

Public Submissions on the Proposed Amendments to the Poisons Standard

Notice under subsections 42ZCZL of the Therapeutic Goods Regulations 1990 (the Regulations)

The delegate of the Secretary to the Department of Health publishes herein all valid public submissions made in response to the invitation for public submission on the proposed amendments to the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* - SUSMP). These submissions were considered by the Advisory Committee on Medicines Scheduling (ACMS) #12 (July 2014 meeting).

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 for Medicines and Chemicals (SPF, 2010), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible at 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
AMOROLFINE	2 submission
CALCIUM HYDROXYLAPATITE	1 submission



The Pharmacy
Guild of Australia

Advisory Committee for Medicines Scheduling Meeting July 2014

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

Closing date for submission – 8 May 2014

Contact person:

████████████████████

Position: National Manager – Policy and Regulation

██████ ████████████████████

National Secretariat

Level 2, 15 National Circuit, Barton, ACT 2600 Australia

PO Box 7036, Canberra Business Centre, ACT 2610 Australia

Telephone: + 61 2 6270 1888 · Facsimile: + 61 2 6270 1800

Email: guild.nat@guild.org.au · Internet: 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 July 2014.

The Pharmacy Guild of Australia is the national peak body representing community pharmacy. 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.

Community Pharmacists provide professional advice about the safe use of medicines for optimal effect and are supported by a team of pharmacy assistant who are trained to ask questions in order to assist the pharmacist and assess if and when the pharmacist should be consulted

Further information can be found in *Appendix 1*.

Comments on Proposed Amendments

The Guild has provided comments for the following proposed amendments in line with the rationale for our position provided below and in Appendix 1:

- Proposal to amend the Schedule 2 amorolfine entry to also exclude from scheduling preparations for the treatment of onychomycosis (fungal infection of the nail).

The Guild believes that amorolfine must remain as a scheduled medicine for the treatment of onychomycosis as it is essential to maintain access to health professional support to ensure patients at risk of misdiagnosis and/or complications may be supported.

Key Points

1. Co-morbidity risk factor with onychomycosis and diabetes
2. Treatment kits can be difficult to use and health professional oversight is required to maximise the likelihood of effective and appropriate use
3. Amorolfine treatment is not suitable for use in severe infections where the lunula section of the nail is affected. Infections that affect the entire nail matrix require referral to a medical practitioner and alternative treatment.
4. Patients receiving amorolfine treatment need to be advised by a health professional not to visit beauty salons or share manicure equipment with other people to prevent further spread of infection.

The Guild has considered the proposed amendment and provides the reasons for our position with particular reference to relevant subsections of the *Therapeutic Goods Act 1989* – Section 52E (1):

b) the purposes for which a substance is to be used and the extent of use of a substance

- Topical treatment of onychomycosis may take several months and, in some instances up to twelve months therapy. In marketing materials for Loceryl®, a 5 ml nail lacquer bottle contains at least 150 applications. The Guild is not aware of any unscheduled registered medicines that are indicated for such long term use. A product that requires such long term (minimum 6 months) and consistent use, requires support, encouragement, and ongoing assessment as to progress and therefore should only be sold in locations with direct access to health professionals.
- As outlined in the product CMI¹, amorolfine treatment is not suitable for use in severe infections where the lunula section of the nail is affected. Infections that affect the entire nail matrix require referral to a medical practitioner and alternative treatment. Health professional oversight is required to ensure a fungal treatment is diagnosed correctly and the appropriate treatment is recommended.
- Amorolfine treatment kits require multiple, somewhat complex, steps to use, to be the most effective and to stop cross contamination with healthy nails.² A person with poor health literacy may find the multi-step instructions difficult to understand and consequently treatment may be ineffective and/or counterproductive.

(c) the toxicity and safety of a substance

- For both pregnancy and lactation, there is evidence of adverse effects in animals, but not for humans. As such, it is listed as a Category B3 for use in pregnancy and is not recommended for use during either pregnancy or lactation.
- Although rare, the non-active ingredients of amorofline treatments such as methacrylic acid, copolymer, ethyl acetate can cause allergic reactions that result in dermatitis.^{3 4}
- As a scheduled medicine, pharmacy assistant and pharmacists can advise patients of these risks where applicable.

i) Advisory labels

Although advisory labels would outline to consumers instructions for appropriate use, the Guild has consistently argued that risk cannot be addressed by warning labels and information leaflets alone. 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.⁵ As such, the Guild believes, pharmacist oversight is essential in ensuring this product is suitable for individual patients, increase patient education regarding the correct use of an amorolfine treatment kit and hence increase the likelihood the medicine will be taken correctly and safely.

(f) any other matters considered necessary to protect public health

- Onychomycosis is more common in people with diabetes⁶, and it would be important to ensure that these patients have access to professional support. Patient discussion with pharmacists and pharmacy assistants provides an opportunity to inspect the foot for other lesions and provide timely wound care and also potentially recommend medical follow up to exclude undiagnosed diabetes.
- As outlined in the product CMI, use of nail polish or acrylic nails should not be used while undergoing treatment with amorolfine.⁷ In addition, each treatment kit should only be used by a single patient. Fungal infections have been reported as a common occurrence from visiting beauty salons, mainly due to the use of community shared and unsterilised equipment in these premises⁸, particularly ones that are used for manicures and pedicures.⁹ Given the likelihood of patients suffering from onychomycosis may be regular visitors to beauty salons, the Guild believes it is imperative from a public health perspective patients receiving amorolfine treatment are advised by a health professional not to visit beauty salons or share manicure equipment with other people to prevent further spread of onychomycosis. The risk of infections spreading is likely to increase if amorolfine becomes unscheduled for the treatment of onychomycosis.
- The nails serve several important functions and, when they are infected by fungal organisms, these functions are severely impaired. In addition, the quality of life, in terms of self-esteem and social interaction, is adversely affected when fungal nail infections are present. When finger and/or toenails are abnormal this may also interfere with patients' occupations.¹⁰ It is therefore important patients receive timely and appropriate treatment from trained health professionals and any related health issues, such as the ones raised, above are also addressed.

Conclusion

The Guild does not support the proposal and believes the current scheduling for amorolfine remains appropriate. To ensure adherence to the quality use of medicines and to protect public health, access to health professionals is essential to ensure amorolfine treatments are used correctly and to ensure any underlying or related health conditions associated with onychomycosis are examined and referred to medical practitioners where appropriate.

Appendix 1

Quality Use of Medicines

Quality Use of Medicines (QUM) is one of the central objectives of Australia's National Medicines Policy¹¹. 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 Standard¹² 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 uniform approach when delivering professional services and customer care. QCPP accreditation has been shown to support continuous improvement in the supply of medicines.¹³

As of 30 April 2014, approximately 94 per cent of Australian community pharmacies are QCPP 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'¹⁴ 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 Pharmacy Medicines (Schedule 2 or S2) and Pharmacist Only Medicines (Schedule 3 or S3). 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.¹⁵

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.¹⁶ 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 per cent of participants reported use of five or more medicines in the previous 24 hours and almost 11 per cent reported using ten or more medicines.¹⁷

With regards to non-prescription medicines, a research project¹⁸ 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.

Reference Sources:

¹ http://www.nps.org.au/_data/cmi_pdfs/CMI6767.pdf

² IBID

³ Silverberg, N. B., & DeLeo, V. A. (2002). Salon nails: Beautiful, itchy, or infectious. *Cutis*, 70(6), 308-308.

⁴ Kanerva, L., Lauerman, A., Estlander, T., Alanko, K., Henriks-Eckerman, M. L., & Jolanki, R. (1996). Occupational allergic contact dermatitis caused by photobonded sculptured nails and a review of (meth)acrylates in nail cosmetics. *Dermatitis*, 7(2), 109-115.

⁵ M Wazaify, E Shields, CM Hughes et al; Societal perspectives on OTC medicines; Family Practice 2005; 22:170-176

⁶ JA Winston, JL Miller; Treatment of Onychomycosis in diabetic patients; American Diabetes Association Clinical Diabetes; Oct 2006; Vol 24 no 4 160-166

⁷ http://www.nps.org.au/_data/cmi_pdfs/CMI6767.pdf

⁸ Spalding Jr, R. (2008). DEATH BY PEDICURE.

⁹ Silverberg, N. B., & DeLeo, V. A. (2002). Salon nails: Beautiful, itchy, or infectious. *Cutis*, 70(6), 308-308.

¹⁰ Scher, R. K. (1994). Onychomycosis is more than a cosmetic problem. *British Journal of Dermatology*, 130(s43), 15-15.

¹¹ <http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1>

¹² Australian Standard® AS 85000-2011 Quality care Pharmacy Standard – quality management system for pharmacies in Australia

¹³ Chapman J, An Evaluation of the Quality Care Pharmacy Program Part 5; Pharmacy Guild of Australia; 2005

¹⁴

http://www.guild.org.au/Guild_Training/Pharmacy+Assistants+Training/A+Career+in+Pharmacy/Ask+Assess+Advise.page

¹⁵ Quality Improvement in Pharmacy – NCCTG Interim Report October 2011; prepared by the Pharmacy Guild of Australia in conjunction with the Australian College of Pharmacy

¹⁶ Australians paying for medicines – new research; AHHA 13/09/2011; <http://ahha.asn.au/news/australians-paying-more-medicines-new-research>

¹⁷ Morgan TK, Williamson M, Pirotta M; A national census of medicines use: a 24-hour snapshot of Australians aged 50 years and older; MJA 2012; 196(1):50-53

¹⁸ Consumer perception on supply of and access to Pharmacy Medicines; Healthcare Management Advisors; March 2010

Submission

July 2014 meeting of the Advisory Committee on Medicines Scheduling

MAY
2014

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission in relation to the proposal on amorolfine referred by the Delegate for scheduling advice to the July 2014 meeting of the Advisory Committee on Medicines Scheduling. The proposal is:

...to amend the Schedule 2 amorolfine entry to also exclude from scheduling preparations for the treatment of onychomycoses (fungal infections of the nail).

Recommendation

Amorolfine for the treatment of onychomycoses must not be excluded from the Schedule 2 entry. PSA supports the status quo to enable consumers requiring amorolfine therapy to have the opportunity for immediate access to pharmacist advice to support appropriate self-medication practices, tailor therapy to the consumer's specific needs and promote optimal outcomes from therapy.

The role of pharmacists

The prevalence of onychomycosis is reported¹ to be approximately 10% of the general population, 20% in those over 60 years of age and up to 50% of people aged over 70 years. Up to one-third of people with diabetes also have onychomycosis.

Access to medicines. Early intervention of minor ailments through self-medication is an important treatment pathway for consumers.

In Australia, community pharmacies are highly regarded for their accessibility due to the geographical distribution of a network of over 5,000 pharmacies, the mostly generous trading hours and the availability of pharmacist advice without the need for an appointment.

¹ Thomas J, Jacobson GA, Narkowicz CK, Peterson GM, Burnet H, Sharpe C. Toenail onychomycosis: an important global disease burden. J Clin Pharm Ther 2010; 35:497–519.

General practitioners (GPs) and pharmacies have been reported to be the most highly used health care services by consumers in Australia.² Between July 2011 and July 2012, 94% of Australians aged 18 years and over reported using a pharmacy health care service. This proportion increases to 99% for Australians aged 65 years and over. Consumers' rating for health services was the highest for pharmacists with 85% providing a good-excellent rating and consumers also expressed the highest level of satisfaction (89%) with pharmacists.

The high regard by consumers of pharmacy health care services and the focus on quality use of medicines issues by pharmacists indicate that there are significant advantages for medicines to be available for consumers through pharmacies. It is acknowledged that some consumers may prefer the convenience of being able to purchase medicines and grocery items from a single retail outlet, however, non-pharmacy outlets lack the opportunity for consumers to obtain quality health information and advice on optimal use of medicines. While it is a regulatory requirement that standard dosing instructions and warning statements relevant to the active ingredient and dose form are included on the labelling and packaging of any product, consumer factors are diverse and variable and can impact on the therapy outcomes achieved.

PSA believes that the benefits which are likely to accrue to the consumer through a pharmacy setting must be regarded as a priority. Treatment for a stubborn condition such as onychomycosis must not be available in an environment where no guidance can be provided on how best to prepare for treatment, apply the preparation, monitor progress and persist with therapy. Some of these considerations are expanded on below.

Commencement of treatment. The application of amorolfine to the affected nails is a simple process however, to maximise the benefits of therapy, good nail care is essential (e.g. filing down affected areas of the nails, cleaning the nail surface thoroughly, avoiding use of same nail file for healthy nails).³ Filing nails prior to application also enhances penetration and diffusion of the medicine.

Other steps to prevent further damage to the nail or nail bed should be encouraged e.g. if toenails are affected, wearing properly fitted and comfortable shoes and keeping feet clean and dry; if fingernails are affected, avoiding injury and irritants and wearing gloves.

Treatment duration and expectation. While the once or twice weekly application of amorolfine is generally not onerous for consumers, successful treatment outcomes require continued treatment and patience to allow the affected nail to grow out and regrow. As a guide, fingernails may take six months and toenails around 9–12 months.

During this extended treatment period, pharmacists and trained pharmacy assistants will be able to monitor treatment progress with consumers, reinforce practice points and provide additional information if required. Encouragement to continue treatment may be helpful for some consumers. Reasonable expectations around cure rates should also be communicated to consumers.

² The Menzies-Nous Australian Health Survey 2012. 23 Oct 2012. At: <http://sydney.edu.au/medicine/public-health/menzies-health-policy/research/Menzies-NousAustralianHealthSurveyReport2012.pdf>

³ Sansom LN, ed. Australian pharmaceutical formulary and handbook. 22nd edn. Canberra: Pharmaceutical Society of Australia, 2012.

Other health advice or referral (see below) to a GP may be needed in some instances.

Referral. Pharmacists would be able to provide advice and timely referrals for consumers under circumstances including when/for:

- women who are pregnant and seeking treatment or have become pregnant during ongoing therapy;
- women who are currently, or are planning to commence, breastfeeding;
- individuals who may be at higher risk of complications (e.g. those who have diabetes);
- infection appears severe or extensive (e.g. affecting more than 80% of one or two nails);
- physical trauma to the nail/s (other than a possible infection) is evident (e.g. due to ill-fitting footwear);
- condition worsens or has not started to respond within a reasonable period since commencement of treatment.

There are many diseases which can affect the nails and pharmacists would also be able to refer consumers in a timely manner if the cause or condition could not be ascertained.

Supporting consumer health literacy. The importance of health literacy on medicine use is widely known and has been a part of Australia's national health goals and targets for several decades. Health literacy is reported to impact on the level of understanding of dosing instructions and warning statements, correct medication management decisions, adherence to agreed treatment schedules, and correct use of therapeutic devices. Lower health literacy levels can impact on adverse events, health outcomes and health care costs.

A study in 2006 showed that 59% of Australian adults (15–74 years) had health literacy skill levels which were lower than 'adequate' (Level 3).⁴

Pharmacists appreciate the diversity in consumers' health literacy levels as well as an individual's preferences and needs at any particular time. Pharmacists have a key role in assisting consumers with their health information needs and in improving health literacy levels of the broader community.

Previous rescheduling

PSA notes that the rescheduling of amorolfine (5%) from Schedule 3 to Schedule 2 occurred in 2010 (including the maintenance of exemption from scheduling for preparations for tinea pedis).⁵ We note some of the points reportedly raised at the time, for example, the potential for consumers to incorrectly self-diagnose onychomycosis and the importance of availability of health

⁴ Australian Bureau of Statistics. Australian social trends. Health literacy. Canberra: ABS; 2009.

⁵ National Drugs and Poisons Schedule Committee. Record of reasons, 59th meeting. 2010; Jun. At: www.tga.gov.au/pdf/archive/ndpsc-record-59.pdf

professional support. PSA believes such issues remain relevant and therefore support the existing Schedule 2 entry.

Summary

It is PSA's firm belief that the condition and purpose associated with the use of amorolfine, in particular the need for use over many months, warrants this medicine to be available through pharmacies.

Consumer self-management with the support of tailored pharmacist advice is key to enhancing the benefits derived from treatment with amorolfine. Maximising treatment outcomes with an over-the-counter preparation is in the interests of consumers (e.g. lower cost and less traumatic) and will also minimise the need for any further treatment with stronger medicines (e.g. oral therapy) or more invasive treatment (e.g. surgery).

Supporting improvements in health literacy is also a core role for pharmacists who are aware that a consumer's understanding of health information and their health needs and preferences may evolve over time.

In summary, PSA does not support amorolfine preparations for the treatment of onychomycoses being excluded from the current Schedule 2 entry.

Submitted by:

Pharmaceutical Society of Australia
PO Box 42
Deakin West ACT 2600
Tel: 02 6283 4777
www.psa.org.au

Contacts:

██████████ Acting Chief Executive Officer

██████████, Director Policy and Regulatory Affairs
████████████████████

8 May 2014



26 June 2014

The Secretary
Medicines & Poisons Scheduling
Office of Chemical Safety (MDP 88)
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sir / Madam,

Re: SUSMP Proposed Amendments to the scheduling of Calcium Hydroxylapatite - Consultation

I refer to the Notice inviting public submissions under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990, on the proposed amendment (outlined below) for consideration by a joint meeting of the ACCS and the ACMS:

Substance	Proposal
Calcium hydroxylapatite	Proposal to include calcium hydroxylapatite in preparations for injection or implantation when used for tissue augmentation or for cosmetic use in Schedule 4.

DENTSPLY IH Pty Ltd (trading as DENTSPLY Implants) understands that the intent of the proposal to schedule calcium hydroxylapatite is to target use in "tissue augmentation or for cosmetic use" and not necessarily use in dental. However calcium hydroxylapatite is a common substance used in dental bone grafting medical devices. These devices are implanted into patients.

DENTSPLY Implants is concerned that the scheduling of this substance may potentially have an impact on the registration of new dental Medical Devices as well as those registered and marketed in Australia. A potential impact in this area should be considered with the current proposal.

DENTSPLY IH Pty Ltd
ABN: 46 112 267 133

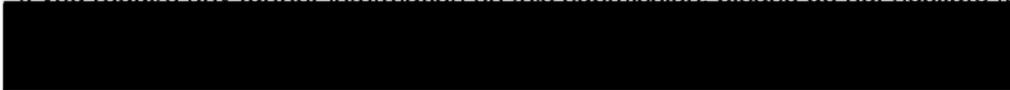
Trading as DENTSPLY Implants

Postal Address:
PO Box 6071
Pymble NSW 2073
Australia

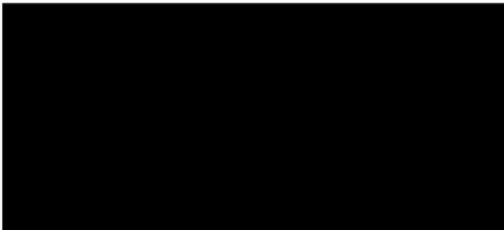
Telephone: +61 2 9488 3500 1800 799 287 (freecall)
Facsimile: +61 2 9440 0744 1800 799 187 (freecall)

DENTSPLY Implants requests that if calcium hydroxylapatite is scheduled, that a caveat of "except in Dental" is applied to the schedule of this substance.

If you require any further information on this submission, please do not hesitate to contact



Yours sincerely,



Regulatory Affairs and Quality Assurance Manager, DENTSPLY (Australia) Pty Ltd:
providing a shared Regulatory service to DENTSPLY Implants