[redacted]

Wednesday, 26 November 2014

The Secretary
Communications and Secretariat
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir,

Re: Public Submission – under Reg. 42ZCZK of the Therapeutic Goods Regulations 1990. ACMS meeting, March 2015

Proposal to create a new entry in Appendix H for esomeprazole in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease (GORD), in packs containing not more than 14 days supply.

[redacted] refers to the pre-March 2015 Scheduling meeting notice. [redacted] would like comment on the proposed amendment to appendix H to include esomeprazole.

Numerous applications have been made in the past to include individual PPIs into Appendix H of the SUSMP, including omeprazole, pantoprazole and rabeprazole. To date no application has been successful.

All PPIs have a similar mode of action, are well tolerated with similar safety and efficacy profiles. This fact has been acknowledged in the delegate's reasons for scheduling, most recently for the down scheduling of esomeprazole, but also previous meetings of the NDPSC.

If this proposal (inclusion of esomeprazole in appendix H) is deemed to be in the best interest of public health, and given the similar safety and efficacy profiles for PPIs, it would be appropriate for the panel to consider including all of the PPIs commercially available in appendix H (omeprazole, esomeprazole, rabeprazole, lansoprazole and pantoprazole).

[redacted]

[redacted]

[redacted]

[redacted]

From: [redacted]
To: Medicines Scheduling
Subject: Appendix H application for esomeprazole
Date: Monday, 8 December 2014 11:20:22 AM
Attachments: [redacted]

The Secretariat
ACMS,

[redacted] have asked me to comment on their Appendix H application for esomeprazole; and I am happy to do so. My comments are attached to this email. [redacted] have also requested that various specific references to aspects of their application not be generally published beyond that required for committee consideration. The sections within my report, therefore, which I would ask to be redacted are highlighted in yellow.

I have also attached a brief personal cv to provide some background information of my qualifications.

Could you please acknowledge receipt of this email?

[redacted]

[redacted]

Medicines Scheduling Secretariat,
Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2606

Appendix H Application for esomeprazole

I have been asked by [redacted]. to provide my opinion with respect to the Appendix H application submitted by [redacted] to the TGA on 15th October 2014. In this application, [redacted] seeks to advertise Schedule 3 esomeprazole magnesium trihydrate to the general public. I have been provided with remuneration from [redacted] for the time I have taken to prepare this report. The opinions expressed in this report are solely my own but are based upon documentation provided by [redacted] published information which I have become aware of myself and my experience as a community pharmacist, as a pharmacist educator and in the regulatory environment, both here in Australia and overseas. I have attached a brief personal cv for your information.

I believe the inclusion of esomeprazole in Appendix H of the Schedule of Medicines in Australia offers clear public health benefits and I strongly support the [redacted] application.

Consideration of benefits to public health should involve not just the overriding issues of safety and efficacy, but also cost benefit and access to and availability of appropriate product and advice to optimise therapy.

With regard, to efficacy, for short term management of frequent heartburn symptoms, proton pump inhibitors (PPIs) are considered to be first line treatment (for appropriate individual patients); and PPIs are more effective than H2 antagonists in controlling symptoms and healing inflammation associated with gastro-oesophageal reflux, regardless of disease severity. (AMH 2014). The side effect profile of PPIs and their potential for drug interactions are consistent with their inclusion in the Pharmacist-Only (S3) category of the Schedule of Medicines. This has been acknowledged by your Committee by the rescheduling to S3 of firstly pantoprazole in 2008, subsequently, lansoprazole, omeprazole and rabeprazole and most recently esomeprazole earlier this year.

It is my experience, and that of my pharmacist colleagues with whom I have spoken, that there is an extremely low level of consumer awareness of the availability of non-prescription PPIs; and therefore a lack of awareness of the convenient availability of a superior product to treat reflux symptoms. [redacted] Whilst, in part, this issue can be addressed by pharmacist intervention at the time of request for symptom relief, the majority of products used to treat heartburn and regurgitation are self selected as a result of self diagnosis, with no reference to the pharmacist. In fact, by far, the majority of products in the heartburn treatment category are sold through grocery, where there is no opportunity to discuss frequency or severity of symptoms with a pharmacist. Advertising of antacids, alginates and H2 antagonists perpetuates this situation; and the inability to advertise PPIs means that consumers are effectively denied knowledge of safe, superior therapy.

Unlike some other products included in S3, such as pseudoephedrine and codeine-containing analgesics, there is little or no likelihood of misuse – either deliberate or inadvertent. The possible masking of a potentially serious condition and therefore the delay in seeking more appropriate treatment is no more likely with PPIs than it is with antacids, alginates or H2 antagonists.

However, the fact that an underlying serious condition *might* exist means pharmacist involvement in the supply of reflux therapy is best practice. [redacted]

Of themselves, reflux symptoms are not life threatening, but they can have a significant impact on quality of life. Pharmacists can help improve the quality of life of sufferers of frequent heartburn with the appropriate recommendation of PPIs, but it's important that consumers are aware of the availability of these products and the need to discuss reflux symptoms with their pharmacist. It's equally important that pharmacists are aware of warning signs which would indicate the need for referral. [redacted] protocol for the provisions of non-prescription PPIs addresses this issue; and evidence is that pharmacists follow this protocol. [redacted]

In the past cost benefit has been raised as an issue. The reality is that, for short term relief of gastro oesophageal reflux symptoms, PPIs are the most cost effective. [redacted] have explained this in their application. In patients for whom short term therapy is not effective, referral (as per [redacted] for investigation and/or long term (even more cost effective) PPI therapy is required.

I am aware that since PPIs first became available as S3 medicines there have been several unsuccessful applications to have them included in Appendix H. I believe that concerns raised by your Committee with respect to previous applications have been more than adequately addressed in this application by [redacted] Furthermore, I believe this application, given the evidence from overseas (particularly the US, the UK and Canada) the now many years experience of PPIs as non-prescription medicines in Australia, the increasing desire of consumers here to take a greater role in health management, and the commitment of [redacted] for responsible and balanced advertising with a comprehensive pharmacist education program, provides a compelling argument for the Appendix H listing of esomeprazole.

I fully and unreservedly support the proposal.

Yours Sincerely,

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

10th December 2014

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au

Dear Sir or Madam,

Notice inviting public submissions under Reg 42ZCZK of the Therapeutic Goods Regulations 1990
Scheduling proposals to be considered at the ACMS Meeting, March 2015

We refer to the notice inviting public comment under Regulation 42ZCZK of the Therapeutic Goods Regulations and would like to provide comment on some of the scheduling proposals that will be referred to the March 2015 meeting of the ACMS.

[redacted]

[redacted] appreciates the opportunity to provide public comment in relation to ACMS agenda scheduling proposals. We wish to address relevant matters under section 52E of the Therapeutic Goods Act 1989, as applicable to the delegate's interim decision on the scheduling of naproxen.

Please find enclosed, under cover of this letter, [redacted] comments in relation to the following scheduling proposals that will be considered by the ACMS at the November 2014 meeting:

Agenda Item 4 – Esomeprazole
Proposal to create a new Appendix H entry for esomeprazole in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease (GORD), in packs containing not more than 14 days' supply.

Agenda Item 5 – Hydrocortisone compounded with Aciclovir
Proposal to amend the Schedule 3 entry for hydrocortisone 1% w/w when compounded with acyclovir 5% w/w or less in primary packs of not more than 2 g for dermal use in adults and adolescents (12 years of age and over.
Proposal to include aciclovir in Appendix H.

Comment on each of these agenda items is presented as a separate attachment.

[redacted]

As an industry representative, [redacted] is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

[redacted]

Agenda Item 4 - Esomeprazole

Proposal to create a new Appendix H entry for esomeprazole in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease (GORD), in packs containing not more than 14 days' supply.

[redacted] believes that raising public awareness of Schedule 3 medicines will deliver a range of benefits – for consumers by increasing awareness of a broader range of therapeutic options; as well as for pharmacists by promoting their professional role in managing conditions for which Schedule 3 medicines are available.

The Schedule 3 Advertising Guidelines (dated November 2000)[1] developed by the NCCTG form the only guidance for sponsors regarding applications for Schedule 3 advertising approval for medicines. [redacted] is concerned that these guidelines are dated and there is no mechanism in place for these to be updated or modernised, as the NCCTG is no longer operational and there is no established policy oversight in this area. As referred to in these guidelines, the following criteria should be used in determining suitability of a medicine for inclusion in Appendix H:

- Potential public health benefit
- Likelihood of advertising leading to inappropriate patterns of use
- The wider regulatory system through both the Therapeutic Goods Advertising Code Council and the therapeutic goods registration process
- Provisions relating to the Therapeutic Goods Advertising Code, that apply to all brand advertisements
- Whether the entry may result in advertising of goods for an indication other than those included in the ARTG
- Ability of the consumer to appropriately use through labelling / CMI
- The level of patient education necessary for correct use

Esomeprazole is a proton-pump inhibitor. It was re-scheduled to Schedule 3 on the 1st June 2014, following its consideration at the November 2013 meeting of the ACMS (ACMS#10). Other PPIs in Schedule 3 are pantoprazole, rabeprazole, omeprazole, lansoprazole. There have been a few applications for Appendix H listing for the PPIs over the past several years, all of which have been rejected:

- Pantoprazole – Appendix H was considered at the February 2009, February 2010 and February 2011 meetings of the then NDPSC and rejected on all occasions;
- Rabeprazole – Appendix H was considered at the June 2010 meeting of the NDPSC and June 2011 meeting of the ACMS and was rejected on both occasions.

PPIs as a group, have been available in Australia as Schedule 3 medicines for many years, since pantoprazole was approved as a Schedule 3 medicine in May 2008. There are few differences between PPIs, and all products have the same indications for Schedule 3 use, the same pack sizes and duration of use, a similar safety profile and require the same consumer warning statements on labelling that are listed in RASML (now the Medicines Advisory Statement Specifications 2014)[2] apply.

---

[1] http://www.tga.gov.au/publication/schedule-3-advertising-guidelines

[2] Medicines Advisory Statements Specification 2014 http://www.comlaw.gov.au/Details/F2014L00693

[redacted] has supported Appendix H listing of pantoprazole and rabeprazole in previous submissions, and consistent with that position, supports Appendix H listing of esomeprazole, as all of these medicines are very similar as a class. [redacted] believes that esomeprazole fulfils the criteria outlined in the Schedule 3 advertising guideline, as described below.

Potential public health benefit from advertising

Many consumers are unaware of Schedule 3 medicines and the treatment options available with pharmacist recommendation. As a consequence, consumers may visit the doctor for minor ailments and other conditions that can be readily managed by the pharmacist; alternatively, consumers may either not treat, or self-treat with products that are familiar to them.

Advertising esomeprazole (as well as the other Schedule 3 PPIs), can benefit the consumer by increasing awareness of the availability of the particular medicine for GORD symptoms and prompting an individual to seek advice of the pharmacist. This can provide two potential benefits – reduction in unnecessary visits to the GP, as well as providing the opportunity for the consumer to be recommended a more efficacious course of treatment from the pharmacist.

For individual consumers, there are benefits from increasing awareness and encouraging discussion with pharmacists. It provides the opportunity for discussion of treatment options for GORD, symptoms for consumers to be aware of and the chance of earlier referral to a medical practitioner if needed.

PPIs as a class have had many years of marketing experience and pharmacists are very familiar with utilising the treatment protocols and referring consumers who may require further medical advice.

Likelihood of advertising leading to inappropriate use

[redacted] has seen no evidence and can envisage no scenarios to suggest that the advertising of esomeprazole would result in inappropriate use.

The wider regulatory system

All advertising to consumers must comply with the *Therapeutic Goods Act,* the *Therapeutic Goods Regulations* and the Therapeutic Goods Advertising Code. Inclusion of esomeprazole in Appendix H will not affect the various requirements imposed by these instruments.

Any advertising for esomeprazole must be consistent with the registered indications, and must contain certain mandatory information (including the statement "Your pharmacist's advice is required". It is not likely that advertising of esomeprazole will lead to advertising for any indications other than those included in the ARTG.

Ability of the consumer to appropriately use through labelling / CMI

In general, consumers are interested in accessing medical and pharmaceutical information and taking some control of their health.

Esomeprazole, being Schedule 3, has a CMI available and the labelling contains all of the required warning statements. RASML has now been updated to include esomeprazole warning statements and esomeprazole has been added to the class statements for all other Schedule 3 PPIs.

In order to assist pharmacists with supply of Schedule 3 esomeprazole, educational tools and treatment protocols are available in order to ensure that pharmacists are able to provide appropriate professional advice.

Conclusion

Esomeprazole is very similar to the other Schedule 3 PPIs that have been marketed for many years. [redacted] has previously supported Appendix H applications for the other marketed PPIs pantoprazole and rabeprazole, and consistent with that position [redacted] believes that esomeprazole should be included in Appendix H.

Agenda item 5 - Hydrocortisone compounded with aciclovir

Proposal to amend the Schedule 3 entry for hydrocortisone 1% w/w when compounded with aciclovir 5% w/w or less in primary packs of not more than 2 g for dermal use in adults and adolescents (12 years of age and older).

To include aciclovir in Appendix H.

1. Proposed Schedule 3 entry

[redacted] supports the proposal to amend the Schedule 3 entry for hydrocortisone 1% w/w to allow for a compounded product containing hydrocortisone 1% w/w combined with aciclovir 5% w/w, for the treatment of herpes simplex labialis.

The existing Schedule 3 entry for hydrocortisone 1% or less allows for combination use under the following circumstances:

- For dermal use with antifungal agents in packs of 30 g or less
- For rectal use with local anaesthetic substances

Aciclovir is exempt from scheduling in dermal preparations of 5% w/w or less, as a single active ingredient. The proposal outlined above seeks to allow for combination use with aciclovir in packs of 2 g or less.

[redacted] notes that the current policy in relation to the scheduling of products containing more than one poison is set out in the SUSMP under *Principles of Scheduling* as follows:

> *If a preparation contains two or more poisons, the provisions relating to each of the Schedules in which those poisons are included apply.*
>
> *Where it is not possible to comply both with a provision relating to one of those Schedules and with a provision relating to another of those Schedules, the provision of the more restrictive Schedule applies, unless a contrary intention is indicated in the Schedules or relevant legislation.*

Based on the above, the combination of hydrocortisone and aciclovir ought to be Schedule 3.

Section 52E(1)(a) – Risks and benefits

Both hydrocortisone and aciclovir have been marketed in Australia as single ingredient products for more than a decade and have well established, well characterised safety profiles. It is likely that the low risks individually associated with dermal hydrocortisone 1% and dermal aciclovir 5% will be similarly low in any combination product.

[redacted] understands that the rationale for the combination is that the aciclovir curtails viral replication, and the hydrocortisone controls the local inflammatory response that occurs during the episode of herpes simplex labialis infection. The benefit of the combination product is that it reduces the risk of an episode of herpes simplex labialis infection progressing to an ulcerative lesion. This is an important goal of therapy for consumers, for whom recurrent episodes of these infections are associated with significant impact on physical, social and emotional well-being.

Consumers who are affected by herpes simplex labialis infections are familiar with the signs and symptoms of the condition and are able to self-diagnose and self manage this condition. They are

generally familiar with the range of products available, and single ingredient aciclovir has been available as an unscheduled product for many years.

A Schedule 3 entry is appropriate for a combination hydrocortisone and aciclovir product as it ensures that the product will be supplied to consumers following consultation with a pharmacist, who can advise on the most appropriate treatment option for each individual. The pharmacist can advise when or if a single ingredient product or combination product is most suitable and can provide important advice to ensure appropriate use, for example that it is important for topical antiviral therapy to be used at the first sign of an outbreak, and what to do at different stages of the infection.

In the absence of any evidence demonstrating increased risk associated with the combination of hydrocortisone and aciclovir, [redacted] suggests that the current policy in relation to scheduling of combination products should be applied and that Schedule 3 is appropriate.

Section 52E(1)(c) – Toxicity

Topical hydrocortisone and aciclovir both have well documented safety profiles and as discussed above, it is likely that the combination products will similarly have a favourable safety profile.

The proposed pack size of 2 g will also ensure that the product is used sparingly and deter from using the product over a large area. The pharmacist's advice will also be provided at the point of supply to reinforce labelling instructions and facilitate appropriate use.

Section 52E(1)(e) – Potential for abuse

Recurrent herpes simplex labialis is a familiar condition to consumers and has been self-managed by consumers for many years. There is no evidence that either of the two ingredients have abuse potential as single ingredients and the combination product will similarly have a low potential for abuse or misuse.

Conclusion

[redacted] believes that there is no evidence that a departure from the existing scheduling policy is warranted for the combination of dermal hydrocortisone and aciclovir and that a Schedule 3 entry is appropriate.

2. Proposed Appendix H entry

[redacted] believes that raising public awareness of Schedule 3 medicines will deliver a range of benefits – firstly for consumers by increasing awareness of a broader range of therapeutic options; secondly, for pharmacists by promoting their professional role in managing conditions for which Schedule 3 medicines are available.

The Schedule 3 Advertising Guidelines (dated November 2000)[3] developed by the NCCTG form the only guidance for sponsors regarding applications for Schedule 3 advertising approval for medicines. [redacted] is concerned that these guidelines are dated and there is no mechanism in place for these to be updated or modernised, as the NCCTG is no longer operational and there is no

[3] http://www.tga.gov.au/publication/schedule-3-advertising-guidelines

established policy oversight in this area. As referred to in these guidelines, the following criteria should be used in determining suitability of a medicine for inclusion in Appendix H:

- Potential public health benefit
- Likelihood of advertising leading to inappropriate patterns of use
- The wider regulatory system through both the Therapeutic Goods Advertising Code Council and the therapeutic goods registration process
- Provisions relating to the Therapeutic Goods Advertising Code, that apply to all brand advertisements
- Whether the entry may result in advertising of goods for an indication other than those included in the ARTG
- Ability of the consumer to appropriately use through labelling / CMI
- The level of patient education necessary for correct use

Dermal hydrocortisone 1% has been listed in Appendix H for 12 years, and aciclovir has been available without prescription for 17 years and has been unscheduled for 12 years. Both of the substances, as single ingredient preparations, may be advertised directly to consumers and for this reason [redacted] believes that it is appropriate to allow the combination product to be listed in Appendix H.

Since hydrocortisone is listed in Appendix H, the combinations of hydrocortisone plus antifungal and hydrocortisone plus local anaesthetic for rectal use are covered by that entry. Should the hydrocortisone plus aciclovir combination be allowed as a Schedule 3 medicine, [redacted] believes that the combination of hydrocortisone plus aciclovir should also be captured by the Appendix H listing for hydrocortisone.

Potential public health benefit

Increasing consumer awareness of an additional therapeutic option for herpes simplex labialis infections is important, and will encourage consumers to visit their pharmacist to discuss their condition and whether this product is appropriate for their condition.

Most consumers who have been self treating and managing their condition with single ingredient aciclovir would find benefit from discussing their condition, ensuring that they are using their current treatment appropriately as well as the pharmacist determining whether a new combination product is suitable for their condition.

Likelihood of advertising leading to inappropriate use

[redacted] has seen no evidence and can envisage no scenarios to suggest that the advertising of a combination hydrocortisone and aciclovir product would result in inappropriate use.

The wider regulatory system

All advertising to consumers must comply with the *Therapeutic Goods Act*, the *Therapeutic Goods Regulations* and the Therapeutic Goods Advertising Code. Inclusion of combination hydrocortisone and aciclovir in Appendix H will not affect the various requirements imposed by these instruments.

Any advertising must be consistent with the registered indications, and must contain certain mandatory information (including the statement "Your pharmacist's advice is required". It is not

likely that advertising of the combination product will lead to advertising for any indications other than those included in the ARTG.

Ability of the consumer to appropriately use through labelling / CMI

In general, consumers are interested in accessing medical and pharmaceutical information and taking some control of their health.

The combination product will contain all of the required warning statements on labelling, a CMI will be available and the pharmacist will also be able to provide further advice at the point of supply.

Conclusion

[redacted] believes that a Schedule 3 combination of hydrocortisone 1% and aciclovir 5% should be allowed to be advertised. Schedule 3 hydrocortisone is listed in Appendix H, and for that reason all Schedule 3 combinations of hydrocortisone covered by the Schedule 3 entry should be allowed to be advertised.

Both hydrocortisone and aciclovir may be advertised as single ingredients. They have a history of use in Australia, a well-established and favourable safety profile and have a very low risk of abuse or misuse. The indication for use in herpes simplex labialis is consistent with self-management and self-treatment. Since Schedule 3 medicines require the pharmacist's advice for supply, this also ensures that consumers will have the benefit of the pharmacist's advice to ensure appropriate use of the medicine.

[redacted] believes that there is sound justification for the combination of hydrocortisone plus aciclovir to be covered by the existing Appendix H entry for hydrocortisone.

[redacted]

[redacted] – TGA/ACMS oral contraceptives new schedule 3 proposal

medicines.scheduling@tga.gov.au

[redacted] opposes the proposal to create new Schedule 3 entries for the oral contraceptives listed at the end of this submission, which will be considered by the TGA Advisory Committee on Medicine Scheduling in March 2015.

There are many reasons why this proposal would have a retrograde impact on the health of Australian women.

Oral contraceptives are not without risks

The side effects of oral contraceptives can be life threatening. These include blood clots, stroke and heart attacks, all of which are exacerbated if women are smoking and/or overweight. Three to seven percent of the Caucasian population has a heritable thrombophilia representing a contraindication to prescription of the combined oral contraceptive pill. Taking a combined oral contraceptive pill in these circumstances can increase the risk of thrombosis thirtyfold[1]. Some contraindications develop over time in a way that would not be identified by a questionnaire or a pharmacist.

These risks have not changed since the TGA determined that oral contraceptives should be Schedule 4 medicines.

Risks will increase when there is less opportunity in a pharmacy setting to undertake a full patient history and examination looking for stigmata of medical illnesses which may not yet be apparent. A full assessment includes identifying interactions with other medicines, such as antibiotics, anticonvulsants, anticoagulants, etc, that may interfere with the effectiveness of oral contraceptives.

Assessment and monitoring by medical practitioners of women considering oral contraceptives is essential to ensure risks are minimised

The decision to prescribe an oral contraceptive is not a simple one. It requires an initial, and then episodic, consultation/s by a medical practitioner to assess whether it is appropriate to start, continue, change or even cease an oral contraceptive and replace it with another contraceptive option.

[1] Khan and Dickerman *Hereditary thrombophilia* Thrombosis Journal 2006 4:15

A questionnaire and blood pressure test alone grossly underestimate the complexity of the assessment required.

Oral contraceptives may be supplied by pharmacists for cycle control, posing risks to women

Women experiencing problems with their menstrual cycles, such as painful heavy bleeding, may self-diagnose the need for an oral contraceptive to provide symptom relief. However, oral contraceptive use in these circumstances can increase future fertility problems in women with hypothalamic problems and can control symptoms in women with undiagnosed endometrial hyperplasia, endometrial polyps or endometrial carcinoma leading to a delay in diagnosis[2].

Endometriosis, a common condition affecting around 10% of women, is now one of the leading causes of subfertility requiring IVF and has a 7-10 year delay in diagnosis following commencement of symptoms such as heavy and painful periods[3][4]. Bypassing examination by a suitably qualified doctor will further delay diagnosis and treatment leading inexorably to an increased demand for future fertility treatments including very expensive and invasive IVF treatment.

There is a risk that women may either fail to inform the pharmacist that their reasons for seeking these medicines is for cycle control rather than contraception, or they may pressure pharmacists to supply oral contraceptives despite the risks involved.

Alternative contraception methods may be safer, more effective and/or more appropriate

There are alternatives to oral contraceptive pills which are safer and more effective. Long acting reversible contraceptives are often the better choice for women seeking safe and effective contraception. Many studies show that intrauterine devices and implants are significantly more effective than oral contraceptives[5].

Women should have the opportunity to make a fully informed decision about the options available to them based on their medical situation and individual circumstances. Pharmacists will not be able to fully discuss, much less offer, all these options.

Pharmacists do not have the skills or training to make assessments about the appropriateness of oral contraceptives for individual women and a pharmacy is not the place for complex discussions about contraception, the most appropriate contraception option, and sexual health. This will have the long term effect of women being less informed about these options.

Oral contraceptives are not a 'one-size-fits all' medicine

The first time prescription of a hormonal medication requires review in 2-3 months to assess side effects and see if that particular product is the best fit for the individual woman involved. Once the correct medication has been found, there is no guarantee that a woman's needs won't change

[2] [redacted] *Submission to ACMS on oral contraceptives proposal*, 1 December 2014
[3] Jean Hailes Foundation *Endometriosis Fact Sheet* 1 April 2014 at http://jeanhailes.org.au/
[4] Black K et al *Medical management of endometriosis* Australian Prescriber Vol 35: no 4, August 2012
[5] Brooke et al, *Effectiveness of Long-Acting Reversible Contraception* New England Journal of Medicine, May 2012

[redacted]

with time. In fact it is more than likely that as a woman ages, her contraceptive needs will change.

Regular GP visits prompted by the need for contraceptive renewal benefit women individually and on a population basis

There are well known and significant preventive health benefits achieved from women visiting their general practitioner at least once a year for an oral contraceptive prescription.

As well as checking blood pressure, general practitioners take this opportunity to discuss protection against sexually transmitted diseases, regular pap smears and breast checks. The latter screening tests are generally conducted in the same consultation as the oral contraceptive is prescribed which is cost effective for both patients and the Government. These consultations also represent the opportunity to talk about future pregnancies, preconceptual vitamins and preconception planning including optimisation of underlying medical conditions.

For many women, a visit to their GP to renew their contraceptive is their only regular preventive health check-up. This greater access to preventive health care tied in with contraceptive prescribing has been considered one of the reasons women more frequently access health care and may play a role in their increased longevity compared to men.

Down-scheduling is likely to lead to higher costs for women and the Government

[redacted] is concerned that the main driver of this proposal is to reduce costs for the Government through fewer GP visits.

However, any health system 'savings' would only be short-term as they are likely to be undermined by a reduction in preventive health care provided by GPs and subsequent downstream costs resulting from later presentations of established illness.

Savings to individual women are likely to be negligible. Oral contraceptive prescriptions provided by GPs are generally for 12 months' supply which does not impose an onerous requirement for GP visits. In that annual GP visit, women are getting far better value for money with a consultation covering a range of health care needs, rather than a single transaction with the pharmacist for an oral contraceptive.

In addition, if women find themselves unexpectedly at the end of their prescription and unable to quickly get a GP appointment for a renewal, they are already able to access an 'emergency' prescription or a 'continued dispensing' prescription from their regular pharmacist under Commonwealth and State legislation.

From a time commitment perspective, the proposal to limit supply from a pharmacy to 3 to 6 months' supply is more inconvenient than an annual GP visit.

[redacted] is also concerned about the conflicts of interest inherent in a pharmacist essentially prescribing a medicine for which they gain a direct financial benefit, particularly a medicine with well-known side effects and for which there are safer, more effective Schedule 4 alternatives.

[redacted]

[redacted]

Summary

The vital role of medical practitioners in the safe and effective prescription of oral contraceptives is encapsulated by the response of one of our members to the proposal to down-schedule these medicines:

> *Starting a woman on an oral contraceptive takes me at least 40 minutes and is often done over multiple consultations. [I cover] the options for contraception, the risks of STDs, the contraindications, and smoking cessation advice as part of the risk of complications for smoking patients. [I also spend a] long time on how to take it, the plan of action if not taken properly and when to institute this plan. [An OCP] is useless if given without education and monitoring. [Lastly], the presentation for repeat scripts is often the only time we get to check proper use, STD risk and initiate important screening tests such as PAP smears.*

11 DECEMBER 2014

[redacted]

Proposal regarding oral contraceptives to be considered by ACMS, March 2015

Substance	Proposal
Oestradiol Desogestrel Ethinylestradiol Norethisterone Levonorgestrel Cyproterone Gestodene Drospirenone Mestranol Medroxyprogesterone Oestrogens Progestogens	To create new Schedule 3 entries for these substances when indicated for oral contraception. The applicant has proposed potential conditions of: • A minor questionnaire by the pharmacist regarding family history of heart problems, hypertension and stroke • An in-pharmacy blood pressure test/results from another recent blood pressure test to ensure suitability for medication Limit of 3-6 months' supply in one transaction

[redacted]

[redacted]

Advisory Committee for Medicines Scheduling

Meeting March 2015

Comments by [redacted] to the proposed amendments referred by the delegate for scheduling advice

- Aciclovir - Schedule 4 to Schedule 2
- Oral contraceptives - new Schedule 3 listing
- Diphenoxylate - Schedule 3 to Schedule 2
- Esomeprazole - Listing on Appendix H
- Hydrocortisone compounded with Aciclovir - amend Schedule 3 entry and include Aciclovir I Appendix H
- Ranitidine - Schedule exemption.

11 December 2014

[redacted]

[redacted]

[redacted]

Introduction

[redacted] 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 March 2015.

[redacted]

Comments on Proposed Amendments

[redacted] has considered the proposed amendments to the SUSMP of relevance to community pharmacy, with particular reference where applicable 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 below and in Appendix 1:

1.1- Aciclovir - Schedule 4 to Schedule 2
1.2- Oral contraceptives - new Schedule 3 listing
1.3- Diphenoxylate - Schedule 3 to Schedule 2
1.4- Esomeprazole - Listing on Appendix H
1.5- Hydrocortisone compounded with Aciclovir - amend Schedule 3 entry and include Aciclovir in Appendix H
1.6- Ranitidine - Schedule exemption.

Proposal 1.1 - Aciclovir-Schedule 4 to Schedule 2

(Proposal to reschedule aciclovir in muco-adhesive tablets containing 50 mg in a pack of two tablets or less from Schedule 4 to Schedule 2.)

[redacted] notes that the only OTC aciclovir 50mg/g products currently available are both topical creams, hence consumers are likely to be unfamiliar with this delivery system for the treatment of herpes labialis. As such, [redacted] is concerned there is potential for this product to be used incorrectly.

It is therefore our view that at that this product should be Schedule 3 so that pharmacists can instruct consumers on proper use of this new delivery system and increase the likelihood consumers will not to crush, chew, suck or swallow the tablets as stipulated in the product instructions.[1] The mandatory intervention of the pharmacist also provides the opportunity differential diagnosis as well as to enquire about potential underlying cause(s) of the condition (e.g. stress, STI, medication side effects) and referral to a doctor if required.

[redacted] supports the listing of aciclovir on Appendix H to increase consumer awareness of this product, subject to any advertisements emphasising the mandatory role of the pharmacist in determining whether the product is suitable. Aciclovir in the same dosage as a topical cream is already advertised hence there is no reason why aciclovir in muco-adhesive tablets should not permitted for advertising.

Recommendation

[redacted] believes the most appropriate schedule for aciclovir muco-adhesive tablets is Schedule 3 to ensure consumers use this delivery system effectively. [redacted] supports listing aciclovir being listed on Appendix H.

Proposal 1.2 Oral contraceptives- new Schedule 3 listing

(Oestradiol, Desogestrel, Ethinylestradiol, Norethisterone, Levonorgestrel, Cyproterone, Gestodene, Drospirenone, Mestranol, Medroxyprogesterone, Oestrogens, Progestogens- To create new Schedule 3 entries for these substances when indicated for oral contraception.)

[redacted] does not support this proposal. We believe the risks associated with initiating supply the oral contraceptive are inconsistent with a Schedule 3 classification. Having not been consulted by the applicant regarding this proposal, [redacted] cannot comment on whether the conditions of supply suggested by the applicant, namely a 'minor questionnaire' and a blood pressure test are adequate in addressing this risk.

However, [redacted] believes there is merit in allowing better access to the oral contraceptive hence [redacted] included *Continued Dispensing of PBS Medicines in Defined Circumstances* (Continued Dispensing) in the Fifth Community Pharmacy Agreement[2]. Continued Dispensing is the supply of an eligible medicine to a person when there is an immediate need for the medicine to continue, if it is not practicable to obtain a prescription, the medicine has been previously prescribed, therapy is stable and there has been prior clinical review by the prescriber that supports continuation of the medicine

[1] http://sitavig.com/wp-content/uploads/2014/07/sitavig-prescribing-information_2014.pdf
[2] http://5cpa.com.au/about-5cpa/

and the medicine is safe and appropriate for the person.[3] Continued Dispensing is limited to supplying a standard PBS quantity of cholesterol lowering medicines and oral contraceptives. For PBS listed oral contraceptives, the standard PBS quantity is for four months' supply, therefore if a woman is eligible for Continued Dispensing supply, she has up to four months to see her GP for review. A recent report[4] on Continued Dispensing indicates that for the period 1 September 2013 to 30 June 2014, over 40% of Continued Dispensing supplies (or 992 instances) have been for the oral contraceptive.

While the oral contraceptive may be prescribed for other indications besides contraception (e.g. acne, dysmenorrhea), [redacted] does note an anomaly with the access to urgent supply for non-PBS listed oral contraceptives. Continued Dispensing specifically applies to PBS listed oral contraceptives. A woman requiring urgent supply of a non-PBS listed oral contraceptive requires this to be covered by emergency supply regulations of the relevant state or territory. Under emergency supply arrangements, some jurisdictions allow the supply of the smallest manufacturer's pack for products that cannot or should not be broken, such as eye drops, creams and inhalers. Some jurisdictions recognise the importance of supplying oral contraceptives as a whole calendar strip and allow the supply of the smallest standard pack. This should be adopted by all jurisdictions as it is not only more convenient for the pharmacist and the consumer, but significantly safer for the consumer – particularly for multi-phasic products. Under current emergency supply arrangements in some jurisdictions, women who are prescribed non-PBS listed oral contraceptives are at a greater disadvantage than those prescribed PBS listed oral contraceptives if they need urgent supply.

While the listing of oral contraceptives on the PBS allows for supply for up to a 12-month period, according to the National Cervical Screening Program website[5], a PAP smear is recommended every two years. With this in mind, we believe there may be opportunities for women who use the oral contraceptive without any complications to collaborate with their prescriber and pharmacist to allow for ongoing supply beyond the 12 months and potentially up to 24 months. [redacted] would be willing to work with government organisations and other interested parties to develop this concept.

As such, given we do not understand the full extent of the current proposal and how pharmacists would be prepared and supported, we do not support the current proposal to list oral contraceptives within Schedule 3 but rather, we believe the focus should be on:

- implementing continued dispensing legislation in every jurisdiction

[3] http://5cpa.com.au/about-5cpa/continued-dispensing-of-pbs-medicines-in-defined-circumstances/
[4] http://www.pbs.gov.au/info/publication/reports/continued-dispensing/report-to-parliament
[5] http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/papsmear

- introducing collaborative arrangements between prescribers, pharmacists and consumers for ongoing supply when the circumstances are safe and appropriate
- allowing the supply of the smallest standard pack of oral contraceptives as part of state/territory emergency supply requirements

Recommendation

[redacted] does not support this proposal. We believe the risks associated with initiating supply of an oral contraceptives are inconsistent with a Schedule 3 classification.

Instead, we believe the focus should be on improving access to the oral contraceptive through Continued Dispensing.

Proposal 1.3 Diphenoxylate-Schedule 3 to Schedule 2

(Proposal to down schedule diphenoxylate 2.5mg or less in packs of 8 or less dosage units, when combined with a quantity of atropine sulphate equivalent to at least 1 per cent of the dose of diphenoxylate from Schedule 3 to Schedule2.)

[redacted] does not support this proposal and believes the current scheduling remains appropriate.

Risks and benefits of the use of a substance[6]

Use in Pregnancy

Diphenoxylate is rated as Australian Category C for use in pregnancy *(Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human fetus or neonate without causing malformations.[7])* and it is advised that women avoid high doses at or near term.[8] [redacted] believes this risk is best mitigated by ensuring these products are only available via the mandatory intervention of the pharmacist.

The purposes for which a substance is to be used and the extent of use of a substance[9]

Dipenoxylate is contraindicated include the following conditions[10]

- Jaundice.

[6] Section 52E(1A)- *Therapeutic Goods Act 1989*
[7] www.tga.gov.au/prescribing-medicines-pregnancy-database
[8] Australian Medicines Handbook-online
[9] Section 52E 1(b)- *Therapeutic Goods Act 1989*
[10] Mims Online- Lofenoxal

- Diarrhoea associated with pseudomembranous enterocolitis which may occur during or up to several weeks following treatment with certain antibiotics.
- Diarrhoea associated with inflammatory bowel disease (e.g. ulcerative colitis, Crohn disease) and bacterial and amoebic colitis, as diphenoxylate may exacerbate the underlying condition

Re-scheduling dipenoxylate to schedule 2 may increase the risk patients with these contrainidcations will self-select this product.

The toxicity of the substance[11]

Use in Children

Diphenoxylate should not be used in children with acute diarrhoea as it can cause significant toxicity with the ingestion of just one tablet or mouthful.[12] Loperamide is sometimes used for chronic diarrhoea (e.g. short gut syndrome) in younger children under specialist supervision.[13]

If diphenoxylate is made a Schedule 2 medication, there is a risk parents will self-select a medication indicated for diarrhoea for their child, without realising the specific risk of administering diphenoxylate. A schedule 3 classification ensures the mandatory intervention of the pharmacist in determining the suitability of diphenoxylate and will prevent the risk of incorrect self-selection.

Recommendation

[redacted] does not support this recommendation and believes the current scheduling remains appropriate. The risk of consumers incorrectly selecting diphenoxylate, particularly to treat diarrhoea in children or in pregnancy warrants such products remaining exclusively Schedule 3 to ensure the mandatory intervention of the pharmacist.

Proposal 1.4 - Esomeprazole-Appendix H Listing

(Proposal to create a new entry in Appendix H for esomeprazole in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease (GORD), in packs containing not more than 14 days' supply.)

[redacted] has no objection to this proposal, providing all advertisements for these products highlight the mandatory role of the pharmacist in determining the suitability of the product for consumers. The fact all Proton Pump Inhibitors (PPIs) are now available as Schedule 3 medicines in Australia in limited pack sizes, [redacted] believes it would be

[11] Section 52E 1(c)- *Therapeutic Goods Act 1989*
[12] Therapeutic Guidelines Limited- drugs and toxins that are highly toxic in small doses in children
[13] Australian Medicines Handbook online- diphenoxylate

of benefit to consumers to be made aware of products that can treat frequent heartburn or GORD, subject to consultation with a pharmacist.

Increase consumer awareness

Increased awareness of alternate treatments for heartburn and reflux may prompt consumers who regularly purchase antacids or ranitidine from supermarkets, where there is no potential for health advice or review, to consult their pharmacist for more information. This would provide a pharmacist with the opportunity to assess the consumer, provide other therapeutic options and/or lifestyle support as required, or to refer them to a doctor if required

Safety Issues

There is no significant abuse potential to justify restricting direct to consumer advertising of Schedule 3 PPIs. The potential for overuse is limited by the fact PPIs are only available as OTC medicines in pack sizes of up to 14 days' supply.

[redacted] believes that there is no more concern with the advertising of Schedule 3 PPIs than there is with antacids and H_2-receptor antagonists. Considering the interaction profile of antacids, and the fact that H_2-receptor antagonists are usually only indicated for the short-term management of reflux symptoms without medical advice, the advertising of Schedule 3 PPIs could actually be in the public interest as it would raise awareness of other therapies and prompt consultation with a health professional.

[redacted] does not believe there is any significant concern that Schedule 3 PPIs would be irresponsibly advertised or that any advertising would be detrimental to public safety.

Recommendation

[redacted] has no objection to this proposal, provided all advertisements for these products highlight the mandatory role of the pharmacist in determining the suitability of the product for consumers. The listing of esomeprazole on Appendix H will increase awareness of effective treatments for heartburn and reflux which may in turn prompt consumers to consult a pharmacist for more information.

[redacted] recommends if this proposal is accepted, consideration should be given to applying Appendix H listing to all PPIs as they broadly have the same risk profile.

1.5 - Hydrocortisone compounded with Aciclovir - amend Schedule 3 entry and include Aciclovir in Appendix H

(Proposal to amend the Schedule 3 entry for hydrocortisone 1 per cent (1%w/w) when compounded with aciclovir 5% (5% w/w) or less in primary packs of not more than 2 g for dermal use in adults and adolescents (12 years of age and older). To include aciclovir in Appendix H.)

[redacted] is not opposed to this proposal as the risk profile for hydrocortisone and aciclovir in their respective strengths have been well established and we are not aware of any additional risks when they are used in combination. [redacted] believes Schedule 3 is an appropriate classification to ensure consumers receive health counselling regarding underlying causes of the condition and potential adverse effects of this medicine which can be managed by the pharmacist.

In relation to consideration for Appendix H, [redacted] is not opposed to this proposal but does have some concerns that are outlined below:

- Advertising hydrocortisone/aciclovir combinations runs the risk that consumers will seek to use combination products as a first line treatment for the treatment of cold sores when ideally they should start with products containing aciclovir as a single active ingredient (assuming medication is the most suitable treatment option) and moving to a combination product only if required. This risk is particularly pertinent given that consumers often regard cold sores as cosmetically displeasing, hence they may a strong desire to remedy the condition as quickly as possible.
- Furthermore, while there have been some studies that have investigated the efficacy of combination of hydrocortisone/aciclovir combination products, we believe further studies are required to demonstrate its efficacy relative to single ingredient aciclovir products[14] in order to justify direct to consumer advertising being permitted, and
- In circumstances where consumers experience an adverse reaction to hydrocortisone or aciclovir but are unaware of it, taking a combination product as first line treatment may make it more difficult to identify which active ingredient was the cause.

Recommendation

[redacted] believes there are no significant issues listing this combination medicine in Schedule 3. In relation to Appendix H listing, while [redacted] is not opposed to listing we have raised some issues that may warrant further consideration.

[14] Hull, C. M., & Brunton, S. (2010). The role of topical 5% aciclovir and 1% hydrocortisone cream (Xerese™) in the treatment of recurrent herpes simplex labialis. *Postgrad Med*, *122*(5), 1-6.

[redacted]

1.6 - Ranitidine - Schedule exemption.

(Proposal to exempt ranitidine from Schedule 2 when in divided preparations for oral use containing 300 mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than 7 dosage units.)

[redacted] does not support this proposal. Our reasons are highlighted below:

Risks and benefits of the use of a substance[15]

[redacted] has concerns that the further scheduling exemptions for ranitidine has the potential risk of masking serious conditions such as gastric cancer or oesophagitis and therefore delay diagnosis.[16] [redacted] argues there is a much greater risk of these products being used to mask the adverse events of other readily available medicines which are exempt from scheduling e.g. ibuprofen and aspirin.

Additionally, [redacted] has concerns about increasing the availability of H_2-receptor antagonists to the elderly patient group without the opportunity for professional intervention. A US article[17] indicates that many elderly consumers may attribute the symptoms of reflux to the normal aging process and will self-treat, but for which the complications can be severe, including laryngopharyngitis, uncontrolled asthma, bronchitis, and aspiration pneumonia. The elderly are particularly susceptible to these respiratory complications.

The purposes for which a substance is to be used and the extent of use of a substance[18]

Although there is availability through non-pharmacy retail outlets of antacid preparations which are exempt from scheduling, these products have to be used regularly to have any effect. The general assumption is that with appropriate labelling of these products, consumers with chronic problems would recognise that continuous, regular dosing requirements (every few hours) of these products is an indication that the condition requires further assessment by a health professional.

However, with a medicine such as ranitidine with only once or twice daily (150mg, 300mg) dosing requirements, the better control and less frequent dosing requirements may reduce the significance for the consumer of the chronicity of their condition and thus facilitate self-treatment rather than professional consultation.

Even though this current rescheduling recommendation is to restrict the pack size to 7 days' supply, there is no restriction to the number of these packs that can be purchased at any one time through such a non-pharmacy retail outlet. With all

---

[15] Section 52E(1A)- *Therapeutic Goods Act 1989*
[16] Mims Online- Ausran
[17] Zagaria MA; Suppressing Gastric Acid in seniors with GERD; US Pharmacist Vol 30:10; 10/19/2005
[18] Section 52E(1B)- *Therapeutic Goods Act 1989*

medicines, including Schedule 2 medicines, pharmacy can and do offer the controls to ensure that even though the public has increased access to such medicines and its use is in line with QUM principles.

Other matters necessary to protect public health[19]

[redacted] also has additional concerns which have been previously raised regarding the ready availability of non-steroidal anti-inflammatory drugs (NSAID) such as ibuprofen and diclofenac through non-pharmacy retail outlets. Because of the risk these products have with producing gastric problems, including ulcers, [redacted] has concerns that increased access to products such as ranitidine could be used by consumers for treating the adverse effects caused by these other medicines and masking more serious health conditions e.g. gastric cancer.

[redacted] contends that in non-pharmacy outlets, there is neither legislation nor quality nor professional standards which would prevent marketing campaigns for products such as ranitidine for reflux symptoms being actively promoted next to/alongside marketing campaigns for medicines such as ibuprofen.

Recommendation

[redacted] does not support this proposal. There is a potential to mask more serious conditions or adverse reactions of other readily available medicines and this can have a significant effect on patient safety and public health. [redacted] contends that the H_2-receptor antagonist medicines are more appropriate for Schedule 2 classification which restricts sales to pharmacies which have the quality and professional standards in place for safe and effective provision of the products to consumers.

[19] Section 52E(1F)- *Therapeutic Goods Act 1989*

[redacted]

Appendix 1

Quality Use of Medicines

Quality Use of Medicines (QUM) is one of the central objectives of Australia's National Medicines Policy[20]. [redacted] 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[21] 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.[22]

As of 1 September 2014, approximately 93 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'[23] in order to triage patient requests and refer to the pharmacist when appropriate.

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.[24] It is essential to protect the most vulnerable consumer groups, particularly children, the elderly, those

---

[20] http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1
[21] Australian Standard® AS 85000-2011 Quality care Pharmacy Standard – quality management system for pharmacies in Australia
[22] Chapman J, An Evaluation of the Quality Care Pharmacy Program Part 5; Pharmacy Guild of Australia; 2005
[23] [redacted]
[24] Australians paying for medicines – new research; AHHA 13/09/2011; http://ahha.asn.au/news/australians-paying-more-medicines-new-research

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.[25]

With regards to non-prescription medicines, a research project[26] 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 consumers do not have issues with accessing non-prescription medicines from community pharmacies.

[25] 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

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