non-prescription medicine packages and that 3.4% rarely or never read the information. Coupled with participants that only sometimes read the manufacturer's information, 10% of the people would be at risk of misusing these medicines.<sup>15</sup>

Despite the restriction to 5 days supply for the treatment of seasonal allergic rhinitis and accompanying warning labels, the Guild is concerned that the lack of quality controls within the supermarket sector means that there is no limit on the number of packs that may be purchased at any particular time, nor for the indication or patient history. A parent will see this as a readily available antihistamine for the treatment of conditions both appropriate and inappropriate, and potentially give their child doses above the labelled recommendations with the associated risks. Unlike pharmacies, supermarket checkout operators do not provide advice or referrals.

### Recommendation

The Guild considers oversight by pharmacy personnel providing healthcare information and advice with referral to a highly trained healthcare professional to be important for children in this age group and therefore recommends there are no further changes to the scheduling exemption for loratadine.

<sup>1</sup> <http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1>

<sup>2</sup> Australian Standard® AS 85000-2011 Quality care Pharmacy Standard – quality management system for pharmacies in Australia

<sup>3</sup> Chapman J, An Evaluation of the Quality Care Pharmacy Program Part 5; Pharmacy Guild of Australia; 2005

<sup>4</sup>

[http://www.guild.org.au/Guild\\_Training/Pharmacy+Assistants+Training/A+Career+in+Pharmacy/Ask+Assess+Advise.page](http://www.guild.org.au/Guild_Training/Pharmacy+Assistants+Training/A+Career+in+Pharmacy/Ask+Assess+Advise.page)

<sup>5</sup> Quality Improvement in Pharmacy – NCCTG Interim Report October 2011; prepared by the Pharmacy Guild of Australia in conjunction with the Australian College of Pharmacy

<sup>6</sup> Australians paying for medicines – new research; AHHA 13/09/2011; <http://ahha.asn.au/news/australians-paying-more-medicines-new-research>

<sup>7</sup> TK Morgan, M Williamson, M Pirotta; A national census of medicines use: a 24-hour snapshot of Australians aged 50 years and older; MJA 2012; 196(1):50-53

<sup>8</sup> Consumer perception on supply of and access to Pharmacy Medicines; Healthcare Management Advisors; March 2010

<sup>9</sup> C.E. Baena-Cagnani, Safety and Tolerability of Treatments for Allergic Rhinitis in Children, Drug Safety, 2004, 27, 12 883-898 <http://link.springer.com/article/10.2165/00002018-200427120-00005#>

<sup>10</sup> MJ Mattila & I Paakkari; Variations among non-sedating antihistamines: are there real differences?; Eur J Clin Pharmacol 1999 Apr;55(2):85-93; <http://www.ncbi.nlm.nih.gov/pubmed/10335901>

<sup>11</sup> University Health Care System- Allergic rhinitis

[http://www.universityhealth.org/body.cfm?id=38948&action=detail&AEArticleID=000077&AEProductID=Adam2004\\_10&AEProjectTypeIDURL=APT\\_10](http://www.universityhealth.org/body.cfm?id=38948&action=detail&AEArticleID=000077&AEProductID=Adam2004_10&AEProjectTypeIDURL=APT_10)

<sup>12</sup> IBID

<sup>13</sup> <http://www.tga.gov.au/newsroom/btn-cough-cold-medicines-121126.htm>

<sup>14</sup> P Fireman, Therapeutic approaches to allergic rhinitis: Treating the child, Journal of Allergy and Clinical Immunology, 105, 6, 2 S616-S621

<sup>15</sup> M Wazaify, E Shields, CM Hughes et al; Societal perspectives on OTC medicines; Family Practice 2005; 22:170-176