# 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 the Advisory Committee on Chemicals Scheduling (ACCS) #6, the Advisory Committee on Medicines Scheduling (ACMS) #7 and the joint ACCS-ACMS #4 (October 2012 meetings).

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had the 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 <a href="https://www.tga.gov.au/industry/scheduling-spf.htm">www.tga.gov.au/industry/scheduling-spf.htm</a>.

Discrete submissions have been grouped by substance. A number of applicants provided submissions that related to multiple substances. These submissions on multiple items have been separately grouped.

### LIST OF SUBMISSIONS

Substance	Total number of public submissions
Thymol	5 submissions (1 submission under 'submissions on multiple substances')
Hydrogen peroxide and carbamide peroxide	7 submissions (3 submissions under 'submissions on multiple substances')
Chloramphenicol	5 submissions (3 submissions under 'submissions on multiple substances')
Diclofenac	1 submission (2 submissions under 'submissions on multiple substances')
Mometasone	7 submissions (1 submission under 'submissions on multiple substances')
Pantaprazole	1 submission (2 submissions under 'submissions on multiple substances')
Teriflunomide	1 submission
Vitamin D	2 submissions (1 submission under 'submissions on multiple substances')

### SUBMISSIONS ON MULTIPLE SUBSTANCES

Four submissions were received.

- One submission was on thymol and hydrogen peroxide and carbamide peroxide;
- One submission was on chloramphenicol, diclofenac, pantaprazole, paracetamol, vitamin D and hydrogen peroxide and carbamide peroxide;
- One submission was on chloramphenicol, diclofenac, mometasone, pantaprazole, paracetamol and hydrogen peroxide and carbamide peroxide; and
- One submission was on chloramphenicol and paracetamol.

12 September 2012

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

Email: SMP@health.gov.au

Invitation for public comment - ACCS meeting, October 2012

Scheduling proposal for a new Schedule 6 entry for thymol

appreciates the opportunity to provide comment on the proposal to include thymol in Schedule 6 of the SUSMP.

is concerned that the proposal, as stated in the Invitation for public comment, gives no indication or detail as to the reason for scheduling as a poison, and also gives no consideration to exempting thymol when used in therapeutic products.

In fact it appears that medicines have been totally disregarded as this issue is only to be discussed by the Advisory Committee on Chemicals Scheduling.

If the proposal is endorsed as is, all products containing thymol will have to be labelled with POISON, regardless of the purpose for use.

Thyme oil, is included in SUSMP, Schedule 5 as follows:

### THYME OIL except:

- (a) in medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert and compliant with the requirements of the *Required Advisory Statements for Medicine Labels*;
- (b) in preparations other than medicines for human therapeutic use, when packed in containers having a nominal capacity of 25 mL or less fitted with a restricted flow insert, and labelled with the warning: KEEP OUT OF REACH OF CHILDREN; or
- (c) in preparations containing 50 per cent or less of thyme oil.

There is currently no SUSMP entry for thymol.

An entry along the lines as outlined in the scheduling proposal will inevitably impact on the many therapeutic goods that are currently available.

The TGA Australian Register of Therapeutic Goods (ARTG) advises that thymol may be used:

- as an Active ingredient for Export Only; Over The Counter; Prescription Medicines;
   Listed Medicines; Solely for Export; and
- as an **Excipient ingredient** for Export Only; Over The Counter; Prescription Medicines; Devices; Listed Medicines; Solely for Export

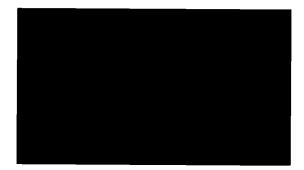
is aware that thymol is used in a diverse range of unscheduled therapeutic products, e.g.:

- Mouthwashes indicated for preventing and reducing plaque and gingivitis, e.g.
- Topical oral gels, e.g.
- Other topical products, e.g.

Given its acceptability as both an active and excipient ingredient in therapeutic goods, and if a Schedule 6 entry is recommended, strongly urges the ACCS to exempt thymol when in therapeutic goods.

We hope these comments are useful in the Committee's consideration of this issue, and look forward to hearing the outcome.

### Yours sincerely





The Secretary Scheduling Secretariat GPO Box 9848 Canberra, ACT 2601

Subject: Proposal for a new Schedule 6 entry for Thymol

Dear Sir or Madam,

This letter refers to the proposed amendment referred by the Delegate for scheduling advice for consideration by the Advisory Committee on Chemicals Scheduling (ACCS). A new Schedule 6 entry is proposed for the substance, Thymol.

hereby makes a submission in accordance with regulation 42ZCZL of the Therapeutic Goods Regulations 1990.

, which contains Thymol as an ingredient.

is concerned that the proposed Schedule 6 entry of Thymol in SUSMP could inappropriately impact the medicine classification of this product and other similar preparations.

believes that the typical levels of Thymol used in currently marketed OTC preparations are safe and effective, and should appropriately remain unscheduled.

would like to make a further submission after the Delegate publishes their interim scheduling decision.

If you have questions about this correspondence please do not hesitate to contact me by phone, fax or email.





The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sirs,

Advisory Committee on Chemicals Scheduling (ACCS) meeting, October 2012

Proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Chemicals Scheduling (ACCS) - Thymol

wishes to make a submission under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990, with regard to the proposed amendments to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in relation to Thymol; specifically the scheduling proposal for a new Schedule 6 entry for Thymol.

- 1.1 is aware that Thymol is used as an ingredient in flavours and fragrances and as a result can be present in cosmetic, therapeutic and household products.
- 1.2 Additionally, the *International Cosmetic Ingredient Dictionary and Handbook* makes reference to its use in many product categories within the cosmetic classification as well as its use in oral health care drugs.
- 1.3 does not support the scheduling of Thymol when present in cosmetic, therapeutic or household products.
- 1.4 requests the opportunity to make further submissions on any interim decisions regarding the Proposal which may be made by the ACCS at their meeting to consider the Proposal in October 2012.



Thymol 4 of 5.

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601 AUSTRALIA

September 11th, 2012

Ref.: Public submissions under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990 - Thymol

Dear Madame or Sir,

has been made aware of the proposed amendments of the Australian Poisons Standard via the invitation for public comment that were published on August 14<sup>th</sup>, 2012 and we would like to submit some comments.

Our comments are entirely focused on Thymol (CAS 89-83-8) as this substance is used as such as a fragrance ingredient but also as an ingredient in natural extracts (such as Thyme oil, which is already included in the Poisons Standard under Schedule 5). Thymol and the essential oils containing it have an important added value in perfumery and can be regarded as a key ingredient from a perfume creativity point of view for specific fragrance accords. In 2011, we estimated the annual world consumption of Thymol at 187 tons for the fragrance manufacture.

The global consumer exposure via consumer products nevertheless is relatively low as most of the fragranced consumer products either do not contain Thymol or only contain it in minute quantities. This is confirmed by the calculation of the 97.5 percentile in fine fragrance products (such as Eau-de-Parfum or Eau-de-toilette), which is 0.025%, meaning that 97.5% of the fine fragrance products marketed worldwide and containing Thymol, contains less than 0.025% of this ingredient. It is important to note that we assessed the 97.5 percentile in fine fragrance products to follow the most conservative approach as this product category usually incorporates high levels of fragrance compounds. Further, we observed that the maximum Thymol concentration that a fine fragrance may contain is considered to be 0.4%.

From the safety point of view, Thymol has a long history of safe use. For example the US Cosmetic Ingredient Review on Thymol concludes that "Thymol is safe at concentrations up to 0.5% in cosmetic formulations" (Att. 01).

<sup>&</sup>lt;sup>1</sup> Andersen A. Final report on the safety assessment of sodium p-chloro-m-cresol, p-chloro-mcresol, chlorothymol, mixed cresols, m-cresol, p-cresol, p-cres



Finally we observed that other fragrance ingredients with similar toxicity profiles and use pattern are already included in Schedule 6 and most of these fragrance ingredients do benefit from specific exemptions for preparations. For instance, Isoeugenol is included in Schedule 6 and presents an average when Thymol presents an average As of today, Isoeugenol is included in the Australian Poisons Standard as following:

Schedule 5: ISOEUGENOL in preparations containing 25 per cent or less of isoeugenol except in preparations containing 10 per cent or less of isoeugenol.

Schedule 6: ISOEUGENOL except:

- (a) when included in Schedule 5; or
- (b) in preparations containing 10 per cent or less of isoeugenol.

For this reason, and knowing the negligible risk that the use of this substance in cosmetic products may cause to the consumer, considers that the ACCS proposal to amend the Poisons Standard and include Thymol in Schedule 6 is unnecessary and should not be required. In case where Thymol would be used in concerning applications, recommends that the Schedule entry is phrased in a way that exempts low Thymol content preparations for non-therapeutic applications. In this context, and based on their similar acute toxicities, we would suggest that Thymol be treated in a comparable approach to Isoeugenol.

We sincerely thank you in advance for considering this comment and remain at your entire disposal for any questions related to this issue.

We look forward to receiving your response.

Very best regards





The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601 12<sup>th</sup> September 2012

Dear Sir/Madam,

RE: Comment on Proposed Amendments to the Poisons Standard referred by the Delegate for scheduling advice – Thymol

would like to provide comments on the proposed amendments referred by the Delegate to the Committee on Chemicals Scheduling (ACCS) for consideration of scheduling advice for a new Schedule 6 entry for Thymol.

<ol> <li>Proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Chemicals Scheduling (ACCS)</li> </ol>		
Substance	Scheduling proposal	
Thymol	Proposal for a new Schedule 6 entry for thymol	

is concerned that the proposal made provides no background or reason for scheduling thymol as a poison, and furthermore provides no clarity around it's consideration to the use of thymol in products for human therapeutic and cosmetic use. Given the proposal has been referred to the ACCS and <u>not</u> the ACMS, it would seem appropriate that the concern is likely to thymol use in chemicals and veterinary products, therefore products intended for human therapeutic or cosmetic use would be excluded. However, while we hope that the intent of the proposal is not to remove these products from the Australian market, a more specific and detailed scheduling proposal would have removed the need for such unnecessary concern. We also believe that better context would lead to a more efficient and effective consultation process.

Due to the nature of the Poisons Schedule, general scheduling of thymol under Schedule 6 will impact all types of products containing this ingredient, regardless of the intent, including therapeutics and cosmetics for human use, therefore we believe it is necessary to provide public comment in this regard to ensure products intended for human therapeutic or cosmetic use remain excluded.

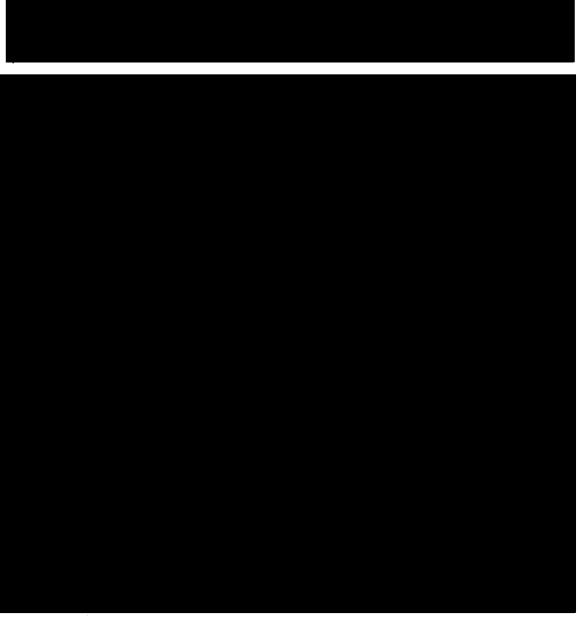
Thymol is an ingredient found in a number of product types including pesticide chemicals, products for human therapeutic use, cosmetics and foods. Thymol is known to have a number of uses when used at varying concentrations including the following 1,2:



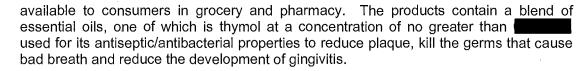
- Anthelmintic
- Ectoparasiticide
- Antiseptic
- Antibacterial

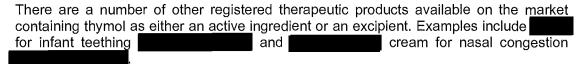
The TGA recognise thymol as an active ingredient for use in Over The Counter (OTC), Prescription and Listable medicines, and as an excipient for use in OTC, Prescription, Listed medicines and Devices.

The review of data from 1999 to 2012 does not identify any safety issues that cause concern for thymol.



The range of mouthwash products have been readily available for use by consumers for over 100 years and the safety and efficacy of a number of the variants listed above has been assessed and considered acceptable by the TGA. mouthwash is an unscheduled product (registered medicine or cosmetic) readily





The implications of including thymol in schedule 6 of the Poisons Standard would be that therapeutic and cosmetic products such as mouthwashes, which are considered safe for their intended use by consumers, would inadvertently be captured and would be required to include strict warning statements on consumer packaging, including the words POISON on the front label, which is not appropriate nor warranted for a mouthwash product commonly used by consumers.

It is view that any schedule entry for thymol should be limited to the novel use of the substance that led to it to be included on the ACCS scheduling agenda. Thymol contained in products for human therapeutic and cosmetic use should remain exempt from this proposal, and that any proposed entry for thymol in the Poison's Schedule be specific to the types of chemical use which are of concern to the delegate and the applicant.

The support behind proposal is outlined below.

### OVERSEAS REGULATORY STATUS OF THYMOL

The table below outlines the Regulatory Status for products containing thymol for human therapeutic use in the USA, Canada, European Union and NZ.

TABLE 2. OVERSEAS REGULATORY STATUS OF THYMOL USED IN PRODUCTS FOR HUMAN THERAPEUTIC USE

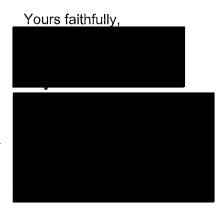
FOR HUMAN THERAPEUTIC USE				
COUNTRY	CLASSIFICATION	WARNING STATEMENT		
USA	Thymol is recognized as an OTC active ingredient in mouthwash and oral health care products. It is considered a GSL (general sale) ingredient.	No specific warning statements required for therapeutic OTC or cosmetic use.		
Canada	<ul> <li>Thymol is classified as a medicinal ingredient and is recognised for its antibacterial properties in therapeutic mouthwash products. It is considered a GSL (general sale) ingredient.</li> <li>Thymol is also recognised as a non medicinal ingredient (flavor/fragrance/preservative)</li> </ul>	No specific warning statement required for mouthwash containing thymol (therapeutic or cosmetic).		
European Union	Thymol is allowed as a cosmetic ingredient. It could be classified as medicinal active based on indications. It is not classified as a Poison	Not aware of any specific warning statements		

New Zealand	Thymol is recognised for its antibacterial properties in therapeutic mouthwash products, however it is not a classified medicine and is considered a GSL (general sale) ingredient for use in cosmetics or therapeutics	No warning statements required for cosmetic or therapeutic use of thymol		
that of thymol in	ry classifications of thymol in human thera n Australia. Thymol is currently unschedu statements associated with its medicinal ar	led in Australia and has no		
There are no regulatory or safety issues in the key global markets above that we are aware of for therapeutic or cosmetic use of thymol. Additionally there are no required warning statements for the use of thymol in medicinal or cosmetic type products.				
SAFETY OF THY	<u>/MOL</u>			
Adverse events on where thymol is an ingredient, are on intentional ingestion and oral discomforts. The review of the data received from 1999 through 2012 does not identify any safety issue that can cause a concern (attached as an addendum). The data are consistent with the safety profile outlined in the current Reference Safety Information (RSI) and/or reflect the background incidence in the target population. The favourable risk-benefit balance remains unchanged. No changes to the current RSI is recommended. It is specified, however, that				
in sm and the highest t Cosmetic Ingredi by Cosmetic Ing Expert Panel, in a	imary cannot isolate thymol. Thymol is all amounts. Thymol content in hymol content among the variant variant sents Found Safe, with Qualifications (throus redients Review (CIR), thymol is listed as published journal (International Journal of that the current levels of use of thymol is ects.	packets would be ts would be ts would be fight February 2012) released s safe until <5%. The CIR f Toxicology, 25(S1): 29-127,		
product is calcu	nticipated exposure to thymol arising from lated to be This GRAS substance.	the typical daily use of this represents an insignificant		
The maximum a calculated to be	nticipated exposure to thymol arising from	m unintentional exposure is egarded as safe (GRAS).		
SUMMARY				
and cosmetic us	view is that the proposal made by the I 5, should exclude thymol when used in pro- e, and that any scheduling entry for thym	ducts for human therapeutic nol should be limited to the		

novel use of the substance that led to it to be included on the ACCS scheduling agenda. Including products for human use in this proposal will restrict the supply of well known commonly used consumer goods, such as mouthwash which has been demonstrated to have a good safety profile. Therefore we trust these types of products

were never intended to include products used for human use.

We trust the Delegate will consider our comments when making a decision on the scheduling of thymol.



### **REFERENCES**

(References 3 – 17 available on request)



Hydrogen Peroxide and Carbanide Peroxide Scheduling Changes - Comment on Resolution

## HYDROGEN PEROXIDE AND CARBAMIDE PEROXIDE SCHEDULING CHANGES

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:

3. Proposed amendments referred by the delegate for scheduling advice for consideration by the a joint meeting of the ACCS and ACMS		
Substance Scheduling proposal		
,	Proposal to exempt teeth whitening products containing 3% or less of hydrogen peroxide and 9% or less of carbamide peroxide from scheduling.	
Hydrogen peroxide and carbamide peroxide	Proposal for teeth whitening products containing between 3% - 6% of hydrogen peroxide and between 9% - 18% of carbamide peroxide to be only legally accessible from a registered health practitioner. Patients to be permitted to use these products 'at home' only after consultation with their registered health practitioner.	
	Proposal for teeth whitening products containing more than 6% hydrogen peroxide and more than 18% carbamide peroxide be legally accessed by registered health practitioners.	

- Currently, hydrogen peroxide at ≤ 3% is scheduled in Schedule 6, while hydrogen peroxide at ≥ 3 to 6% is scheduled in Schedule 5. Higher concentrations of hydrogen peroxide are currently unscheduled.
- Currently, carbamide peroxide at ≤ 9% is scheduled in Schedule 6, while carbamide peroxide at ≥ 9 to 18% is scheduled in Schedule 5. Higher concentrations of carbamide peroxide are currently unscheduled.
- Currently, these products are not regulated by the TGA, being captured in Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 with dental bleaches and dental whiteners being goods intended for use in humans declared not to be therapeutic goods.
- supports the scheduling proposal outlined above to have teeth whitening products that are not exempt from scheduling regulated through restriction of product availability to patients after consultation with a registered health practitioner, or at higher concentrations, to be available only by registered health practitioners within the dental surgery i.e. for in-office use only.

As no information has been given regarding how this proposal would be achieved, we propose the following (as per our previous communication on this matter):

1.	To appropriately regulate these products,	supports the modification of
	Schedule 5 to capture all teeth whitening	products of $\ge$ 3% hydrogen peroxide and $\ge$ 9%
	carbamide peroxide.	

24 May 2012 Page 1 of 2

2. In addition, supports the inclusion in Appendix C of hydrogen peroxide and carbamide peroxide in teeth whitening products **except** when supplied to registered dental professionals (registered health practitioners).

The modifications outlined above will meet the aim of adequately restricting the supply of all teeth whitening products to appropriately qualified dental professionals, thereby effectively safeguarding consumers from potential adverse effects, without increasing the regulatory burden.

24 May 2012



12 September 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

E-mail: SMP@health.gov.au

Invitation for public comment – joint ACMS / ACCS meeting, October 2012

Hydrogen peroxide and Carbamide peroxide:

- Proposal to exempt teeth whitening products containing 3% or less of hydrogen peroxide and 9% or less of carbamide peroxide from scheduling.
- Proposal for teeth whitening products containing between 3% 6% of hydrogen peroxide and between 9% - 18% of carbamide peroxide to be legally accessible from a registered health practitioner. Patients to be permitted to use these products 'at home' only after consultation with their registered health practitioner.
- Proposal for teeth whitening products containing more than 6% hydrogen peroxide and more than 18% carbamide peroxide be legally accessed by registered health practitioners.

Thank you for providing the opportunity to comment on this issue which is to be discussed by a joint ACMS/ACCS meeting.



supports the proposals for hydrogen peroxide/carbamide peroxide as set out in the Invitation for comment, and considers that they are generally in line with requirements in other jurisdictions.

We consider that exempting from scheduling those teeth whitening products containing less than 3% hydrogen peroxide / 9% carbamide peroxide will ensure that therapeutic goods currently containing these concentrations, including oral hygiene products such as toothpastes and mouthwashes, that make a tooth whitening claim will not be impacted.

In relation to the proposal for the higher concentration hydrogen peroxide/carbamide peroxide teeth whitening products, supports the proposed access restrictions.

However, the proposal gives no indication as to how the measures are to be implemented. We are therefore unable to provide any further valid comment at this stage.

We hope these comments are helpful in the Committees' deliberation and look forward to hearing the Delegate's decision.

Yours sincerely,



Hydrogen peroxide 3 of 7.

The Secretary

Scheduling Secretariat

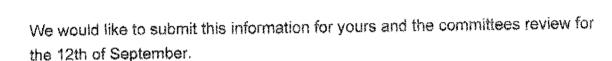
**GPO Box 9848** 

**CANBERRA ACT 2601** 

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3rd September 2012



### THERAPEUTIC GOODS ACT 1989 - SECT 52E

Secretary to take certain matters into account in exercising powers

(1) (b) the purposes for which a <u>substance</u> is to be used and the extent of use of a <u>substance</u>;

(f) any other matters that the <u>Secretary</u> considers necessary to protect public health.

Re: Scheduling 6% Hydrogen Peroxide

years for both dentists and retail products we have not seen any reason to reduce the limit to 3% for OTC use, as during this time with hundreds of

thousands of people using between 6%-8% hydrogen peroxide we have had no complaints as to the safety of the products. The pH being neutral plays a major factor in sensitivity for customers and we always have ensured our products have maintained this. Not having any acids or abrasives in the whitening products is also another way to ensure reduced sensitivity issues with customers.

As long as customers are aware that the whitening process may cause slight sensitivity and are informed via instruction manuals that it isn't harming their teeth in any way, as proved over the past 45 years of peroxide formulas being used for teeth whitening, we have found our customers are happy and satisfied with the whitening process.

We have two major concerns **THERAPEUTIC GOODS ACT 1989 - SECT 52E section 1) B and F** 

If you do limit the percentage to 3%.

The first is reducing to 3% will in effect reduce the effectiveness of the product and take consumers more than double the time to whiten their teeth causing longer contact time and in effect could still cause the same if not even more sensitivity. This could also cause possible safety concerns to the teeth if companies are using low pH level formulas which can over time permanently etch the enamel to try and get the teeth to appear whiter for consumers who like to see results immediately. It would be better and safer for the consumer to purchase an effective product with a neutral pH and one that is acid free with a level of 6% Hydrogen peroxide that they only need to wear for 1 hour a day over 14 days instead of needing to wear a 3% for up to 4 hours over at least 28 days.

Our second major concern is companies will introduce "non peroxide whitening systems" such as Chlorine Dioxide and Sodium Perborate which are proven to be harmful and cause devastating side effects to the enamel. Companies will claim that these teeth whiteners are better than the existing peroxide whiteners that you will put a ban on and ill-informed consumers will purchase and use these systems believing them to be superior and "better for their teeth".

Please see below article on the effects of Chlorine Dioxide.

Papers published in the British Dental press...

The Dangers of Chlorine Dioxide Tooth Bleaching - Dr Linda Greenwall;

### Aesthetic Dentistry Today - July 08 issue (PDF)

Below are links to information about tooth whitening and consent forms for professionals

The Dangers of Chlorine Dioxide

Tooth Bleaching Linda Greenwall BDS MGDS MRD MSc FFGDP BDBS back to top

The Author does not have any financial interest in the companies whose materials are included in this article.

### Introduction

There have been numerous reports in the UK press and media about Chlorine Dioxide Tooth Whitening. This has come about due to the legislation surrounding bleaching in the UK and ways of seeking a means to bypass the legislation and offer alternative to whitening. These whitening treatments have been offered by non dentists namely beauty therapists and hair dressers as a means of by passing the legislation using hydrogen peroxide tooth bleaching. It has been postulated that this is a "safer and more gentle method for whitening teeth" as it does not use harsh hydrogen peroxide and in fact the reverse is true. Many UK dentists are now seeing patients who have experienced the damaging effects of chlorine dioxide tooth bleaching. There are not many established protocols in how to deal with the resulting damage and how to repair this damage. It is the aim of this article to discuss the dangers of this material as a bleaching treatment and the harmful resultant effects that have been seen on teeth. Guidance on repairing the damage will be also discussed.

### UK Legislation and Historical Background

In the UK the bleaching materials have been classified as cosmetics according to the ruling of the Law Lords in 2001. The House of Lords Judgement in June 2001 confirmed that tooth whitening agents are covered by European Council Directive on Cosmetic Products 76/768/EEC, which allows the supply and use of tooth

whitening products provided they contain no more than 0.1% hydrogen peroxide present or released. This limit is statutory in this country under the UK Cosmetic Products (Safety) Regulations 1996.

In March 2005 the European Commission's Scientific Committee for Consumer Products (SCCP) issued an 'Opinion' that tooth whitening products containing up to 6% hydrogen peroxide present or released would be safe. In the light of this recommendation at the time the Government issued a directive to all Trading Standards Officers in the UK to adopt a 'laissez faire' attitude to enforcement; what they termed a 'flexible policy'.

In the eighteen months that followed, the debate continued to rage as more manufacturers and importers sold equipment to dentists and, increasingly, to beauty therapists. Was it legal to supply products containing more than 0.1% hydrogen peroxide? Most of the products that have proven effectiveness and safety studies (Haywood and Heymann 1989) contain a minimum of 3% hydrogen peroxide

A new report published by the SCCNFP, Scientific committee in Europe in January 2008 recommends the use of up to 6% HP being a safe limit to use. The committee has however not recommended the use of over the counter products being sold direct to consumers. They recommend that these products are only prescribed and administered by dentists. As a result of this statement it is expected that eventually this recommendation will be ratified by the European Council and this will eventually be ratified by the UK government. The time scale on this is not clear. This present situation effectively means that UK dentists by supplying the home bleaching materials containing from 3% HP which is equivalent to 10% carbamide peroxide are supplying these products illegally to their patients.

The General Dental Council issued a statement in June 2007 that only registered dentists may undertake tooth whitening. As such they will prosecute any non dentist for undertaking such whitening treatment no matter which bleaching agent they use. This has led to numerous reports to the General Dental Council (GDC) which they are at present dealing with.

At this present stage this means that the Department of Trading Standards can send trading standards officers into a dental practice without warning and ask to inspect the bleaching products which a dentist supplies. Some dentists have been issued with warning notices from trading standards officers in the regions of Yorkshire and Lincolnshire. This is causing worry to these dentists so they are discontinuing offering whitening treatments to patients.

# The Introduction of Chlorine Dioxide Tooth whitening gel

These gels have been introduced as a means of bypassing the whitening legislation. Many of these materials have been sold directly to beauty therapists and other non dental practitioners, such as health spas and beauty spas on cruise liners. Many of these companies supplying these Chlorine dioxide agents are supplying cruise liners in the hope that these beauty products will thus be under maritime legislation as the treatments are not officially conducted in the UK soil.

These products are causing harm to teeth. These products are thus subject to the Consume Safety Act of 1987 and Product safety legislation of 2005 that states that no product should cause harm to the consumer. There are no published studies on the safety and effectiveness of chlorine Dioxide as a whitening treatment on the pubmed website which keeps records of all published medical and dental research in peer reviewed journals. The beauty therapists are advised to check their product safety assessment which

## History of chlorine dioxide as a whitening agent

As early as 1848, non-vital tooth bleaching with chloride of time was practiced Dwinelle (1850). Truman is often cred-ited with introducing, well before 1864, the most effective technique for bleaching non-vital teeth, which used chlorine from a solution of calcium hydrochlo-rite and acetic acid (Haywood 1992) chlorine was also inserted into non-vital teeth in attempts to lighten them in the late 1880s. Many of these allergy attempts resulted in regression and some of the dental colleagues at the time advised that it was not worth the effort to whiten these

teeth. The most effective technique for bleaching nonvital teeth, which used chlorine from a solution of calcium hydrochlo-rite and acetic acid (Fasanara 1992). The commercial derivative of this, later known as Labarraque's solution, was a liquid chloride of soda Kirk (1889).

Chlorine dioxide is a green-yellow gas which oxidise rapidly. Chlorine dioxide has also been used as a germ –killer, pesticide, reduction of oral malodour for breathe neutralisation. It is often used in the paper and pulp industries for whitening purposes. In relatively low concentrations of chlorine dioxide, when contained in or released by tooth whitening compositions it may be effective and useful in whitening teeth. The chlorine dioxide contained in or released by tooth whitening compositions, when placed in contact with the tooth surface, is observed to rapidly oxidize tooth stains, rendering the treated tooth surface relatively whiter after the contact (Montgomery 1999)

### Chlorine Dioxide and the Beauty therapists

It appears that the majority of non dental practitioners who are using these treatments are the beauty therapists. The UK Beauty therapists website BABTAC .co.uk advises their members "that you could well have a claim against the person who sold you the equipment and consumables under The Sale Of Goods Act 1979 (the equipment not being 'fit for the purpose') or the Supply of Goods to Consumers Regulations 2002 - and the Misrepresentation Act 1967 might get you out of any lease agreements on the hardware. BABTAC has already helped one member secure their position in this way".

# The current chlorine dioxide whitening treatments.

The current whitening treatments are sold as a chairside procedure in the beauty spa. The material consists of two products which are mixed together. One is a sodium chlorite and the other one portion contains a chlorine dioxide precursor (CDP), such as sodium chlorite, and another portion contains an acidulant (ACD) containing 2.0% anhydrous citric acid. The composition formed from an admixture of the two portions may be placed in contact with a stained tooth

surface to effect whitening.

A low concentration of chlorine Dioxide gel is applied directly to the teeth. This material is then left in pace for a period of about twenty minutes to forty minutes. The process is enhanced with an LED light. Usually three applications are applied to the teeth. The client ( Patient) is then given a take home kit which either contains further chlorine dioxide gels or other carbamide peroxide gel to continue the whitening effect for a period of time. This take home kit is often a brush on applicator which is used to enhance the whitening. It is stated in some of the websites that the product is completely safe because it is a food additive and the effects will last permanently as long as the home brush on kit is used twice a week on a long term basis. If eating is undertaken then the brush on applicator should be used half an hour before and half an hour after.

## Problems arising

Many of the Chlorine Dioxide gels are acidic. The pH range is from 1-3. As a result of the acid effect directly on the teeth, the resultant effect is that of etching the tooth permanently. At the end f the treatment the teeth appear white and this may be due to the dehydration effects as with other power whitening chairside techniques. The tooth looses its tooth lustre or shine and this can be a permanent effect. This loss of tooth lustre also makes the tooth feel more rough. Many of the clients have reported that the teeth seem to pick up further staining and become even more discoloured than before the treatment. The resulting discolouration is yellow to brown. Many patients report increased tooth sensitivity which is difficult to manage and not easy to desensitise.

### Further problems

These chlorine dioxide treatments are advertised as safe for teeth. It is certainly not the case. They also contain further instructions for the consumer which often gives misleading advice "when asked will it lighten my crowns and veneers?, it states that it will only return to the original colour". Research has shown that porcelain crowns are not affected by the process of whitening.

Clients are then advised to use the "white teeth diet" which is to drink their coffee

through a straw and to drink white wine instead of red wine and to refrain from drinking cranberry juice and to rather drink grapefruit juice. This is misleading information as the grapefruit juice has a very low pH and drunk in excessive amounts can cause erosion onto the surfaces of the teeth.

### Table 1:

## The damaging effect of Chlorine Dioxide Whitening Treatment on teeth:

Etching of teeth
Loss of tooth lustre
Teeth appearing more discoloured
Teeth absorbing more stains than before

Teeth feeling rough

Teeth more sensitive

Teeth permanently sensitive.

Table 2:

# Reported Systemic Effects of the toxic problems associated with Chlorine Dioxide Whitening Treatment for teeth.

Inhalation and other breathing difficulties Exacerbation of patients asthmatic condition Increased heart rate and palpitations

Heart irregularities

Eyes watering

Admission into the casualty and the emergency room

Table 3: Options/suggestions for treatment post chlorine dioxide whitening treatment.

### Dealing with sensitivity:

Desensitising the teeth with the normal desensitising agents

Making a home tray for the patient in which to apply the

desensitising agents for longer lasting effect.

The application of amorphous calcium phosphate directly onto the surfaces of the teeth or into the whitening tray to return the

calcium and phosphate back into the tooth.

### Dealing with the discolouration:

Re-whitening the teeth using normal home bleaching agents such as 10% carbamide peroxide particularly those which have added desensitisers to reduce likelihood of further sensitivity. These teeth may require prolonged whitening as it may take time to eradicate the brown discolouration from the tooth.

### Dealing with the loss of tooth lustre:

Applying bonding agents directly to the affected teeth
Applying enamel glazes effects to restore the lustre to the teeth
Dealing with the permanent effect of enamel damage

If all the above simple measures are not effective, it may be necessary to place porcelain veneers over all the affected teeth

However etching the teeth to place the veneers may be difficult. References

Haywood and Heymann (1989) Nightguard vital bleaching. Quintessence Int Van B Haywood (1992) History, safety, and effectiveness of current bleaching techniques and applications of the nightguard vital bleaching technique.

Ouintessence Int 23:471-488

Dwinelle WW (1850) Ninth Annual Meeting of American Society of Dental Surgeons. Article X. Am J Dent Sci 1:57-61.

Kirk EC: (1889) The chemical bleaching of teeth. Dental Cosmos 31:273-283 Tom S. Fasanaro D.D.S. (1992) Bleaching Teeth: History, Chemicals, and Methods Used for Common Tooth Discolorations. Journal of Esthetic and Restorative Dentistry 4 (3), 71–78

Montgomery E (1999) US Patent Application no 08/901261

www.Babtac.com the Beauty Therapists website. http://www.julietsdayspa.com http://www.zmedspa.com/toothWhitening.asp

http://www.templeofbodysoul.com.au/dayspa/teethwhitening.html

http://www.mandaraspa.com/Main/SpaView.aspx?SpaID=72 this is the spa in Disney land at the Anaheim grand California hotel.



The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sirs,

Advisory Committee on Medicines Scheduling (ACMS) and Advisory Committee on Chemicals Scheduling (ACCS) meetings, October 2012

Proposed amendments referred by the delegate for scheduling advice for consideration by a joint meeting of the ACCS and ACMS - Hydrogen peroxide and Carbamide peroxide

wishes to make a submission under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990, with regard to the proposed amendments to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in relation to hydrogen peroxide and carbamide peroxide when used in teeth whitening products (the **Proposal**).

### 1. Executive Summary

- 1.1 considers that the current scheduling classification in the SUSMP for teeth whitening preparations containing hydrogen peroxide and carbamide peroxide is appropriate.
- 1.2 However, also considers that tooth whitening preparations which contain high levels of hydrogen peroxide or carbamide peroxide in Schedule 6 of the SUSMP should be used under the supervision of a dental professional in order to support their safe, cosmetic use. The therefore proposes the inclusion of a new entry for hydrogen peroxide at greater than 6% and carbamide peroxide at greater than 18% for tooth whitening if not supplied through a registered dental professional, which would be included in Appendix C of the SUSMP.

### 2. Outline of the Proposal

- 2.1 The Proposal is comprised of the following three parts:
  - (a) an exemption from scheduling of teeth whitening products containing 3% or less of hydrogen peroxide and 9% or less of carbamide peroxide (Part 1 of the Proposal);

- (b) amendments to the SUSMP to provide for teeth whitening products containing between 3%-6% hydrogen peroxide and between 9%-18% carbamide peroxide to be "only legally accessible" from a registered health practitioner, and for patients to be permitted to use these products 'at home' "only after consultation with their registered health practitioner" (Part 2 of the Proposal); and
- (c) amendments to the SUSMP to provide for teeth whitening products containing more than 6% hydrogen peroxide and more than 18% carbamide peroxide to be "legally accessed by registered health practitioners" (Part 3 of the Proposal).
- 2.2 This submission deals with each part of the Proposal under the separate, relevant headings below.

### 3. Part 1 of the Proposal

- 3.1 Currently, preparations containing 3% hydrogen peroxide or 9% carbamide peroxide, or less, are unscheduled. Accordingly, the SUSMP is already consistent with Part 1 of the Proposal and no amendments to the SUSMP are required in order to implement Part 1 of the Proposal.
- 3.2 supports and agrees with Part 1 of the Proposal.

#### 4. Part 2 of the Proposal

### **Current Scheduling Approach**

4.1 Preparations containing from above 3% to 6% hydrogen peroxide and from above 9% to 18% carbamide peroxide (**Schedule 5 Preparations**), are currently listed in Schedule 5 of the SUSMP and must comply with the following key labeling statements set out in Part 2 of the SUSMP<sup>1</sup>:

"CAUTION"

"Keep out of reach of children"

"Read Safety Directions"

"Do not swallow"

Concentration of hydrogen peroxide

Specific Directions for Use

"Safety Directions"

"Irritant. Avoid contact with eyes"

"First Aid Instructions"

"For advice contact a Poisons Information Centre (e.g. phone Australia 131 126, New Zealand 0800 764 766) or a doctor. If swallowed, do NOT induce vomiting.

If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised by a Poisons Information Centre or a doctor, or for at least 15 minutes. If skin or hair contacts occurs, remove contaminated clothing and flush skin and hair with running water.

The SUSMP also specifies certain requirements for the immediate containers of these preparations.

<sup>&</sup>lt;sup>1</sup> Note: only hydrogen peroxide labeling example given in full.

### Comprehensive reviews of Hydrogen Peroxide and Carbamide Peroxide

- 4.2 In establishing, and then subsequently reconfirming as appropriate, the above scheduling approach for Schedule 5 Preparations, the former Australian National Drugs and Poisons Scheduling Committee (NDPSC) undertook a comprehensive review of the toxicology and safety of hydrogen peroxide and carbamide peroxide<sup>2</sup>.
- 4.3 Very recently, in 2011, the then New Zealand Environmental Risk Management Authority (ERMA) also conducted a full review of the controls on dental products containing or releasing hydrogen peroxide, as part of its amendment of The Dental Products Group Standard. Following this full review, the ERMA endorsed cutoffs for hydrogen peroxide in tooth whitening products which are consistent with the current cutoffs specified in the SUSMP<sup>3</sup>.

#### Related Australian Law and Policy

- 4.4 The Dental Board of Australia's Interim Policy on Teeth Whitening/ Bleaching 2010 (the **DBA Policy**), which is made under section 39 of the Health Practitioner Regulation National Law, permits use of teeth whitening products containing 6% or less hydrogen peroxide by consumers.
- 4.5 In July 2012 the Australian Competition and Consumer Commission (ACCC) published a Product Safety Bulletin entitled "Safety of do-it-yourself (DIY) teeth whitening products for at home use". The approach taken by the ACCC in that Bulletin supports a regulatory approach to teeth whitening products whereby products containing 6% or less hydrogen peroxide or 18% or less carbamide peroxide are directly available to consumers. The ACCC does not advocate for products containing between 3%-6% hydrogen peroxide or 9%-18% carbamide peroxide to 'only be legally accessible from a registered health practitioner'.
- 4.6 The ACCC is responsible for administering the Australian Consumer Law, which forms Schedule 2 to the Competition and Consumer Act 2010 (ACL). This law contains extensive product safety provisions and wide statutory powers to ensure the safety of consumer goods. Teeth whitening products available to consumers are cosmetic, consumer goods which are subject to the provisions of the ACL.
- 4.7 Teeth whitening products are also regulated as cosmetics under the *Industrial Chemicals* (Notification and Assessment) Act 1989, in conjunction with the regulatory compliance obligations of the SUSMP on packaging and labelling.
- 4.8 It should also be noted that under clause 4(e) Therapeutic Goods (Excluded Goods) Order No. 1 2011 dental whitening and bleaching products are "declared not to be therapeutic goods" for the purpose of the Therapeutic Goods Act 1989 (the Act). Since teeth whitening products are not therapeutic goods, they are not (and cannot be) regulated as medicines under the Act. This is because section 3 of the Act requires that a "medicine", as defined in the Act, be a therapeutic good, whereas the clear purpose of tooth whitening products is cosmetic, i.e., to beautify. Moreover, as demonstrated by the safety review (see Annexure A), tooth whitening products do not affect the structure or function of the body, and thus do not otherwise meet the definition of therapeutic goods.

<sup>&</sup>lt;sup>2</sup> See Record of Reason NDPSC Meeting June 2005.

<sup>&</sup>lt;sup>3</sup> See ERMA 200472 Decision.

### Rationale for Part 2 of the Proposal

- 4.9 There is no new, scientific evidence or other relevant rationale offered for implementing Part 2 of the Proposal. Specifically, there is no scientific basis available which supports the precise percentage thresholds for hydrogen peroxide and carbamide peroxide which are set out in Part 2 of the Proposal.
- 4.10 Further, Part 2 of the Proposal is not made on the basis of any rigorous, balanced review of the extensive and longstanding, available scientific data relating to hydrogen peroxide and carbamide peroxide<sup>4</sup>.

### Available Safety Data

4.11 By way of contrast, the safety profile of both hydrogen peroxide and carbamide peroxide has been subject to extensive review over many years. conducted a recent review of the published clinical and preclinical safety studies of hydrogen peroxide, and is of the view that there is no new data on the safety of hydrogen peroxide or carbamide peroxide that would require the Committees to re-review the previous toxicology and safety review of these substances conducted by the NDPSC or the ERMA.

4.12 has a distinguished and longstanding reputation as a world leader in the consumer and professional oral care industries. For over 200 years the company's reputation has been built upon the quality and safety of its products. In the absence of any scientific justification or relevant rationale, and based on the robust safety data available, does not support or agree with Part 2 of the proposal.

### 5 Part 3 of the Proposal

### **Current Scheduling Approach**

5.1 Preparations containing above 6% hydrogen peroxide or 18% carbamide peroxide are listed in Schedule 6 (Schedule 6 Preparations) and must comply with the following key labeling statements set out in Part 2 of the SUSMP<sup>5</sup>:

"POISON"

"Keep out of reach of children"

"Read Safety Directions"

"Do not swallow"

Concentration of hydrogen peroxide

Specific Directions for Use

"Safety Directions"

If concentration of hydrogen peroxide is up to 10%

<sup>&</sup>lt;sup>4</sup> See letters dated 11 May 2012 and 28 May 2012 from the Australian Dental Association to the Scheduling Secretariat. Source: <a href="http://www.ada.org.au/newsroom/articles,category,submissions.aspx">http://www.ada.org.au/newsroom/articles,category,submissions.aspx</a>, accessed 20 August 2012.

<sup>&</sup>lt;sup>5</sup> Note: only hydrogen peroxide labeling example given in full.

"Irritant. Avoid contact with eyes"

- If concentration of hydrogen peroxide is more than 10% and up to 20%
  "Irritant. Attacks eyes protect eyes when using"
  "First Aid Instructions"
- For preparations containing up to 20% hydrogen peroxide "For advice contact a Poisons Information Centre (e.g. phone Australia 131 126, New Zealand 0800 764 766) or a doctor. If swallowed, do NOT induce vomiting. If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised by a Poisons Information Centre or a doctor, or for at least 15 minutes. If skin or hair contacts occurs, remove contaminated clothing and flush skin and hair with running water.
- For preparations containing over 20% hydrogen peroxide "For advice contact a Poisons Information Centre (e.g. phone Australia 131 126, New Zealand 0800 764 766) or a doctor at once. Urgent hospital treatment is likely to be needed. If swallowed, do NOT induce vomiting. Immediately give a glass of water. If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised by a Poisons Information Centre or a doctor, or for at least 15 minutes. If skin or hair contacts occurs, remove contaminated clothing and flush skin and hair with running water. The SUSMP also specifies certain requirements for the immediate containers of these preparations.

#### Safety Considerations

5.2 As the available scientific literature indicates, given that some consumers may have preexisting conditions which counter-indicate the use of teeth whitening products containing high levels of hydrogen peroxide or carbamide peroxide, such products should be used under the supervision of a dental professional<sup>6</sup>.

5.3	agrees that the use of tooth whitening preparations which contain high
	concentrations of hydrogen peroxide and carbamide peroxide in Schedule 6 are not suitable
	for "self-selection", and should be used under the supervision of a dental professional to
	support their safe, cosmetic use. Consistent with this view,
	supplied its Schedule 6 tooth whitening products to dental professionals.

### **Proposed Amendment to the SUSMP**

To ensure Schedule 6 Preparations are used under the supervision of a dental professional, proposes that a limitation of the scope of the Schedule 6 entries for hydrogen peroxide and carbamide peroxide is added to the SUSMP.

5.5 This limitation could be introduced through including limited Appendix C entries for hydrogen peroxide and carbamide peroxide in the SUSMP to restrict the supply of tooth whitening preparations containing greater than 6% hydrogen peroxide or 18% carbamide peroxide, except where supplied through registered dental practitioners. The existing wording for the Schedule 5 and Schedule 6 entries would remain unchanged.

5.6	Suggested	drafting	for the new	Annendix (	Centries i	s as follows:
3.0	JURRUJICU	ululule	IOI LIE HEW	ADDCHUIA 1	C C	3 UJ IUIIU 113.

Appendix C entry (new):

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<sup>&</sup>lt;sup>6</sup> For example, see Li Y. Safety controversies in tooth bleaching, Dent Clin North Am. 2011 55(2): 255-63.

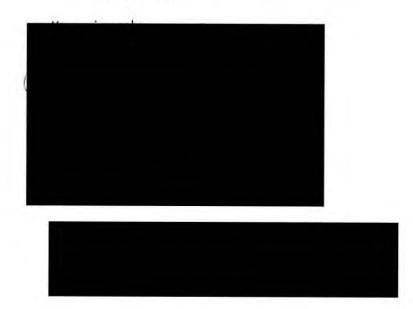
**HYDROGEN PEROXIDE** (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide **except** in preparations supplied through a registered dental practitioner as part of their dental practice. In the exception circumstances, this substance is not an Appendix C substance.

**CARBAMIDE PEROXIDE** (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide **except** in preparations supplied through a registered dental practitioner as part of their dental practice. In the exception circumstances, this substance is not an Appendix C substance.

5.7	Having regard to the extensive, available safety and toxicology data on hydrogen peroxide and carbamide peroxide, the strong consumer demand <sup>7</sup> for teeth whitening products and services, and the associated need for safe teeth whitening products to therefore be readily available to meet consumer demand, believes that the proposed new entries in Appendix C would achieve the appropriate balance between important public safety objectives and the ready availability of safe products for use.
5.8	The proposed new inclusions in Appendix C would effectively confine high concentration tooth whitening products to usage which is overseen by a registered dental professional, whilst ensuring that safe products containing lower concentrations of hydrogen peroxide or carbamide peroxide would remain available to meet consumer demand for whitening products.
5.9	supports implementation of Part 3 of the Proposal through inclusion of the above, new Appendix C entries in the SUSMP.
6.	Conclusion
6.1	supports and agrees with Part 1 of the Proposal and notes that the SUSMP is already consistent with Part 1 of the Proposal.
6.2	In the absence of any new, scientific evidence or other relevant rationale, and having regard to the current, applicable law and policy for teeth whitening products and the robust, available safety data, does not support or agree with Part 2 of the Proposal.
6.3	supports the implementation of Part 3 of the Proposal through the inclusion of new Appendix C entries as previously described in this submission.

8.	Further	Submissions

8.1 would welcome the opportunity to provide any further information or to answer any further questions which may be of assistance to the Scheduling Secretariat in its consideration of the above matters. Additionally, requests the opportunity to make further submissions on any interim decisions regarding the Proposal which may be made by the ACMS and ACCS at their joint meeting to consider the Proposal in October 2012.





The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601 10 September 2012

Dear Sir/Madam,

RE: Comment on Proposed Amendments to Poisons Standard referred by the delegate for scheduling advice

supports the delegate's proposal to exempt teeth whitening products containing 3% of less of hydrogen peroxide and 9% or less of carbamide peroxide from scheduling.

Should you have any questions in relation to the comments raised, please do not hesitate in contacting the undersigned.

Yours sincerely,



Email: SMP@health.gov.au

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

Dear Sir,

Invitation for public comment - ACMS and ACCS meetings, October 2012
3. Proposed amendments referred by the delegate for scheduling advice for consideration by a joint meeting of the ACCS and ACMS - Hydrogen peroxide and Carbamide peroxide
seeks to make a public submission under Regulation 42ZCZK of the Therapeutic Roods regulations 1990, concerning a submission for amendment to the access of hydrogen peroxide and carbamide peroxide teeth whitening preparations.
tooth whitening systems that contain carbamide peroxide at levels of 6% (2% Hydrogen peroxide), which are currently exempt from scheduling. These products meet the regulatory requirement of the Industrial Chemicals (Notification and Assessment) Act 1989, and the ACCC labelling requirements for cosmetic products.
The proposal for consideration retains the status quo for the scheduling cutoff for teeth whitening products containing hydrogen peroxide or carbamide peroxide:
"Proposal to exempt teeth whitening products containing 3% or less of hydrogen peroxide and 9% or less of carbamide peroxide from scheduling."
supports the proposal that products containing 3% or less of hydrogen peroxide, and 9% or less of carbamide peroxide, remain unscheduled.
does not supply teeth whitening products with higher levels of peroxide, so neither endorses or supports the proposed changes to the Schedule 5 or Schedule 6 entries for these substances.

### Table of Contents

tenders this submission to the Department of Health and Ageing pursuant to Regulation 42ZCZK of the *Therapeutic Goods Regulations* (Cth) 1990, with regard to the proposed amendment to the scheduling of hydrogen peroxide and carbamide peroxide when used in teeth whitening preparations, to be included in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

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## Introduction

tenders this submission to the Department of Health and Ageing pursuant to Regulation 42ZCZK of the *Therapeutic Goods Regulations* (*Cth*) 1990, with regard to the following proposed amendments to the Uniform Scheduling of Medicines and Poisons (SUSMP) which have been referred by the delegate for scheduling advice for consideration by the a joint meeting of the Advisory Committee on Chemicals Scheduling (ACCS) and the Advisory Committee on Chemical Scheduling (ACMS):

## Scheduling proposal —

- Proposal to exempt teeth whitening products containing 3% or less of hydrogen peroxide and 9% or less of carbamide peroxide from scheduling;
- Proposal for teeth whitening products containing between 3% 6% of hydrogen peroxide and between 9% - 18% of carbamide peroxide to be only legally accessible from a registered health practitioner. Patients to be permitted to use these products 'at home' only after consultation with their registered health practitioner; and
- Proposal for teeth whitening products containing more than 6% hydrogen peroxide and more than 18% carbamide peroxide be legally accessed by registered health practitioners.

In recognising that that there may be a risk to public health associated with over-strength teeth whitening products, respectfully recommends that the proposal be set aside and in so doing tenders an alternative regulatory solution. The basis for this is set out below:

#### Failings of the scheduling proposal —

- The proposal lacks scientific rigour insofar as it its proponents cite no research, clinical data or other evidence to warrant a change;
- The proponents seek to use the SUSMP as a means of boosting the business interests of its members to the detriment of competing business; and
- The proposal increases public health risk by creating an environment where consumers will no longer have direct access to Schedule 5 teeth whitening products, and will be driven towards purchases of generic hydrogen peroxide at concentrations of between 3% to 6% for use as a tooth whitening agent without the benefits of appropriate instructions for safe use.

believes that the current scheduling of hydrogen peroxide and carbamide peroxide in Schedule 5 and Schedule 6 remains appropriate and in so doing again reiterates that no research, clinical data or other evidence have been produced to warrant a change. However, to address the potential risks of inappropriate consumer self selection of teeth whitening products containing hydrogen peroxide and / or carbamide peroxide at higher strengths, it is proposed to include new Appendix C entries for hydrogen peroxide and carbamide peroxide to confine the use of high concentration teeth whitening preparations to under the supervision of a professional registered by the Dental Board of Australia (DBA).

## Chapter 1: Current arrangements

The current Scheduling approach for teeth whitening products containing hydrogen peroxide and carbamide peroxide in the SUSMP can be summarised as follows:

- a. Preparations containing 3% hydrogen peroxide or 9% carbamide peroxide, or less, are unscheduled:
- b. Preparations containing from more than 3% hydrogen peroxide up to and including to 6% hydrogen peroxide or from more than 9% carbamide peroxide up to and including 18% carbamide peroxide, are included in Schedule 5; and
- c. Preparations containing above 6% hydrogen peroxide or above 18% carbamide peroxide are included in Schedule 6.

In its previous deliberations to set appropriate scheduling cut-offs for hydrogen peroxide, and subsequently for carbamide peroxide, the National Drugs and Poisons Schedule Committee (NDPSC) established and subsequently confirmed the above Scheduling classifications. As part of these reviews, the NDPSC comprehensively reviewed the toxicology and safety of hydrogen peroxide, and in so doing noted:

The Committee, taking into account the public submissions, confirmed that the current scheduling of hydrogen peroxide remain appropriate on the basis of toxicity. The Members also concurred with the conclusion of the February 2005 NDPSC meeting that, despite carbamide peroxide also being a source of hydrogen peroxide, industry had not always recognised the scheduling ramifications of this and as a consequence there were some inappropriately labelled tooth whitening products. On the basis of the hydrogen peroxide toxicity profile and the need for clarity, the Committee agreed to confirm the inclusion of specific entries for carbamide peroxide within the SUSPD.

NDPSC Record of Reasons National Drugs and Poisons Schedule Committee (June 2005)

It is noted that the current proposal before the ACCS / ACMS has tendered no new evidence to challenge the base assumptions in the earlier deliberations of the NDPSC.

supports the current percent cutoffs confirmed by the NDPSC following its previous review of these substances for the unscheduled, Schedule 5 and Schedule 6 entries for hydrogen peroxide and carbamide peroxide, as providing appropriate levels of control for the safe use of preparations containing these substances.

In 2011 the (Environmental Risk Management Authority) ERMA in New Zealand conducted a review of the controls on dental products containing or releasing hydrogen peroxide, as part of it amendment of The Dental Products Group Standard. ERMA's decision, which included a review of the regulatory controls of these products in international jurisdictions, supported cutoffs for tooth whitening product classifications that are consistent with the current SUSMP arrangements. The ERMA included in its consideration the regulatory importance of Trans Tasman harmonization, and the relevance of the minimisation of trade barriers for Australian exporters when there is no risk to public health.

# Chapter 2: has now made two attempts to restrict the supply of certain teeth whitening products for sale only through its members. These proposals dated 14 February 2012 and 11 May 2012 tendered for consideration by the ACCS and the ACMS cite no research, clinical data or other evidence to warrant a change to existing scheduling arrangements. has suggested that its position has been formed by its "professional experts" however no advice as to how its proposal is justified from a risk based approach. This is not a solid basis upon which to restrict patient access to certain teeth whitening products. Failing the test of good regulation has not made a strong case for strengthening the regulatory controls to restrict sales of teeth whitening products that are currently available for over-thecounter sale. Indeed, has not effectively answered the fundamental question of whether regulatory action is required. The Australian Government requirements promote well-designed regulation by: Requiring a case to be established for acting in response to a perceived policy problem, including addressing whether regulatory action is required and whether the proposed regulation achieves the policy objective in a manner that minimises costs for business and the community. Best Practice Regulation Handbook Attorney Generals Department (2010) proposals are inconsistent with Australian Government guidelines that have reaffirmed a commitment to evidence-based policy making. No new research has been quote, clinical trials cited. The scenarios referenced in submission paper refer to the use of teeth whitening products containing hydrogen peroxide at concentrations above 6%, thus do not demonstrate a need to amend the current scheduling controls of teeth whitening products containing hydrogen peroxide at concentrations between 3% and 6%. The safety profiles of both hydrogen peroxide and carbamide peroxide have been subject to extensive review over many years, and the appropriateness of the current regulatory controls have been affirmed. In its 14 February 2012 proposal, refers to cases of injury, and cites one case where a Schedule 6 product was used by a non-dental professional.

#### **DBA Policy inconsistency**

effective use of hydrogen peroxide in teeth whitening.

Beyond lacking merit from a safety perspective, the proposal before the ACCS / ACMS is inconsistent with the current interim policy of the Dental Board of Australia (DBA). The DBA's authority to develop and approve codes and guidelines that provide guidance to health practitioners registered in the profession arises from Section

also selectively cites a single study from the body of evidence that supports safe and

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35(c)(iii) of the Health Practitioner Regulation National Law as enacted in all states and territories. The DBA's current interim policy in teeth whitening policy states:

Teeth whitening / bleaching, is an irreversible procedure on the human teeth and any tooth whitening / bleaching products containing more than 6% concentration of the active whitening / bleaching agent, should only be used by a registered dental practitioner with education, training and competence in teeth whitening/bleaching.

Interim Policy - Teeth Whitening / Bleaching Dental Board of Australia (November 2010)

The DBA policy is extraordinarily clear in the concentrations of teeth whitening product (implicit in the policy is a reference to hydrogen peroxide) that the DBA sees no safety concerns with teeth whitening products containing hydrogen peroxide at concentrations of 6% and below.

If the ACCS / ACMS were to accept proposal, an environment would be created in which there would be conflict between the SUSMP and DBA policies.

Other jurisdictions have considered the appropriate regulatory framework for the supply of teeth whitening products and have effectively reinforced current regulatory arrangements which permit over-the-counter sales of teeth whitening products containing hydrogen peroxide at concentrations of 6% or less and / or concentrations of carbamide peroxide at concentrations of 18% or less.

#### **ACCC** Policy inconsistency

The Australian Competition and Consumer Commission (ACCC) is also able to regulate teeth whitening products pursuant to the Australian Consumer Law (which forms Schedule 2 to the *Competition and Consumer Act 2010*). The ACCC has produced a bulletin to provide information for consumers about hydrogen peroxide and carbamide peroxide in do-it-yourself teeth whitening products. The ACCC's information bulletin states:

The ACCC's position is that DIY teeth whitening products containing concentrations of more than 6 per cent hydrogen peroxide or more than 18 per cent carbamide peroxide are unsafe for self-administered home use.

Product Safety Bulleting – DIY Teeth whitening products for at home use Australian Competition and Consumer Commission (July 2010)

As with the DBA interim policy, this ACCC statement is also extraordinarily clear in the concentrations of teeth whitening product which are considered safe for over-the-counter take-home kits. It effectively reinforces the appropriateness of current scheduling arrangements.

In this context, if the ACCS / ACMS were to accept the proposal an environment would be created in which there would be conflict between the SUSMP and ACCC policies, in addition to the aforementioned conflict between the SUSMP and DBA policies.

Currently, there is alignment between the DBA interim policy and ACCC\*guidance which are also consistent with current scheduling arrangements for teeth whitening products contain hydrogen peroxide and carbamide peroxide. Given that has tendered no research, clinical data or other evidence to warrant a change, there is no basis upon which to create confusion that will result from changes to the SUSMP that will be inconsistent with DBA and ACCC positions.

## OTC Sales of hydrogen peroxide

DBA and ACCC guidance on this matter.

The proposal before the ACCS and ACMS is also problematic insofar as it will restrict teeth whitening products containing hydrogen peroxide a strengths above 3%, yet generic hydrogen peroxide at strengths up to and including 6%, not specifically labelled for teeth whitening, will remain available via over-the-counter (OTC) sales.

In this environment it is not improbable, that individuals wanting to whiten their teeth, without incurring the cost of a visit to the dentist, will purchase hydrogen peroxide at strengths up to and including 6% and simply use it as a mouth wash — without appropriate directions for use in teeth whitening — thereby unnecessarily exposing themselves to risk.

in its 14 February 2012 proposal, refers to cases of injury, and cites one case where
a Schedule 6 product was used by a non-dental professional.
single study from the body of evidence that supports safe and effective use of hydrogen
peroxide in teeth whitening. The study referred to in submission discusses potential
adverse events which may occur when non dental professionals provide high concentration
peroxide tooth whitening (certainly above hydrogen peroxide at concentrations between 3%
and 6% and / or carbamide peroxide at concentrations between 9% and 18%). The study
concludes that the involvement of dental professional is required to minimise risks for high
concentration peroxide containing tooth whitening products - however, it could be argued
that the selective citation of this study is self serving for interests in the
commercial supply of teeth whitening services (i.e. using the SUSMP to restrict provision of
teeth whitening services by registered dentists), however it is perspective that the
scheduling control framework is not to be used to achieve commercial objectives.
does support the view that tooth whitening preparations containing high concentrations
of hydrogen peroxide or carbamide peroxide ( <i>i.e.</i> in those preparations included in Schedule
6) should be used under the supervision of a registered dental practitioner in the first
instance, available for supply to patients upon recommendation of professional registered by
the DBA. However, considers that proposal is not an appropriate regulatory
solution for products that are cosmetics.
respectfully recommends that the ACCS / ACMS set aside the proposals as they lack
merit, may inadvertently increase consumer risk and if adopted will be inconsistent with both
Highly High High Action in the case consumer have and it adopted will be inconsistent with both

## Chapter 3 - Commercial Impact

has undertaken considerable consultation with its members on the proposal. Businesses that supply dental product are of the one view, that the proposal would severely restrict hitherto legitimate sales of teeth whitening products (containing hydrogen peroxide at concentrations between 3% and 6% and / or carbamide peroxide at concentrations between 9% and 18%) is unnecessary, given the absence of robust scientific evidence to support the change.

## Providing commercial protection to the dental profession

The rationale for the submission to the ACCS / ACMS is assumed to be solely in response to the stated interest in public safety, however this argument has not been fully developed and lacks a factual basis based upon the information provided by the

It is noted that the proposal tendered by serves to provide a direct commercial benefit to dentists as it suggests that only dentists should have responsibility for the sale to the public of teeth whitening products containing concentration of hydrogen peroxide at concentrations above 3% and / or carbamide peroxide at concentrations above 9%. These products are currently available via over-the-counter sale in a manner that is consistent with both DBA and ACCC policies.

The use of the SUSMP to support the profitability of the dental profession in a difficult economic climate is not appropriate.

The proposal before the ACCS / ACMS lacks evidence to justify the proposed changes to the scheduling controls, rather, it appears designed to protect the commercial interests of the dental profession.

## Section 4 - Scheduling as a medicine

has continued to suggest that the matter be considered by the ACCS and ACMS, however revised proposal acknowledges the lack of necessity to regulate peroxide teeth whitening products in the therapeutic schedules, principally Schedule 4. in light of this change, questions the need for this matter to be considered by the ACMS. Notwithstanding this position, it is appropriate to highlight problems with this approach, as it unnecessarily escalates the regulatory compliance burden to such a level that lawful supply of teeth whitening products would not be commercially sustainable.

Teeth whitening products are regulated as cosmetics under the *Industrial Chemicals* (*Notification and Assessment*) Act (*Cth*) 1989, and when teeth whitening products contain concentrations of hydrogen peroxide or carbamide peroxide at levels subject to the SUSMP, the additional labeling and packaging controls of Schedule 5 and Schedule 6 of the SUSMP apply.

Conversely, Schedule 4 is for medicines, and is the domain of prescription medicines for humans and animals. The definition of "medicines" in the *Therapeutic Goods Act (1989)* 1989 requires that they are therapeutic goods, something confirmed by the National Drugs and Poisons Schedule Committee (NDPSC) which confirmed:

The TGA currently does not register tooth whitening products because they are considered to be cosmetic and not therapeutic goods

NDPSC Record of Reasons National Drugs and Poisons Schedule Committee (February 2005)

This is confirmed in the *Therapeutic Goods (Excluded Goods) Order No. 1 2011*, which specifies that dental whitening and bleaching products are "declared not to be therapeutic goods". Since dental whitening and bleaching products are excluded goods, and therefore not medicines, where views a proposal to consider their inclusion in Schedule 4 inappropriate.

If the Scheduling Committee were to determine to include these substances in Schedule 4, Australian manufacturers and suppliers have tendered advice to Limit that the proposal, in its current form, unnecessarily raises the regulatory compliance burden and will result in significant additional cost for business. Given the relatively small market for teeth whitening has been advised that the likely outcome is that current suppliers of teeth whitening products will withdraw from the Australian market. In this environment and given the high level of consumer interest in teeth whitening, the consequence of this action may result in dental practitioners and consumers sourcing products through alternate channels of distribution, such as the internet. Such products would be non compliant with the local regulatory requirements, and consequently would be unlikely to provide appropriate instructions to ensure safe use for teeth whitening. The inadvertent outcome of this proposal would be the denial of access for dentists and patients to compliant products, and the likely increase of significant consumer risk, due to the use of non compliant products. Significantly, one of the suppliers who has signaled an intent to withdraw from the Australian market is a domestic manufacturer, thus if the proposal is accepted a directed consequence will be job losses.

# Chapter 5: Alternative proposal

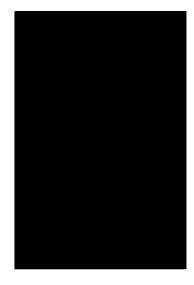
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is mindful of the recent activity by the ACCC concerning high concentration hydrogen peroxide and carbamide peroxide tooth whitening kits, particularly do-it-yourself products. The products concerned contain levels of hydrogen peroxide or carbamide peroxide that fall within Schedule 6, and have been sold online or through non dental distribution channels. supports the position that products containing concentrations of peroxide that necessitate Schedule 6 classification, are likely to achieve better efficacy and reduced risks it used under the supervision, in the first instance, of a registered dental practitioner.
Consequently, proposes an amendment to the availability of hydrogen peroxide and carbamide peroxide teeth whitening preparations in Schedule 6, to limit their access to DBA registered professionals who would, in the first instance, administer treatment to the patient and then comfortable that there were no adverse reaction, supply the patient with take-home kits. This restriction of access to consumers could be achieved by the addition of new Appendix C entries for hydrogen peroxide and carbamide peroxide. The net result of these proposed new Appendix C entries would be to effectively prohibit use of Schedule 6 teeth whitening preparations other than when supplied to a registered dental practitioner. The existing wording for the Schedule 5 and Schedule 6 entries would remain unchanged.
It is noted that this proposed amendment would be consistent with the aforementioned DBA Interim Policy on Tooth whitening / bleaching published in 2010. Suggested drafting for the new Appendix C entries is as follows:
Appendix C entry (new):
HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide except in preparations supplied through a registered dental practitioner.
CARBAMIDE PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide except in preparations supplied through a registered dental practitioner.
considers that this amendment is consistent with the public safety concerns raised by but provides a solution that retains teeth whitening products within a cosmetics regulatory framework.
As advised, believes that the Scheduling of hydrogen peroxide and carbamide peroxide in Schedule 5 and Schedule 6 remains appropriate, and the proposed addition of the Appendix C entries to confine the use of high concentration preparations to under the supervision of a registered dental practitioner, provides additional controls to address the potential risks of inappropriate consumer self selection that resulted in the episodes of misadventure, that instigated the recent ACCC investigation.
considers that the current Schedule 5 entry and the exemption from scheduling for low

concentrations of hydrogen peroxide and carbamide peroxide (3% hydrogen peroxide or 9% carbamide peroxide, or less) are appropriate, as there is no indication of regulatory failure or

public safety concern at these levels.

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

email: SMP@health.gov.au



Dear Secretary

## Application for chloramphenicol scheduling review

supports the rescheduling of chloramphenicol eye drops from a Schedule 3 medication to a Schedule 4 listing.

In 2010 to the strongly against chloramphenicol eye drops being rescheduled from Schedule 4 to Schedule 3.

Our views have not changed. The use of chloramphenical eye drops should be reserved for bacterial eye infections or to prevent serious infection postoperatively.

There is a great variety of different causes of a red discharging eye. It is very easy for an incorrect diagnosis to be made, and the wrong drug provided. Some eye diseases can cause irreversible loss of sight.

Pharmacists have not been trained to be competent in diagnosing eye disease and do not have the appropriate equipment to properly examine an eye.

First-line eye care is the domain of general practitioners and optometrists, who are readily accessible to patients. General practitioners have been specifically trained in clinical diagnosis and appropriate drug use.

Yours sincerely



12 September 2012

12 September 2012

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

Email: SMP@health.gov.au

Invitation for public comment - ACMS meeting, October 2012

Scheduling proposal to reschedule chloramphenicol for ophthalmic use from Schedule 3 to Schedule 4



We appreciate the opportunity to provide comment on this scheduling proposal, albeit being unaware of the reasoning behind the proposal to reschedule to Schedule 4 status.

In October 2009, the National Drugs and Poisons Schedule Committee (NDPSC) determined to harmonise with NZ by including chloramphenical for ophthalmic use in Schedule 3. Members generally agreed that there appeared to be little, if any, significant difference between the ability of GPs and pharmacists in providing differential diagnosis between mild cases of bacterial or other eye infection. The NDPSC also noted that availability of an effective OTC treatment for conjunctivitis would aid in early detection of the condition, thereby benefiting consumers.

Chloramphenicol ophthalmic preparations have been available as a Schedule 3 medicine since 1 May 2010.

To coincide with the implementation of the Pharmacist-Only scheduling of chloramphenicol eye preparations, the Pharmaceutical Society of Australia (PSA) developed an algorithm that provides pharmacists with step-wise guidance in fulfilling their professional responsibilities in determining the patient's needs and appropriateness of supplying chloramphenicol.

The protocol clearly informs pharmacists how to differentiate between bacterial conjunctivitis and viral or allergic conjunctivitis, and when referral to an optometrist or general practitioner is required.

This protocol is available to pharmacists online from the PSA website, as well as published in the *Australian Pharmaceutical Formulary* (APF).

In 2011, the Advisory Committee on Medicines Scheduling (ACMS) was asked to change the Schedule 3 entry to specify bacterial conjunctivitis. Having again considered the benefits and risks of having chloramphenical available to the consumer following consultation with a pharmacist, the ACMS agreed that a more restricted wording of the Schedule 3 chloramphenical entry would not result in further benefits concerning its ophthalmic use and agreed to recommend to the delegate that the current wording chloramphenical remained appropriate.

Over the last two decades, the role of the pharmacist in health care activities has been encouraged with the development of standards for good pharmacy practice. This includes activities associated with self-care such as providing consumers with advice and, where appropriate, supply of a medicine for conditions that the consumer can self-diagnose and self-manage.

With the availability of the PSA protocol, *Provision of chloramphenicol for ophthalmic use as a Pharmacist Only medicine*, this process is enhanced.

The World Health Organisation (WHO), in its document *The Role of the Pharmacist in Self-Care and Self-Medication*<sup>1</sup>, the notes that responsible self-medication can:

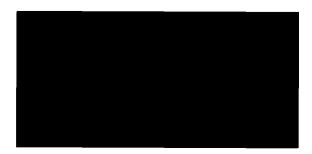
- help prevent and treat symptoms and ailments that do not require medical consultation:
- reduce the increasing pressure on medical services for the relief of minor ailments, especially when financial and human resources are limited;
- increase the availability of health care to populations living in rural or remote areas where access to medical advice may be difficult.

As denoted in the title, the pharmacist's role in this process is implicit and essential.

In the absence of a signal denoting a safety concern, believes that the proposal to reschedule chloramphenical eye preparations to Schedule 4 represents a retrograde step for pharmacists and devalues their role in self-care. It also takes away from the consumer the ability to easily access an effective and proven treatment.

We therefore consider that chloramphenicol for ophthalmic use should remain in Schedule 3.

We hope these comments are useful in the Committee's consideration of this issue, and look forward to hearing the outcome.



<sup>1</sup> http://apps.who.int/medicinedocs/pdf/whozip32e/whozip32e.pdf

10 September 2012

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

Dear Sir/Madam,

Re: Proposal to Reschedule Chloramphenicol for Ophthalmic Use from S3 to S4

hereby refers to the "Proposed amendments referred by the delegate for scheduling advice for consideration by Advisory Committee on Medicines Scheduling (ACMS)" which will be considered at the October 2012 ACMS meeting. The proposal is to reschedule chloramphenical for ophthalmic use from Schedule 3 (S3) to Schedule 4 (S4).

Thank you for the opportunity to comment on this proposal.

strongly objects to the proposed rescheduling from S3 to S4 since this denies patients immediate access to medication and will increase the burden on the national health budget.

## Prescribing by pharmacists

On 1 May 2010, the National Drugs and Poisons Schedule Committee confirmed that (chloramphenicol) Eye Drops and Eye Ointment would be rescheduled from S4 to S3, allowing pharmacists to prescribe these products directly to patients. This downscheduling decision has given patients easier and quicker access to appropriate treatment from their pharmacist – the same medication they would have most likely been prescribed anyway if they had spent time and money consulting a doctor.

At the request of the TGA on 9 November 2010, the indication for (chloramphenicol) Eye Drops and Eye Ointment changed from "For the treatment of bacterial conjunctivitis and other superficial ocular infections caused by chloramphenicol-sensitive organisms" to "For the treatment of bacterial conjunctivitis. For use under medical supervision only in the treatment of other superficial ocular infections caused by chloramphenicol-sensitive organisms." With the addition of the words "under medical supervision", it is clear that pharmacists are restricted to treating bacterial conjunctivitis only. Discussions with pharmacists and other health professionals at the time of the down-scheduling in 2009/2010, have surmised that this recent up-scheduling proposal has most

likely come from the two original opposing groups – Australian Medical Association and Royal Australian and New Zealand College of Opthalmologists. These groups most probably fear the products are being dispensed for the incorrect indication (viral, fungal or allergic as opposed to bacterial conjunctivitis) and with such widespread use, bacterial resistance could very well be a problem in the not too distant future. Despite newer generation antibacterial ocular products being available overseas, Australian ophthalmologists have been reluctant to show support for these new products so chloramphenicol is essentially the only molecule used to prevent/treat ocular infection.

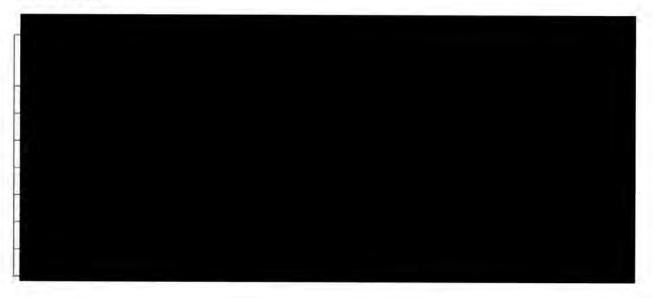
As chloramphenicol is currently S3, pharmacist intervention is mandatory before is given to the patient. This means the patient should still be differentially diagnosed to ensure the medication is appropriate, and then counselled on how to use it. The "supply protocol for chloramphenicol for ophthalmic use" developed by the Pharmaceutical Society of Australia is designed to enable pharmacists to handle this specific medicine properly and responsibly. It is important to note that the diagnosis and treatment given by a doctor is not necessarily going to be more comprehensive than the pharmacist's.

While conjunctivitis is usually benign and self-limiting in otherwise healthy individuals, complications of the condition can be sight-threatening. If were to be upscheduled back to S4, a potentially large number of patients will not visit the doctor due to cost and time implications. Given that bacterial conjunctivities is so prevalent, this can potentially lead to contagion with the condition not being treated quickly and properly.

## Safety

Table 1 shows the low number of adverse events reported for chloramphenicol for the periods January 2008 to April 2010 - S4 schedule and May 2010 to July 2012 - S3 schedule. The types of adverse events reported to the TGA since chloramphenicol was rescheduled to S3 are considered minor, eg. site reaction. Please refer to Attachment 1 for the DAENS report. This shows that there is no safety concern with the current scheduling.

Furthermore, the number of adverse events as a % of sales has not changed with the reschedule from S4 to S3. For the two compared periods, the actual % is the same at a very low 0.0005%.



## Prescribing Data

Analysis of IMS dispensed data coupled with Pharmaceutical Benefit Scheme (PBS) data suggests that currently 38% of chloramphenicol eye drop sales and 25% of chloramphenicol eye ointment sales are made without a formal prescription by a doctor, ie. prescribed by a pharmacist. The discrepancy between the drops and the ointment is most likely explained by the ointment being used slightly more in the elderly who are on some type of PBS benefit, whereas the drops are more often used in children over 2 years of age, many who do not have PBS benefit options. Additionally, the ointment is mostly used at night only (once daily) whereas the drops are given throughout the day (2-3 times daily). This means that patients will finish the drops sooner and therefore will need to purchase more drops, ie. the same elderly patient may need two bottles of drops per one tube of ointment.

An up-scheduling of from S3 to S4 would require patients to spend time and money to visit the doctor or other healthcare professional with prescribing rights. It is unlikely that all 100% of current non-script sales would transfer to GP visits, but a large number would. Since bacterial conjunctivitis is most prevalent in children, it is common policy for children to be taken out of childcare centres/schools when they have the infection and only allowed back 24 hours after starting a course of antibiotic treatment. Parents cannot afford to delay treatment.

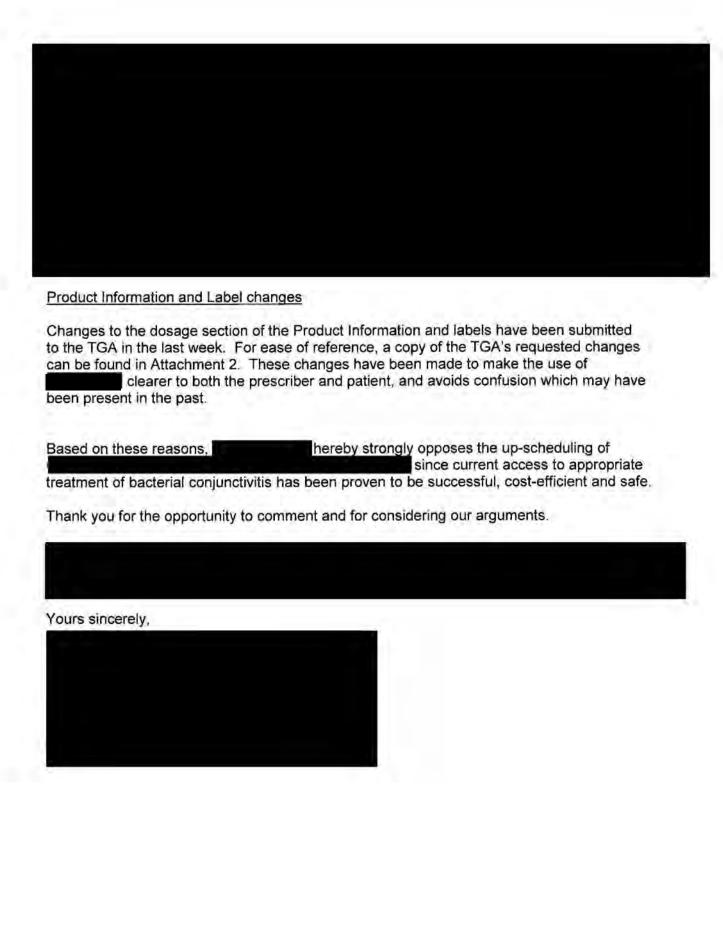
### Cost to Medicare

The potential cost to the national health budget of the up-scheduling is detailed in Table 2. If the average monthly requirement for drops and ointment remains constant, an additional 63,000 GP visits per month would need to be found and made. With the Medicare rebate for a standard consultation at \$35.60, this equates to an additional cost to government of \$2.25 million per month, or \$27 million annually.

Total GP visits required (100% take- up)	63,313 / month
Health cost @ \$35.60 / Medicare rebate for standard consultation	\$2,253,943 / month

If average usage per month of chloramphenicol does reduce in future months, it is unlikely to go below 50% given the prevalence of the condition. A 50% reduction will require an additional 31,000 GP visits per month, costing Medicare \$1.1 million each month or \$13.5 million annually. Please refer Table 3.

A more likely scenario is probably between 70-90% of existing sales.



4 September 2012

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

Dear Sir/Madam,

Re: Scheduling Proposal to reschedule chloramphenicol for ophthalmic use from Schedule 3 to Schedule 4

Thank you for providing the opportunity to make a submission in regard to the proposed upscheduling of chloramphenicol for ophthalmic use from Schedule 3 to Schedule 4.

group concurs with all of the information put forward to the ACMS Expert Advisory Committee<sup>1</sup> to support that the current scheduling of chloramphenical remained appropriate. In addition, we would like the committee to take the following into consideration.

Chloramphenicol was first registered in an oral dosage form. Currently the chloramphenicol products on the ARTG register since its inception in 1991 are:

Product Name	ARTG start date
CHLOROMYCETIN SUCCINATE chloramphenicol 1.0g (as sodium succinate) powder for injection vial	4/2/97
CHLOROMYCETIN chloramphenicol 5mg/mL eye drops bottle	9/9/96
CHLOROMYCETIN chloramphenicol 5mg/mL ear drops bottle	9/9/96
CHLOROMYCETIN chloramphenicol 10mg/g eye ointment tube	30/7/96
MINIMS CHLORAMPHENICOL 0.5% 5mg/ml eye drops tube	30/10/91
Chloromyxin Eardrops 5mL	9/10/91
Chlorsig 1% chloramphenicol 10 mg/g eye ointment tube	14/10/91
Chlorsig chloramphenicol 5 mg/mL eye drops bottle	14/10/91

http://www.tga.gov.au/industry/scheduling-decisions-1106-final.htm

Searches on the TGA's Database of Adverse Events Notifications<sup>2</sup> for chloramphenicol showed the following number of notifications:

	1971-1980	1981-1990	1991-2000	2001-2008	2009-2012	All
Number of reports (cases)	52	114	102	55	17	340
Number of cases with a single suspected medicine	35	56	50	37	13	191
Number of cases where death was a reported outcome	3	3	1	0	0	7

174 of the total of 340 reports of adverse events notifications, 91 of the 191 cases with a single suspected medicine and 6 of the 7 cases of death, were before the ophthalmic preparations were introduced in 1991. Although it is not possible to establish when the oral formulations of chloramphenicol were phased out/discontinued, it can be assumed that it is before 2000.

Taking underreporting into account, following the OTC classification of chloramphenical since 2009, the incidence of adverse events notifications has not been shown to increase at alarming levels.

The pharmacists protocol for the OTC supply of ophthalmic chloramphenicol<sup>3</sup> clearly states that "referral to an optometrist or GP would be appropriate for children < 2 years". The evidence presented above demonstrates that the protocol has worked well.

do not agree with the proposed upscheduling of chloramphenicol for ophthalmic use from Schedule 3 to Schedule 4 and maintain that the ACMS Expert Advisory Committee and delegate's decision as published in the "Reasons for Delegates' final decisions, June 2011" that the current scheduling of chloramphenicol for ophthalmic use remained appropriate.



<sup>&</sup>lt;sup>2</sup> http://www.tga.gov.au/daen/daen-entry.aspx

<sup>&</sup>lt;sup>3</sup> http://i2p.com.au/article/psa-media-releases-april-2010

Dicolfenac 1 of 1.



11/09/2012

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

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Email: SMP@health.gov.au

Re: Invitation for public comment – for ACMS meeting, October 2012

Proposal to amend the Schedule 2 entry for diclofenac when presented in a transdermal drug delivery system for topical use (containing 140 mg or less).

Dear Secretary,

notes that the Advisory Committee for Medicines Scheduling (ACMS) is considering a proposal to amend the Schedule 2 entry for diclofenac when presented in a transdermal drug delivery system for topical use (containing 140 mg or less).

Currently the Schedule 2 entry reads

#### DICLOFENAC when:

- (a) in divided preparations for oral use containing 12.5 mg or less of diclofenac per dosage unit in a pack containing 20 or less dosage units and labelled with a recommended daily dose of 75 mg or less of diclofenac; or
- (b) in preparations for dermal use containing 4 per cent or less of diclofenac **except** in preparations for dermal use containing 1 per cent or less of diclofenac or for the treatment of solar keratosis.

## **Discussion on Proposal**

Diclofenac – the Advisory Committee for Medicines Scheduling (ACMS) is considering a proposal to amend the Schedule 2 entry to include diclofenac when presented in a transdermal drug delivery system for topical use (containing 140 mg or less). No alternative approaches are noted.

supports the proposed scheduling arrangements for a topical diclofenac preparation presented in a transdermal drug delivery system dosage form for topical use and containing 140 mg or less on the following basis.

Diclofenac is a widely available non-steroidal anti-inflammatory drug (NSAID) used in effective alleviation of musculoskeletal pain and inflammation. Whilst it is acknowledged that NSAIDs are associated with potential adverse events related to systemic (NSAID) therapy, the development of

topical formulations stemmed partially from the need to reduce the possible incidence of those potential adverse effects.

At least four topical transdermal "drug in patch" diclofenac delivery systems are available globally as either approved medicine or medical device products and contain less than 140 mg of active ingredient/patch. These products are not associated with any evidence of increased rates of adverse event and have been compared favourably with "non patch" products.

## **Quality Use of Medicines**

believes that QUM is best supported by the supply of medicines assessed by the TGA and reviewed by the ACMS with input from interested stakeholders. Assigning an S2 classification for a new dose form of an already well established medicine retains access to professional support and advice from a pharmacist if needed. Access through the community pharmacy sector is extensive, with reasonable after-hours access and emergency access should the need arise.

## **Key Points**

has considered the scheduling proposal with particular reference to the following subsections of the *Therapeutic Goods Act 1989 – Section 52E (1)*:

## (a) the risks and benefits of the use of a substance

With respect to presenting a balanced submission, for dose forms of diclofenac (NSAID) specifically targeting a systemic effect for efficacy:

- All NSAIDs have a similar capacity to cause renal impairment, congestive heart failure, hypertension and oedema.<sup>2</sup>
- Systemic NSAID availability is associated with significant cardiovascular risks, diclofenac, second in ranking to ibuprofen, is associated with the high risk of stroke and diclofenac associated with the highest risk of cardiovascular death.<sup>3</sup>
- iii. Chronic sustained systemic exposure to NSAIDs, particularly in patients over 65 years of age is of concern owing to documented increased risk of gastrointestinal and cardiovascular events.<sup>4</sup>
- iv. Evidence based reviews show 1% topical diclofenac to be an effective and well tolerated treatment in painful and inflammatory conditions for short-term use. <sup>5</sup>
- v. There is some systemic exposure to diclofenac following normal use whereas up to 6% of the systemic levels can be observed from a single oral dose of diclofenac sodium. Concomitant administration of diclofenac gel with oral NSAIDs or aspirin may result in increased adverse NSAID effects.<sup>6</sup>
- vi. With the unrestricted availability of aspirin and ibuprofen, there is a potential for people to combine these with topical diclofenac use, increasing the risk of systemic adverse effects. The elderly may be particularly at risk and considering the incidence of osteoarthritis in this age group, there is a strong likelihood that they may use topical NSAID preparations as well as oral NSAIDs; particularly with targeted marketing campaigns.

Counter to above points i, ii and iii, and in support of a topical transdermal drug delivery system (such as may be encountered with a 'drug in patch' or 'drug in reservoir' presentation) the presence of the active ingredient can be effectively and rapidly removed from a patient thus quickly eliminating the source of diclofenac and cutting off further systemic delivery (exposure) should a patient experience the onset of potential adverse effects.

Some review of the suitability for use in the elderly might be warranted though the limit of systemic availability of diclofenac from topical use of a product containing less than 140 mg likely and in a transdermal delivery mechanism such as a "drug in patch" might not warrant this concern given the potential for skin tear injury when removing adhesive plaster or patches, common in the elderly, this might not be a sensible choice of delivery system for some of that patient class and thereby potentially limits exposure.

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

- i. Though the scheduling proposal does not identify a proposed indication, as an antiinflammatory, the recommended dosage for 1% topical diclofenac (in a gel) is:
  - 2g per joint per application for upper extremities (hand, elbow, wrist), with a maximum of 4 applications (8g) per joint per day,
  - 4g per joint per application for lower extremities (foot, ankle, knee), with a maximum of 4 applications (16g) per joint per day to a total maximum of 32g per day.

With this dosage in mind assume that a topical preparation in a transdermal delivery system might equate to existing approved commercially available dose forms including products approved globally and that a total maximum quantity of diclofenac available from such a delivery system, absorbed during 24 hours might be 6.6 mg (assuming a 24 hour site application).



suggests that ideally this dose form would present consumers with a more accurate delivery of the diclofenac and through discussion with a pharmacist at point of purchase, better compliance with dosing recommendations as the dose is captured in a finite delivery mechanism.

## (c) the dosage, formulation, labelling, packaging and presentation of a substance

acknowledge that applying restrictions to different strengths of a medicine under one schedule of the SUSMP might be confusing for pharmacists however under the proposal, diclofenac available in a transdermal delivery system is particularly finite as the approved systems available on the global market are typically single use and only contain a finite amount of the encapsulated active ingredient per 'patch' whereas other dose forms might permit the consumer to take or apply an imprecise quantity.

are aware of previous scheduling discussions regarding scheduling of diclofenac particularly in respect to suggestions of limiting the SUSMP entries by strength rather than indication to provide greater clarity to consumers and pharmacists.

In this specific proposal however, believe it is very relevant that the discriminating factor with a transdermal drug delivery system will be the dose form as opposed to the strength or indication and thereby is unique in that the argument regarding potential confusion in pharmacy

regarding strengths and schedules for diclofenac becomes invalid as the strength, formulation and indication are 'predetermined' by way of the in-system availability of the diclofenac in the 'discrete' dose form.

## (d) other matters in public health interest

The National Coordinating Committee on Therapeutic Goods (NCCTG) provides an annual report on the outcomes from the Standards Maintenance Assessment (SMA) Program (previously known as the Mystery Shopper Program), conducted as part of the Quality Care Pharmacy Program (QCPP).

The most recent SMA results indicate a trend for improvement in SMA scores with almost all consumers receiving some advice from pharmacy personnel with the purchase of S2 medicines.

It is also worth noting that pharmacy assistants must complete appropriate training regarding S2 and S3 medicines as part of QCPP accreditation and refresher training for pharmacy assistants, focused on applying S2/S3 professional supply protocols, has been needed for QCPP re-accreditation.

## Conclusion

Topical diclofenac is a useful and relatively safe treatment for pain and inflammation when used appropriately. Diclofenac and other commonly available NSAIDs are associated with increased cardiovascular risks. The use of topical preparations do decrease these risks and a transdermal drug delivery system would provide a more accurate mechanism for delivery of diclofenac with added advantage that rapid elimination of the source of the active ingredient can be effected with such a system.

Inappropriate use is unlikely with a transdermal drug delivery system such as a 'drug in patch' type product and it could reasonably be envisaged that packaging and labelling would clearly advise on potential incorrect use such as applying more than the recommended quantity of the system delivery mechanism during a certain time frame such as within a 24 hour period or multiple application to larger areas, or concomitant use with oral NSAIDs or aspirin.

therefore considers and supports the proposal of scheduling diclofenac for topical use via a transdermal drug delivery system to be entirely appropriate:

- as an S2 medicine for preparations containing 140 mg or less of diclofenac, irrespective of indication



## References:

- 1. http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1 accessed 10/09/2012
- 2. NPS RADAR, August 2005; Elevated cardiovascular risk with NSAIDs?
- 3. Trelle, S., Reichenbach, S., Wandel, S., et al; Cardiovascular safety of non-steroidal anti-inflammatory drugs: network meta-analysis; BMJ 2011; 342:c7086 doi:10.1136/bmj.c7086
- 4. Safety of diclofenac topical solution compared with oral diclofenac for treatment of osteoarthritis of the knee in patients aged ≥65 years; 30th Annual Scientific Meeting of the American Pain Society; 19 May 2011
- 5. Zacher, J., Altman, R., Bellamy, N., et al; Topical diclofenac and its role in pain and inflammation: an evidence-based review; Current medical research and opinion; 2008; Vol 24, No 4; pp 925-950
- 6. Voltaren gel, Prescribing Information; September 2009; <a href="http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm193047.htm">http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm193047.htm</a>



September 4, 2012

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

SMP@health.gov.au

To the Secretary of the ACMS,

#### Mometasone

I am writing to you regarding the "Invitation for public comment - ACMS and ACCS meetings, October 2012", particularly the proposal to reschedule Mometasone from Schedule 4 to Schedule 3 in preparations for topical use containing 0.1 percent or less of mometasone in packs containing 30 g or less of the preparation when labelled for the treatment of adults and children 12 years and over.

I have been an eczema sufferer all my life and have found mometasone to be invaluable in helping me control my skin condition. But unlike the medications that I use for my asthma and hay fever, every time I need a new tube of mometasone I have to go to the doctor for a prescription. Given that I know and understand my eczema and know what I need to treat it, the fact that I have to continually go to the doctor to get a prescription is a waste of my time and money, the doctor's time and the government's money.

I now have two small children which make a visit to the doctor even more difficult. If I could just go to the pharmacy to get the medication for my eczema it would be a great relief both time wise and financially.

I fully support mometasone for topical use being available as schedule 3. Pharmacists are excellently trained healthcare professionals who would know how to handle mometasone, and having it available without prescription would save consumers like myself time and money, while also providing easier access to medicines that can help our eczema. I would have no hesitation in talking to the pharmacist about the treatment or about any problems if I ever had any although having used this product for many years I know to stop using it when my eczema settles down.

Making mometasone schedule 3 would be a very positive move.



## 3 September 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601
SMP@health.gov.au

#### To the ACMS

I would like to express my support for the proposed rescheduling of mometasone from S4 to S3 for topical use being considered at the October ACMS meeting.

Mometasone is already available as a S2 for allergic rhinitis, but when I need to use mometasone for my eczema I have to go to the GP for a prescription. Given that I work full time, getting to a GP involves an afterhour's visit to a clinic, paying \$65, and then going to a Medicare office to get my rebate. This is a time consuming and frustrating cycle, just to get a medication that I have been using for many years whenever I get a flare-up of my eczema.

I would welcome the freedom that having mometasone available from the pharmacy would give me. I would be able to purchase a new tube very easily and would not have to frantically get to a GP when I felt my eczema flaring up or getting worse. I am very sure that those suffering from other conditions such as psoriasis that use mometasone would also be pleased to have it available from their pharmacy.

Making mometasone S3 would be a big assistance in my life as I look after my skin, and I am sure would be of use to many other Australians.



12 September 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: <u>SMP@health.gov.au</u>

Notice inviting public submissions under Regulation 42ZCZK of the Therapeutic Goods
Regulations 1990

Proposal to reschedule Mometasone from Schedule 4 to Schedule 3 in preparations for topical use containing 0.1 percent or less of Mometasone in packs containing 30 g or less of the preparation when labeled for the treatment of adults and children 12 years and over.

Dear Sir/Madam,

Thank you for your invitation to comment on the plan currently being considered by the National Drugs and Poisons Schedule Committee (NDPSC) to reschedule 0.1% dermal Mometasone preparations from Schedule 4 to Schedule 3

dermal Mometasone preparations from Schedule 4 to Schedule 3

Following a brief review of know topical corticosteroid side effects I will then outline the reasons behind our objection to the rescheduling of Mometasone

### Topical corticosteroid side effects

Atrophy has been shown to be caused by all topical corticosteroids. Intertriginous areas such as the axillae, groin folds and submammary area are particularly susceptible, due to increased temperature, moisture, the occlusive effect of skin on skin and the thinner skin present. It is likely that the atrophy is due to reduced synthesis of collagen and acid mucopolysaccarides, as well as decreased fibroblast growth. Atrophy is the most common adverse effect of topical corticosteroid therapy.

Telangiectasia occur, particularly on areas such as the face, due to corticosteroids stimulating dermal microvascular endothelial cells. As a consequence, capillaries and arterials abnormally dilate causing prominent vessels.

Striae are caused by cutaneous atrophy with the disruption of collagen along the lines of mechanical stress.

Steroid rosacea and perioral dermatitis, characterised by papules and pustules which clear with the use of topical corticosteroids but recur with increased severity upon cessation, on a background of erythema, are commonly seen on the face of patients who have been using Mometasone on their face.

Hypertrichosis, characterised by the growth of vellus hairs, may be seen with topical corticosteroid use. Hypopigmentation may occur in dark-skinned individuals due to interference with the synthesis of melanin by melanocytes.

Glaucoma and cataracts may occur when topical corticosteroids are used incorrectly around the eye

Systemic absorption (suppression of the hypothalamic-pituitary-adrenal axis) has been reported following widespread chronic use in both adults and children

## Argument against rescheduling Mometasone from Schedule 4 to Schedule 3

I would like to address some of the issues that may be relevant to the current consideration for rescheduling:

- 1. Whilst the incidence of side effects reported to the Adverse Drug Reaction Advisory Committee relating to the use of Mometasone is relatively low, this situation is not reflected in clinical practice. Our experience is well supported in the attached article from the 2006 Journal of the American Academy of Dermatology. As the authors of the review article state, "Despite encouragement to report adverse drug reactions, the clinical practice of reporting is poor and incomplete". Because Australian dermatologists so frequently see the effects of inappropriate use of topical corticosteroids, we are unlikely to report these adverse effects to the authorities. If the National Drugs and Poisons Schedule Committee were to contact any Fellow of College, I am certain that every Fellow would be opposed to Mometasone becoming a non-prescription item and every Fellow will have seen at least one or two patients each week (thousands each year) with the adverse effects of rosacea, perioral dermatitis, acne, as well as the extra facial adverse effects of striae, (particularly in the flexures), atrophy and purpura. Similarly, ophthalmologists frequently see ocular adverse effects of topical corticosteroids such as Mometasone, but do not report them because they are so common.
- 2. There is an incorrect perception that most side effects that result from topical corticosteroids are transient and mild and as a result rescheduling Mometasone to Schedule 3 cannot result in significant harm. Such an assumption is paramount to negligence. Corticosteroid-induced rosacea can persist for months or even years, resulting not only in psychological and financial distress (due to the cost of ongoing specialist consultation and treatment) to the sufferer, but financial strain on employers and the economy due to days lost at work. In the case of striae of the flexures this side effect is a permanent disfigurement for which no corrective treatment exists. Facial telangiectasia do not always clear following the withdrawal of the offending topical steroid, necessitating the use of laser therapies at significant cost to the patient.
- 3. Whilst available safety data may imply that despite mometasone's moderate potency, there is a marked disassociation of potency from increased risk of side effects (such as dermal atrophy), this data is based on the early short term studies which were provided to the TGA for approval of mometasone in Australia. This is not the situation in clinical practice. Potency of the topical corticosteroid is directly proportional to the

potential for inducing skin atrophy and other dermatological side effects.

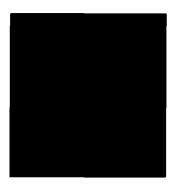
Mometasone furoate is now Australia's most common cause of corticosteroid induced skin atrophy and corticosteroid-induced rosacea.

- 4. The NDPSC may consider that by appropriate labeling and Pharmacist counseling Mometasone will not be used incorrectly, for instance on skin infections, or on inappropriate sites such as around the eye or flexures. In response to such assumptions:
  - a. Patients often have difficulty distinguishing skin infections from moderate or moderately severe eczema. It is quite common in clinical practice for us to see patients with eczema herpeticum (severe herpes infection on areas of skin eczema), and impetigo, which have been treated with topical mometasone. This is quite a dangerous situation with spread of the viral or bacterial infection, and will most likely occur more frequently should this scheduling change occur.
  - b. Tinea is commonly misdiagnosed as eczema by patients and pharmacists. When a potent steroid is used on tinea it spreads and develops pustules but is less inflamed because of the immunosuppressive effect of the topical steroid. It will flare when the steroid is not applied leading patients to continue to use it for long periods of time. Patients may continue to use a potent steroid for several months leading to a large area of skin being involved. This reinforces the need for a correct diagnosis being made, which is not done in the pharmacy, before a potent steroid is used.
  - c. Due to our multicultural society many patients lack the language skills to be able to understand instructions given with regard to the use of potent topical corticosteroids such as Mometasone. This may lead to incorrect use of Mometasone with resultant side effects. The preparation, deemed to be just a simple "cream" may potentially be used on young children who are at greater risk of side effects. By retaining the Schedule 4 status of Mometasone, General Practitioners and Dermatologists can utilise interpreter services when dealing with such patients thereby avoiding potential adverse effects. Even without language difficulties patients using Mometasone as an over the counter preparation will inevitably use it in inappropriate situations including on their young children.
  - d. Pharmacists occupy one of the most important and well respected positions in Australian society but as a group they lack the diagnostic skills required to recommend a potent topical steroid such as Mometasone. In the state of NSW where I preside, not one Pharmacy lecture is delivered at any University by a specialist dermatologist (despite my personal offer of assistance) and post graduate courses only sporadically contain any dermatologic content of relevance to the use of topical corticosteroids. I make this comment not only as a dermatologist but more importantly as a Pharmacist (Bachelor of Pharmacy, Sydney University), previous Fellow of the Australian College of Pharmacy Practice and often invited speaker at Pharmacy Education Seminars. Our concerns are such that the Australasian College of Dermatologists is currently working on a certificate course aimed at improving this deficiency amongst the Pharmacy profession. Without the diagnostic expertise required to assess skin conditions, it follows that a potent topical corticosteroid such as Mometasone cannot safely be recommended by Pharmacists to patients
  - e. There is a false perception that chronic over usage is required before side effects manifest. On the contrary, side effects such as topical steroid induced rosacea may

occur within only a few weeks of use of Mometasone where small quantities less than the standard 15 gram tube have been applied

- 5. According to the seven class ranking of topical corticosteroid preparations, Mometasone ointment is ranked as Class 2 (potent) and is therefore considered stronger than other prescription items such as triamcinolone acetonide, betamethasone valerate and methylprednisolone. If mometasone furoate were rescheduled to Schedule 3, then there would be a convincing argument that all other topical corticosteroid preparations (with the exception of Diprosone OV) should also be reclassified. Such as situation in my view would be paramount to negligence
- 6. In the event that NDPSC considers that similar corticosteroid preparations such as Hydrocortisone have previously been reclassified with no increase in adverse effects noted, and that a similar finding may result from rescheduling of Mometasone, I would like to stress that Mometasone is 100-150 times more potent that Hydrocortisone. Such a magnitude increase in potency will be reflected by a substantial increase in adverse effects
- 7. Conditions such as eczema and psoriasis, requiring the use of potent topical corticosteroids such as Mometasone, should be managed by General Practitioners and where necessary Dermatologists. The severity of these conditions is never fixed, treatment modalities are often multiple, concurrent factors such as the role of irritants, stress and allergy must be addressed, and there is the need for ongoing regular follow up to maintain remission and treat flares. In addition, many patients require Authority Prescription for adequate supplies of topical preparations. Rescheduling of Mometasone to Schedule 3 will severely jeopardize the long term care of such patients with significant potential for greater cost and morbidity to patients

view with grave concern the proposed rescheduling of mometasone furoate. This is a moderately potent topical corticosteroid which is the strongest available topical corticosteroid in Australia that has a PBS subsidy, and the second strongest if one includes all available topical corticosteroids. Mometasone furoate should only be used under strict medical supervision because of the potential for cutaneous side effects, such as corticosteroid-induced rosacea, permanent skin atrophy and striae, and a significant exacerbation of skin infections. These adverse events are common and of significant harm potential as far as the general public is concerned.







# MOMETASONE, ACLOMETASONE AND CLOBETASONE Chemical File No.: Meeting/Item No.: 48/10.1, 12.1.3

Thank you for request to comment on the Plan of the National Drugs and Poisons Schedule Committee to consider rescheduling 0.1% dermal Mometasone preparations from Schedule 4 to Schedule 3. Please find enclosed a copy of the Continuing Medical Education review article published in the Journal of the American Academy of Dermatology in January 2006 entitled "Adverse effects of topical glucocorticosteroids". Although topical corticosteroids are certainly not a new form of treatment, they are the mainstay of topical dermatological therapy, and as such I would not wish to jeopardise their place in our armamentarium. However, when these very useful agents are used inappropriately, significant adverse effects may occur. The majority of these adverse effects will be seen cutaneously. Systemic adverse effects are unlikely to occur if Mometasone were to be listed as a Schedule 3 item as very limited quantities would be available. However, if it was a child being treated and the parent or guardian were to go to a number of different pharmacies, it would be possible for the child to be exposed to sufficient corticosteroid to cause a systemic reaction. Such reactions would include hyperglycaemia, adrenal insufficiency/suppression of the hypothalamic-pituitary-adrenal axis and glaucoma. The rest of my comments will relate to the cutaneous adverse effects due to abuse of topical Mometasone furgate.

As the authors of the review article state, "Despite encouragement to report adverse drug reactions, the clinical practice of reporting is poor and incomplete". Because dermatologists so frequently see the effects of inappropriate use of topical corticosteroids, we are unlikely to (I suspect) report these adverse effects to the authorities. If the National Drugs and Poisons Schedule Committee were to contact any Fellow of College, I am certain that every Fellow would be opposed to Mometasone becoming a non-prescription item and every Fellow will have seen patients with the adverse effects of rosacea, perioral dermatitis, acne, as well as the extra facial adverse effects of striae, (particularly in the flexures), atrophy and purpura. Similarly, ophthalmologists frequently see ocular adverse effects of topical corticosteroids such as Mometasone, but do not report them because they are so common.

As the review article so eloquently put it, whilst the introduction of corticosteroids in 1952 was a major landmark in dermatologic therapy, owing to the anti-inflammatory and anti-proliferative effects, these same mechanisms were reported to cause adverse effects within a few years of their introduction.

Different sites absorb topical corticosteroids to different extents. Whilst it maybe appropriate for an individual to apply Mometasone ointment to a lichenified, infiltrated area on the forearm where absorption may be as low as 1%, the patient may be under the misapprehension that being a pharmacist-only agent, that it would be safe and could be used on other sites. If such an agent was to be applied to the scrotum where up to 35% of applied drug may be absorbed or other areas such as the face where increased amounts of corticosteroids are absorbed, local side effects will be more common and more pronounced.

Because the cutaneous adverse effects of inappropriate topical corticosteroid use are so common, they are rarely published or reported to regulatory agencies. Therefore, I suspect a paucity of reports giving an inappropriate reassurance that these medications are without adverse effects.

While I would not like to see the use of Mometasone further restricted, I think more strongly worded warning to avoid the use on the face and flexures would be appropriate and the rescheduling to a non-prescription item would be tantamount to negligence. According to the seven class ranking of topical corticosteroid preparations, Mometasone ointment is ranked as Class 2 (potent) and is therefore considered stronger than other prescription items such as triamcinolone acetonide, betamethasone valerate and methylprednisolone. Therefore I feel the College cannot support the rescheduling of this agent.

To cover each side effect individually, atrophy has been shown to be caused by all topical corticosteroids. Intertriginous areas such as the axilla, groin folds and submammary area are particularly susceptible, due to increased temperature, moisture, the occlusive effect of skin on skin and the thinner skin present. It is likely that the atrophy is due to reduced synthesis of collagen and acid mucopolysaccarides, as well as decreased fibroblast growth. Atrophy is the most common adverse effect of topical corticosteroid therapy.

Telangiectasia occur, particularly on areas such as the face, due to corticosteroids stimulating dermal microvascular endothelial cells. As a consequence, capillaries and arterials abnormally dilate causing prominent vessels.

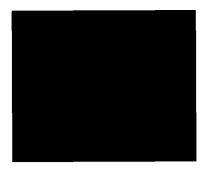
Striae are caused by cutaneous atrophy with the deposition of collagen along the lines of mechanical stress.

Steroid rosacea and perioral dermatitis, characterised by papules and pustules which clear with the use of topical corticosteroids but recur with increased severity upon cessation, on a background of erythema, are commonly seen on the face of patients who have been using Mometasone on their face.

Hypertrichosis, characterised by the growth of vellus hairs, may be seen with topical corticosteroid use. Hypopigmentation may occur in dark-skinned individuals due to interference with the synthesis of melanin by melanocytes.

Whilst the appropriate use of topical corticosteroids to treat inflammatory dermatoses in the majority of cases does not cause significant adverse effects, their use may cause problems and this is much more likely to occur if patients are mistakenly using the therapy on inappropriate sites on the understanding that there is no limits as to how often, how widely or where the therapy is applied as it is a non-prescription item.

I would strongly advise the Schedule Committee to consider the views of the craft group particularly concerned with any particular medication that they are considering. This is particularly so of the topical steroids. Published literature does not always reflect what is thought to be common medical practice by the craft group specifically concerned with a particular agent. This statement is well-reflected in the attached article from the 2006 Journal of the American Academy of Dermatology.



September 7, 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601



To the ACMS,

RE: Invitation for public comment - ACMS and ACCS meetings, October 2012

I would like to submit my comments regarding the proposal to reschedule mometasone as detailed below:

Mometasone	Proposal to reschedule mometasone from Schedule 4 to
	Schedule 3 in preparations for topical use containing 0.1
	percent or less of mometasone in packs containing 30 g or
	less of the preparation when labelled for the treatment of
	adults and children 12 years and over.

I have worked as a nurse since 1998, including in Critical Care and Emergency. In this time I have seen many cases of eczema, dermatitis and psoriasis that, while not serious, require treatment with topical medications that just haven't been available at pharmacy. Many patients struggle to find the time to go back to the doctor for a script for something they know will work.

Mometasone is a very effective topical corticosteroid, that has an excellent safety profile and I believe would be very beneficial if it was made available without a script as Schedule 3, making access to it simpler with advice from the pharmacist.

I have both a son and a daughter myself and as such I can understand the struggle parents have in trying to care for a chronic skin condition and not having many self care options available. When a flare-up begins it is vital to get an appropriate treatment such as mometasone onto the skin as soon as possible. And while we have late night pharmacies available to us, the same options cannot be said for GP's.

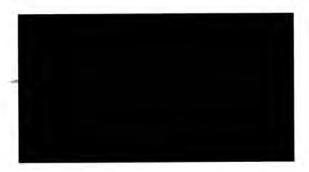
To then sit in a hospital emergency department to get a prescription for mometasone seems very inappropriate and a waste of time, money and effort.

With most families having both parents working, it is increasingly difficult to get time to see a GP. Between working and dropping off kids to school/activities, the day disappears and when you realise in the evening that your son or daughter or yourself needs something for their skin, it's then too late in the day to see a GP. You then have to wait till the next day, at which point you may not even be able to get an appointment.

It is also frustrating to have to sit in a GP's waiting room surrounded by sick people with colds, gastro bugs etc, hoping that you don't contract anything that will require you to take time off work. You don't want to get sick just because you need a script!

Rescheduling topical mometasone to S3 would allow patients ready access, without them having to waste precious time in going to see a doctor to get a prescription. Chronic skin conditions such as eczema, dermatitis and psoriases, can be extremely uncomfortable and distressing and it seems only right that mometasone be readily available to assist in treating them given its known safety and efficacy.

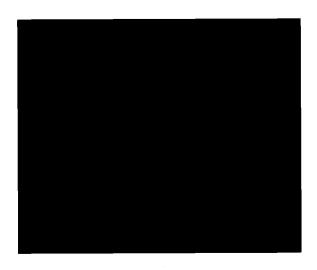
As a nurse, I fully support mometasone being available as Schedule 3 as I believe it would make a difference to patients and their families as they live with chronic skin conditions.



12 Sep 2012

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

Email: SMP@health.gov.au



Dear Sir/Madam,

Re: Comments on Proposal to Reschedule Mometasone from S4 to S3 in Preparations for Topical Use Containing 0.1% or Less of Mometasone in Packs Containing 30g or Less of the Preparation When Labelled for the Treatment of Adults and Children 12 Years and Over for ACMS and ACCS October 2012 Meetings

Thank you for the opportunity to provide comments on substances to be considered for rescheduling by the ACMS in the forthcoming October 2012 meeting.

does not support the proposal to reschedule topical mometasone 0.1% or less from Schedule 4 to Schedule 3 in packs containing 30g or less of the preparation for the treatment of adults and children 12 years and over, for the following reasons:

#### 1. Access of topical mild-moderate corticosteroid for self-medication

Table 1 presents a Classification of the Potency of Commonly Used Topical Corticosteroid (Therapeutic Guidelines – Dermatology) currently available in Australia. To date, both hydrocortisone 0.5% & 1% (mild topical corticosteroid) and clobethasone 0.05% (moderate topical corticosteroid) are available as OTC to provide access to patients to treat mild eczema, skin irritation or non-infective dermatoses for up to 7 days. If symptoms persist, the patients are referred to their medical practitioners.

believes this is appropriate and consistent with the current treatment guidelines in clinical practice to initiate treatment with the least potent topical corticosteroid and use a stepped-care program by increasing potency with severity of the skin conditions <sup>1-4</sup>.

Down scheduling a potent corticosteroid poses a risk that would lead to increased use of a higher potency product in condition that can be treated with the use of a mild-moderately potent corticosteroid. This is not consistent with the Quality Use of Medicines.

Table 1: A classification of the potency of commonly used topical corticosteroid (Therapeutic Guidelines – Dermatology)

	corticosteroid (Therapeutic Guidelines – Dermatology)			
CLASS I - MILD				
	Schedule			
Hydrocortisone 0.5%	S2*; 30 g			
Hydrocortisone 1%	S3*; 30 g BS/RPBS			
	S4; 50 g PBS/RPBS			
* Indicated for mild eczema/ski	n irriation/priritis, and n	on-infective inflammatory dermatoses for		
≤7 days				
CLASS II - MODERATE				
Clobetasone butyrate 0.05%	S3*; 15g			
Betamethasone valerate	S4, 100g			
0.02%	PBS/RPBS			
Betamethasone valerate	S4, 15g PBS/RPBS			
0.05%				
Triamainalana aastanida	C4 400~			
Triamcinolone acetonide 0.02%	S4, 100g PBS/RPBS			
CLASS III - POTENT	PD3/RPD3			
	CO. 20 m			
Clobetasone butyrate 0.05%	S2; 30 g			
Betamethasone dipropionate	S4, 15g PBS/RPBS			
0.05%	S4; 50g			
Betamethasone valerate 0.1%	S4, 30g RPBS			
Methylprednisolone	S4; 15g PBS/RPBS			
aceponate 0.1%	04.45			
Mometasone furoate 0.1%	S4, 15g PBS/RPBS			
	S4, 30g			
OLAGO IV. VEDV DOTENT	S4, 45g RPBS			
CLASS IV - VERY POTENT	04.00			
Betamethasone dipropionate	S4, 30g			
0.05% in optimised vehicle				

#### 2. Access of topical potent corticosteroid requires medical supervision

Consistent with the principles of scheduling classification which underpins the need for particular healthcare professionals to be involved in the supply of certain medicinal substances in order to promote safe and quality use of medicines, believes that more severe skin conditions of eczema and psoriasis require proper diagnosis from medical practitioners and the use of potent corticosteroids should be under medical supervision.

There is much evidence to suggest that use of potent topical corticosteroids for more severe and more complicated skin conditions such as chronic, thickened or hyperkeratotic dermatoses (Table 2) require medical intervention as these skin conditions are not easily diagnosed and improper diagnosis can lead to the masking of a more serious underlying condition and could cause harmful effects.

Potent topical corticosteroids in particular mometasone have a potential of 'thinning' skin effect in particular on face and eyelids. Used for long term, or inappropriate use could be a major area of concern which may cause unwanted skin damage including atrophy, telangiectasia, striae, steroid rosacea and periorifical dermatitis and hypertrichosis<sup>1-3</sup>.

Table 2: Comparison of potency and uses of topical corticosteroids<sup>3</sup>

Table 2. Comparison of potency and uses of topical controlsteroids				
Conticosteroid	Some findications			
Mild	And the second s			
hydrocortisone (0.5-1%)	facial and flexural dermatitis and psoriasis; nappy dermatitis			
hydrocortisone acetate (0.5–1%)				
Moderate				
betamethasone valerate (0.02 & 0.05%)	mild-to-moderate atopic dermatitis, adjunctive treatment in extensive psoriasis			
clobetasone (0.05%)				
desonide (0.05%)				
triamcinolone (0.02%)				
Potent				
betamethasone dipropionate (0.05%)	short term use in severe inflammatory dermatoses			
betamethasone valerate (0.1%)				
mometasone (0.1%)	more severe conditions, eg discold eczema			
methylprednisolone (0.1%)				
Verypoient				
betamethasone dipropionate in an optimised vehicle (0.05%)	severe eczema and psoriasis, eg refractory lichen simplex chronicus; also useful for eczema of hands and feet (occlusion may be used but atrophy may occur)			

### 3. Scheduling status of topical corticosteroids

The scheduling status of topical (dermal) mometasone in USA, Canada, UK and New Zealand has remained unchanged; it is scheduled as Prescription Medicine.

In Australia, most of the widely prescribed moderately potent topical corticosteroid has remained as Prescription Medicine (Aristocort, Betnovate ½; Betnovate 1/5 and Celestone M; Table 1). It would be more appropriate to down schedule those moderately potent topical corticosteroid prior to down schedule more potent topical corticosteroid for self-medication. Supports the Committee's decision that we need to first gain experience with lower potency corticosteroids as schedule 3 substances as outlined in its Feb 2007 meeting.



### References:

- 1. New Zealand Dermatological Society incorporated. Topical steroids. DermNet NZ. <a href="http://www.dermnetnz.org/treatments/topical-steroids.html">http://www.dermnetnz.org/treatments/topical-steroids.html</a>. Accessed 12 Sep 2012.
- Typharm Dermatology Topical Corticosteroids Medical Education (Approved by British Dermatological Nursing Group). <a href="http://www.topicalsteroids.co.uk/start\_here/welcome.htm#">http://www.topicalsteroids.co.uk/start\_here/welcome.htm#</a>. Accessed 12 Sep 2012.
- Australian Medicine Handbook. Comparison of potency and uses of topical corticosteroids.
   <a href="http://www.mmrtraining.guild.org.au/AMH/chapter8/tablecomp-inf-topical-corticosteroids.tb">http://www.mmrtraining.guild.org.au/AMH/chapter8/tablecomp-inf-topical-corticosteroids.tb</a>. Accessed 12 Sep 2012.
- 4. Ross T. et al (2005). Eczema, practical management issues. Australian Family Physician 34(5): 319-324.

10/09/2012

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Facsimile: 02 6289 2650

### Re: October ACMS meeting

This letter is in response to the notice inviting public submissions under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990 regarding a proposed amendment to the scheduling of a medicine as follows:

Mometasone Proposal to reschedule mometasone from Schedule 4 to Schedule 3 in preparations for topical use containing 0.1 percent or less of mometasone in packs containing 30 g or less of the preparation when labelled for the treatment of adults and children 12 years and over.

I am a pharmacist and have been in practice for 7 years. During this time I have dispensed many prescriptions for mometasone furoate for the treatment of patients suffering from atopic dermatitis and other dermatoses. Rarely have I had a customer return for advice on a side effect or other problem occurring with their use of this corticosteroid.

Mometasone furoate is a highly effective potent corticosteroid however the correlation between potency and side effects with this particular compound suggests that an S3 classification is warranted as it does not appear to have the same level of side effects as other potent corticosteroids. As a pharmacist I believe I am well placed to advise on and recommend mometasone for those patients experiencing flare-ups of their dermatoses, particularly with the assistance of treatment protocols and educational/training materials provided by sponsors when a product is down-scheduled from S4 to S3.

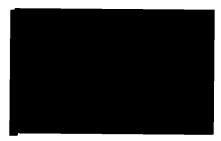
The indications for which mometasone is normally prescribed by a physician are generally easily recognised by the consumer, most of whom have had their condition for many years, and with the help of their pharmacist to confirm the most appropriate corticosteroid for their

condition, reinforces the relationship between the healthcare professional and the consumer, without the need for consumers to continually visit the doctor for a script each time a flare-up occurs.

It is my view that once daily application of mometasone for up to four weeks in adults and children over 12 years should not lead to any potentially serious side effects. Consumers can be counselled at the time of dispensing to return to the pharmacy if they notice any of the side effects listed in the package insert.

As a responsible healthcare professional, I fully support the move to down schedule mometasone furoate to S3 in pack sizes up to 30g.

### Yours truly,



Mometasone 7 of 7

September 12, 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Facsimile: 02 6289 2650

Email: SMP@health.gov.au

Re: October ACMS meeting

This letter is in response to the notice inviting public submissions under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990 regarding a proposed amendment to the scheduling of a medicine as follows:

Mometasone - Proposal to reschedule mometasone from Schedule 4 to Schedule 3 in preparations for topical use containing 0.1 percent or less of mometasone in packs containing 30 g or less of the preparation when labelled for the treatment of adults and children 12 years and over.

I am a clinical dermatologist and currently hold the position of

During the course of my career I have examined many hundreds of patients suffering from atopic dermatitis and other dermatoses who have used mometasone furoate on different anatomical locations over different periods of time and in various quantities without apparent harm.

Topical corticosteroids have been the mainstay of topical dermatological therapy for many years with little evidence of the potential for the systemic side effects seen with oral corticosteroids due to the low systemic absorption.

While classed as a highly potent corticosteroid, a study by Wiedersberg et al (2007)<sup>1</sup> supports the contention that mometasone furoate is identified as one of the first 'soft-steroids' which means that it exhibits significant anti-inflammatory activity and elicits similar skin atrophy *in vivo* to hydrocortisone and methylprednisolone aceponate which are classified as Class 7, least potent topical corticosteroids according to the National Psoriasis Foundation Classification. The Wiedersberg study supports the fact that although mometasone is a very effective, potent corticosteroid, it has a safety profile similar to that of hydrocortisone which is already an OTC medicine. In my experience, side effects in clinical practice are very rare with topical mometasone furoate, even with long term use.

The most significant influence on the side effect profile of topical corticosteroids such as mometasone is the actual patient use (or misuse) of the product. For example the length of time the product remains undisturbed on the skin, the skin surface area where the product is applied, and the anatomical site to which the product is applied and the amount or thickness of the product applied. These are all patient-dependant factors that are of greater relevance to the issue of whether or not there are likely to be adverse effects associated with the product. With appropriate counselling at the time of dispensing the product, a pharmacist can help minimise the potential for adverse effects.

Oral corticosteroids have a potential for more serious side effects such as Cushing's Syndrome or adrenal suppression, however with topical steroids which have much greater and more widespread use than oral corticosteroids, these side effects are rarely if ever seen. I understand that ADRAC reports for topical corticosteroids show that there were some 237 reports of adverse events reported out of over 20 million units of mometasone furoate dispensed over a 16 year period, with only one report possibly related to adrenal suppression, however the patient was also taking an oral corticosteroid at the same time. Locally occurring (cutaneous) side effects such as acne, burning, redness, dry skin and striae are generally mild and transient, mostly reversible after stopping application of the corticosteroid and certainly not life-

<sup>&</sup>lt;sup>1</sup> Wiedersberg S, Leopold CS, Guy R H. Bioavailability and bioequivalence of topical glucocorticoids. *Eu J Pharmaceutics & Biopharmaceutics* 2008, March 68(3): 453-46.

threatening. Use in children under 12 years should be restricted unless prescribed by a doctor.

I fully support the availability of mometasone furoate as a Schedule 3 preparation when dispensed by a pharmacist who can assess whether it is the appropriate treatment for the patient and counsel on correct use.





The Secretary
Medicines and Poisons Scheduling Secretariat (MDP88)
GPO Box 9848
CANBERRA ACT 2601

12 September 2012

Dear Sir/Madam,

Re: Invitation for public comment - ACMS and ACCS meetings - October 2012
Proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling (ACMS)

Pantoprazole - Proposal to amend the current Schedule 3 pantoprazole entry to increase the maximum allowed pack size from 14 to 28 dosage units

refers to the notice inviting public submissions under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990 in relation to the October meeting of the Advisory Committee on Medicines Scheduling (ACMS). would like to provide comment in relation to the proposed amendment to the current Schedule 3 pantoprazole entry to increase the maximum allowed pack size from 14 to 28 dosage units referred by the delegate for scheduling advice.

wishes to take this opportunity to indicate that it opposes the proposed amendment to the current scheduling of pantoprazole to increase the maximum number of dosage units available under Schedule 3 and considers the current schedule to be appropriate i.e. pantoprazole 20 mg or less, in packs containing no more than 14 dosage units (equivalent to 14 day's supply) in Schedule 3. This is in alignment with our previous stance submitted in May 2012 regarding a similar proposal for omeprazole.

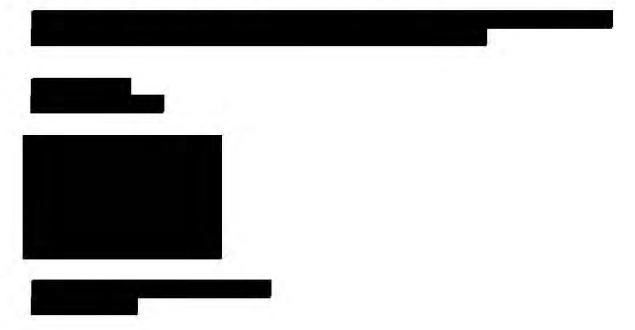
Like omeprazole, pantoprazole is approved for the relief of heartburn and other symptoms of Gastro-oesophageal reflux disease (GORD) as short-term use in the over-the-counter (OTC) setting when recommended by a pharmacist. Considers OTC therapy with a Proton Pump Inhibitor (PPI) should be limited to those patients with mild symptoms likely to respond to the lowest effective dose. Patients with an unsatisfactory response to short term OTC PPI therapy should be referred to a physician for further assessment to eliminate the possibility of a more serious underlying disease.

GORD is a chronic relapsing disease as a result of the inappropriate relaxation of the lower oesophageal sphincter. If left untreated it can develop into erosive oesophagitis and other complications such as oesophageal strictures, oesophageal ulcers, Barrett's oesophagus and oesophageal carcinoma. Patients with GORD presenting with typical reflux symptoms may have either symptomatic non-erosive reflux disease (without mucosal damage) or erosive oesophagitis (with mucosal breaks). As the symptom severity of GORD does not correlate with the disease severity, proper evaluation and management by a healthcare professional is considered necessary to ensure the best health outcomes for patients.

There are readily available alternative treatments for the relief of the symptoms of heartburn which can be used by patients for the self management of their condition. However, should a patient experience a poor response to usual treatments then a pharmacist may offer, with appropriate counseling, short-term PPI treatment.

PPIs are recognised as probably the most efficacious treatment for heartburn and other symptoms of GORD. The limited availability provided by Schedule 3 restrictions for supply of not more than 14 days treatment of the more effective PPIs affords the opportunity of reevaluation of therapy by an appropriate healthcare professional. This evaluation should be undertaken at the earliest possible time-point in a patient that responds poorly to PPI therapy to ensure appropriate management of the condition can be implemented. An increased duration of OTC PPI therapy may not serve in the patient's best interest as it could delay diagnosis and appropriate intervention. A patient requiring treatment with a PPI in excess of 14 days should be investigated to eliminate the possibility of a more serious underlying disease state.

considers that increased duration of therapy available over the counter of pantoprazole and PPIs in general not to be in the best interest of patients. Given the relatively short period of availability of PPIs as an over-the-counter treatment, the option to provide increased treatment duration at this time would be premature. Therefore consider that in the interest of achieving best health outcomes it is neither appropriate nor necessary that pantoprazole be available for greater than 14 days without the intervention of a pharmacist or another health professional.





12<sup>th</sup> September, 2012

The Secretary Medicines and Poisons Scheduling GPO Box 9848 Canberra ACT 2601

Email: SMP@health .gov.au

Dear Sir/Madam,

Re: Public Submission – under Regulation 42ZCZK of the Therapeutics Goods Regulations 1990 – ACMS Meeting October 2012

In reference to the pre-October 2012 Scheduling Meeting notice inviting public comment, notes the scheduling proposal for teriflunomide as outlined below and supports the new entry in Schedule 4:

Proposal for a new Schedule 4 entry, Appendix L and Appendix F entry for teriflunomide.

would appreciate being advised of the Committee's consideration with the opportunity for further comment, if appropriate.

Yours faithfully,



12 September 2012

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

Email: SMP@health.gov.au

RE: Submission on the proposal to schedule Vitamin D

Thank you for the opportunity to provide comment on this proposal.

We wish to submit comment on the following:

- Proposal for a new Schedule 3 entry to allow a weekly dose of Vitamin D up to 175 micrograms (7000IU) per recommended dose.
- Proposal to also include Schedule 3 Vitamin D in Appendix H.

has no objection in principle to the proposal to schedule high doses of 175 mcg vitamin D per recommended dose, intended for use as a once-weekly dose, as S3: Pharmacist only. However we consider that doses below 175 mcg should remain unscheduled.

In consideration of Section 52E(1) of the Act:

### a) The risks and benefits of use of Vitamin D.

According to Commonwealth of Australia 2006, *Nutrient Reference Values for Australia and New Zealand, Including Recommended Dietary Intakes,* endorsed by the NHMRC on 9 September 2005, vitamin D is an essential nutrient involved in calcium homeostasis. It is known to be crucial in bone mineralisation and possibly in muscle strength, immune function and skin health.

While adequate calcium can be obtained from the diet alone, this is almost impossible for Vitamin D. Historically, synthesis in the skin has been the major source of the vitamin. Western populations, including Australians, are showing high rates of sub-clinical and even clinical deficiency due to lifestyle changes: sun-smart practices, sedentary lifestyles, and office environments. The elderly are at particular risk.

Because of the increasing prevalence of osteoporosis in older Australians, there have been a number of public health initiatives encouraging Australians to get more calcium and vitamin D. Thus supplementation is advisable for a high percentage of the population; and those who are deficient in the vitamin require considerably more than the normal recommended daily intake.

The risk associated with excessive vitamin D intake is hypercalcemia of the large arteries, however this occurs at much higher doses that proposed (refer below for further information).

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

Vitamin D supplementation is used to support, maintain or improve bone calcification, especially in those whose are deficient or whose lifestyle places them at risk of deficiency. It is usually given as a daily supplement, and less frequently as a massive dose given by injection annually or semi-annually.

The recommended intake for adults is 5-15mcg per day. This equates to a weekly dose of 35-105mcg.

### c) The toxicity of a substance

Excessive intake of vitamin D may produce hypercalcemia in the large arteries. The studies quoted in the text report NOAEL as 60mcg per day over months, equivalent to 420mcg per week. Although one study reported hypercalcemia at 95mcg per day – equivalent to 665mcg per week – another reported NOAEL at 100mcg.

### d) The dosage, formulation, labelling, packaging and presentation of a substance

The upper level (UL) of intake for an adult has been set by the NHMRC at 80mcg per day, equivalent to a weekly dose of 560mcg. Thus the proposed cutoff of 175mcg for a onceweekly dose is unlikely to pose a risk of hypercalcemia, and in fact this limit appears overly conservative.

The necessity for the consumer to confer with a pharmacist when purchasing an S3 product gives an additional measure of safety.

### e) The potential for abuse of a substance;

are unaware of any history of abuse of Vitamin D.

### f) Any other matters that the Secretary considers necessary to protect public health

It is known that some consumers find it difficult to take supplements every day. The convenience of a single weekly dose may aid compliance in this population.

In consideration of the importance of vitamin D to bone health, and the increasing prevalence of both vitamin D deficiency and osteoporosis, and therefore in the interests of public health, supports the proposal to permit advertising.

In summary, supports the proposal for a new Schedule 3 entry to allow a weekly single dose of 175 mcg Vitamin D, and for this to be included in Schedule 3 to inform consumers of the availability of a more convenient once-a-week dosage regimen.

Once again, we thank you for the chance to comment.

Yours sincerely





12th September, 2012

The Secretary Scheduling Secretariat GPO Box 9848 Canberra ACT 2601

Email: SMP@health .gov.au

Dear Sir.

Re: Public Submission – under Regulation 42ZCZK of the Therapeutics Goods Regulations 1990 – ACMS Meeting October 2012

In reference to the pre-October 2012 Scheduling Meeting notice inviting public comment,
affirms it's support for the commentary relating specifically to the scheduling proposal for vitamin
D as outlined below:

Vitamin D - Proposal to a new Schedule 3 entry to allow a weekly dose of Vitamin D up to 175 micrograms (7000IU) per recommended dose.

Proposal to also include Schedule 3 Vitamin D in Appendix H.

would appreciate being advised of the committee's consideration with the opportunity for further comment, if appropriate.





The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sir/Madam

Public Comment Submission to the October 2012 joint-meeting of the Advisory Committee on Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACMS)

We refer to the notice published on 14 August 2012 inviting public submissions, with respect to certain substances, addressing a matter raised in s.52E of the *Therapeutic Goods Act 1989*.

wishes to provide information on **thymol** for consideration at the October 2012 meeting of the ACCS, and **hydrogen peroxide and carbamide peroxide** for consideration at the October 2012 joint-meeting of the ACCS and ACMS

Please see attached submission for details.

Yours faithfully



12 September 2012



### ACCS meeting: October 2012

### **Thymol**

notes the proposal to include thymol in Schedule 6 of the Poisons Standard.

Thymol has a range of key uses including as a fragrance material, denaturant, and as an oral health care ingredient. For example, according to the International Cosmetic Ingredients Dictionary (INCI), thymol is used in:

- mouthwashes and breath fresheners (liquids and sprays),
- · douches.
- bath oils, tablets and salts,
- foot powders and sprays,
- hair conditioners,
- · hair dyes and colours,
- · hair tints.
- pastes masks (mud packs),
- skin fresheners, and
- miscellaneous skin care preparations.

As the scheduling notice did not elaborate on the need to change current practices, and given that the proposal is for a chemical schedule rather than for a medicine/chemical schedule consideration, we assume that the proposal relates to a new use of thymol in either agricultural or veterinary medicine use.

Given that thymol is currently used in a wide range of products, we are disappointed that the public consideration on scheduling proposal was not limited to the specific new use. It would be more useful if industry could have been provided with the context of the scheduling proposal.

received a number of queries from member companies and from our international colleagues trying to understand the reason behind the proposal. As many of our members' products are available for self-selection for consumer, cosmetic or therapeutic use, the inclusion of the signal word 'POISON' on the label would not be acceptable. As a consequence, many of these products could be removed from the Australian market.

While we hope that the intent of the proposal is not to remove these products from the Australian market and our Members apprehensions are proven to be unnecessary, a more specific and detailed scheduling proposal would have removed the need for such unnecessary concerns. We also believe that better context for stakeholder comments would have led to a more efficient and effective consultation process.

As we are unaware of the concerns that led to the scheduling proposal we are unable at this point to respond to the concerns in any detail. However, as far as we are aware, no restrictions are imposed in the EU or the US for the use of thymol in our sectors' products.

Any schedule entry for thymol should be limited to the novel use of the substance to ensure that current products containing thymol are not inadvertently affected by the new schedule entry. If the committee believes that the risk posed by the current uses of thymol is unacceptable, we would urge that a more detailed scheduling proposal be put forward for full consideration and comment by stakeholders.

### ACCS/ACMS Joint-meeting: October 2012

### Hydrogen peroxide and carbamide peroxide

notes the proposal to amend the current scheduling entries for teeth whitening products containing 3% or more hydrogen peroxide or 9% or more carbamide peroxide.
has reviewed the second submission  Scheduling Secretariat published on the concerned with 'unsafe' teeth whitening practices, we note that little evidence has been put forward to support the suggestion that the current scheduling entries are inadequate and need to be changed.
For the last joint-meeting of ACCS and ACMS, provided comments on the now withdrawn first proposal by and put forward a solution to address what we thought was concern; the availability of teeth whitening products containing greater than 6% hydrogen peroxide or 18% carbamide peroxide.

Our solution was to add new Appendix C entries for hydrogen peroxide and carbamide peroxide to limit the access to teeth whitening products containing above 6% hydrogen peroxide or 18% carbamide peroxide. Schedule 5 and Schedule 6 entries would stay unchanged. The proposed wording for the Appendix C entries is as below:

Appendix C entries (new):

HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide **except** in preparations supplied through a registered dental practitioner.

CARBAMIDE PEROXIDE in teeth whitening preparations containing more than 18 per cent carbamide peroxide **except** in preparations supplied through a registered dental practitioner.

Please see our previous submission at Attachment 1 for the full reasoning behind this proposal.

We believe this solution should address the and the Australian Consumer and Competition Commission (ACCC) concerns over access to teeth whitening products containing high levels of hydrogen peroxide. We understand that the recent recalls of teeth whitening products by ACCC have all contained over 6% hydrogen peroxide, or 18% carbamide peroxide.

Whether the products containing above 6% hydrogen peroxide or above 18% carbamide peroxide should be available as a take home kit after the initial consultation with the dental practitioner should be up to the professional judgement of the dental practitioner. This is normal practice for prescription medicines; however we recognise that these products are not therapeutic and this is reflected in our proposal.

There are many prescription medicines currently available that are orally ingested, topically applied and some that are intravenously injected that the medical practitioner sees fit to supply to their patients to take home. We are concerned that the move to limit professional judgement for teeth whitening products is out of step with current practice for prescription medicines and in the future may impact on the scheduling decisions for prescription medicines.

view that no new evidence has been put forward by to support the proposal to limit access to teeth whitening products containing between 3% and 6% hydrogen peroxide (and 9% and 18% carbamide peroxide) to dental professionals only. We note that teeth whitening products containing between 3% and 6% hydrogen peroxide has been available in Australia for self-selection by consumers as a Schedule 5 poison for a number of years. We are unaware of any evidence to suggest that this is an unsafe practice. Given the lack of evidence, we support maintaining status quo for products containing between 3% and 6% hydrogen peroxide, and between 9% and 18% carbamide peroxide.

### ACCS/ACMS Joint-meeting: June 2012

### Hydrogen peroxide and carbamide peroxide

notes the proposal to schedule all hydrogen peroxide and carbamide peroxide containing teeth whitening products to Schedule 4.
has reviewed the submission by While it is apparent that
concerned with "unsafe" teeth whitening practices, it is not clear whether this is mainly a supply chain concern, or concerns with the current hydrogen peroxide/carbamide peroxide concentration directly retailed to consumers. As the Committee members are aware, teeth whitening products containing between 3% and 6% hydrogen peroxide are Schedule 5, and can be marketed to consumer with a signal heading "CAUTION". Products containing below 3% are not scheduled, and above 6% are Schedule 6 – due to the signal heading required for Schedule 6 products (POISON), teeth whitening products containing more than 6% hydrogen peroxide are essentially unavailable as self-select products.
We also understand that there have been a number of recalls of teeth whitening products by the Australian Consumer and Competition Commission (ACCC). However, as far as we are aware, none of the recalled products were meeting the labelling requirements set-out in the Poisons Schedule. We believe that the compliance activity was appropriate. However, we do not believe that such compliance activity on products that are currently not meeting their legal requirements should in any way in itself support changes to the current scheduling requirements.
We have attempted to break-down and examine proposal and its underlying concerns, and suggest a potential solution which we believe may address these concerns.
Cosmetic or therapeutic?
is concerned that a primarily therapeutic schedule entry has been proposed by for a cosmetic use ingredient. Teeth whitening is a purely cosmetic procedure and cannot be considered artificially therapeutic.
The Therapeutic Goods (Excluded Goods) Order No. 1 of 2011, declares that teeth whitening products are not therapeutic.

- "For the purpose of the *Therapeutic Goods Act 1989* and subject to section 5 of this Order, the following goods, being goods intended for use in humans, are declared not to be therapeutic goods:
  - a. hair bleaches, hair dyes, hair-colorants or hair-perming preparations;
  - b. household and personal aids, or furniture and utensils, for people with disabilities;
  - c. menstrual pads other than tampons;
  - d. incontinence pads, mattress overlays or mattress protectors;
  - e. dental bleaches or dental whiteners;
  - f. preparations that are applied topically to the nails to harden, or to deter biting of, the nails;
  - g. compressed gases when supplied for use as a power source for medical devices;

- h. piped medical gas systems installed to comply with AS 2896-1998/Amdt No. 1-1999 : Medical gas systems Installation and testing of non-flammable medical gas pipeline systems;
- i. disinfectant and sterilant gases;
- j. equipment for use in the purification or treatment of drinking water;
- k. sanitation, environmental control or environmental detoxification equipment;
- I. goods for the measurement of alcohol level either in body fluids or exhaled air;
- m. goods related to colostomy and ileostomy that are adhesive removers or non-medicated skin cleansers;
- n. goods for retail sale to the ultimate consumer for retention, cushioning or repairing of dentures;
- o. fresh viable human organs, or parts of human organs, for direct donor-to- host transplantation and used in accordance with applicable laws and standards;
- p. fresh viable human haematopoietic progenitor cells for direct donor-to-host transplantation for the purpose of haematopoietic reconstitution;
- g. human tissue and cells that are:
  - i. collected from a patient who is under the clinical care and treatment of a medical practitioner registered under a law of a State or an internal Territory; and
  - ii. manufactured by that medical practitioner, or by a person or persons under the professional supervision of that medical practitioner, for therapeutic application in the treatment of a single indication and in a single course of treatment of that patient by the same medical practitioner, or by a person or persons under the professional supervision of the same medical practitioner;
- r. reproductive tissue for use in assisted reproductive therapy."

If proposal was to be supported by the Committee, we strongly encourage that the Committee consider all the potential consequences of a Schedule 4 entry for cosmetic ingredients including the costs and benefits before making a recommendation to the Delegate to the Secretary of the Department of Health and Ageing.

### Concentration of hydrogen peroxide/carbamide peroxide in teeth whitening products

As far as we are aware, since the last scheduling decision for hydrogen peroxide/carbamide peroxide in 2005, no new information on hydrogen peroxide/carbamide peroxide toxicity/side-effects when used as teeth whitening agents has emerged.

According to the Record of Reasons from the June 2005 meeting of the then National Drugs and Poisons Scheduling Committee (NDPSC), the decision to exempt teeth whitening products containing up to 3% hydrogen peroxide from scheduling requirements was based on the US Food and Drugs Administration (FDA) review of hydrogen peroxide in oral care products which considered that hydrogen peroxide was safe at concentrations up to 3% for everyday use. This still stands as there has been no comprehensive review of its kind since 2005.

The decision to schedule teeth whitening products containing between 3% and 6% hydrogen peroxide to Schedule 5 was based on the European Commission's Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) opinion on hydrogen peroxide, which stated that products containing between 0.1% and 6% hydrogen peroxide were safe after an initial consultation with a dentist.

In September 2011, the European Commission adopted the new Directive on tooth whitening products, to be transposed into national legislation by each of the EU member states within 12 months.

- Only tooth whitening products with less than 0.1% hydrogen peroxide may be sold on the open market in the European Union.
- Products containing between 0.1%-6% hydrogen peroxide content may only be sold to dentists, and only under the following conditions:
  - The first use of each cycle of the product must be completed by a dentist as a clinical examination, after which use may be continued by the patient.
  - Use of these products by clients under 18 years of age is not permitted, even under supervision of a dentist.
- All tooth whitening products with hydrogen peroxide levels higher than 6% are banned in the European Union.

While these conditions appear more restrictive than Australian scheduling controls, it is important to remember that this was a significant relaxation of the rules for Europe – it is our understanding that teeth whitening products containing greater than 0.1% hydrogen peroxide were not legally available in the EU, not even for use by dentists, until the tooth whitening products Directive was implemented.

It is therefore impractical to compare our current scheduling requirements to the EU controls on teeth whitening products – because the EU relaxed its rules rather than tightened its controls, there is no epidemiological evidence from the EU to support consideration of more restrictive controls for teeth whitening products in Australia.

Since the scheduling decisions in 2005, teeth whitening preparations containing up to 6% hydrogen peroxide have been readily available for self-selection purchase by consumers. As far as we are aware, this has not caused major concerns. As the recent ACCC recalls of teeth whitening products highlight, products of concern to date have been teeth whitening products containing higher concentrations of hydrogen peroxide, and not meeting the labelling requirements set-out in the Poisons Schedule.

Last year, New Zealand's then Environment Risk Management Authority (ERMA), now the Environment Protection Agency (EPA), considered a proposal to restrict consumer access to teeth whitening products containing greater than 0.1% hydrogen peroxide, with more severe restrictions for products containing 3.6% or more hydrogen peroxide, including supply through dentists only.

While there was agreement that some controls were necessary for teeth whitening products containing hydrogen peroxide, ERMA did not agree with the proposed concentration cut-off or the proposed controls. ERMA's decision to continue to make available teeth whitening products containing 7% or less hydrogen peroxide (approximately 20% or less carbamide peroxide) for direct sale to public reflects Schedule 5 entry for hydrogen peroxide in teeth whitening products. The overall final decision by ERMA is closely aligned with Accord's proposal detailed in the next section. ERMA's decision on teeth whitening products is available from:

# http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/ERMA200472 ERMA200472%20 Decision%20FINAL%208%20Aug%2011.pdf

As there is no evidence to suggest that teeth whitening products containing up to 6% hydrogen peroxide is causing undue harm when made available for self-selection and use by consumers,

we believe that the current scheduling concentration cut-offs for teeth whitening products remain appropriate.

### Control of supply, concerns with non-compliance

The recalls by the ACCC and the proposal by appear to highlight a problem with compliance for some teeth whitening products. Free availability of teeth whitening products containing high levels of hydrogen peroxide is of some concern to human health. Where companies are not following the current legal requirements, we strongly support ACCC taking compliance action against those companies.

Accord also supports amendments to the Poisons Schedule if it is likely to:

- improve compliance,
- limit unsafe teeth whitening practices,
- continue to allow free availability of teeth whitening products with low levels of hydrogen peroxide (including toothpastes and mouthwashes), and
- continue allow professional judgement of dental practitioners.

Currently, the Poisons Schedule requirement to label teeth whitening products containing greater than 6% hydrogen peroxide with the signal heading "POISON" restricts these products from being marketed directly to consumers. However, they may still be available to non-dental practitioners who can perform "in-chair" teeth whitening procedures.

We believe that this potential problem could be addressed by making these products unavailable except to dental practitioners, by addition of an Appendix C entry. We propose the following wording.

**HYDROGEN PEROXIDE** (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide **except** in preparations supplied through a registered dental practitioner.

And,

**CARBAMIDE PEROXIDE** in teeth whitening preparations containing more than 18 per cent carbamide peroxide **except** in preparations supplied through a registered dental practitioner.

No changes to the current Schedule 5 and Schedule 6 entries would be required.

This would allow continued supply of teeth whitening products containing low concentrations of hydrogen peroxide, including toothpastes and mouthwashes. As Schedule 5 and Schedule 6 entries will be untouched, there will be no impact on companies supplying teeth whitening preparations containing low concentrations of hydrogen peroxide.

Meanwhile, products containing higher concentration of hydrogen peroxide (above 6%) will be restricted to supply through dental practitioners only. This will prevent non-dental practitioners gaining access to teeth whitening products with high concentrations of hydrogen peroxide while allowing flexibility of choice and professional judgement for dental practitioners. e.g. depending on the individual circumstances and suitability, the dentist can choose to use products with relatively higher concentrations of hydrogen peroxide for in-chair treatment, or choose products with relatively lower concentrations of hydrogen peroxide as take home kit with instructions.

### Propose amended schedule entry

Appendix C entries (new):

HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide **except** in preparations supplied through a registered dental practitioner.

CARBAMIDE PEROXIDE in teeth whitening preparations containing more than 18 per cent carbamide peroxide **except** in preparations supplied through a registered dental practitioner.

Schedule 5 entries (remain the same):

HYDROGEN PEROXIDE (excluding its salts and derivatives):

- (a) in hair dye preparations containing 12 per cent or less of hydrogen peroxide **except** in hair dyes containing 6 per cent or less hydrogen peroxide; or
- (b) in other preparations containing 6 per cent (20 volume) or less hydrogen peroxide **except** in preparations containing 3 per cent (10 volume) or less of hydrogen peroxide.

CARBAMIDE PEROXIDE in preparations containing 10 per cent or less of carbamide peroxide **except** in preparations containing 9 per cent or less carbamide peroxide.

Schedule 6 entries (remain the same):

HYDROGEN PEROXIDE (excluding its salts and derivatives) except:

- (a) when included in Schedule 5;
- (b) in hair dye preparations containing 6 per cent (20 volume) or less hydrogen peroxide; or
- (c) in other preparations containing 3 per cent (10 volume) or less hydrogen peroxide.

### CARBAMIDE PEROXIDE except:

- (a) when included in Schedule 5; or
- (b) in other preparations containing 9 per cent or less of carbamide peroxide.



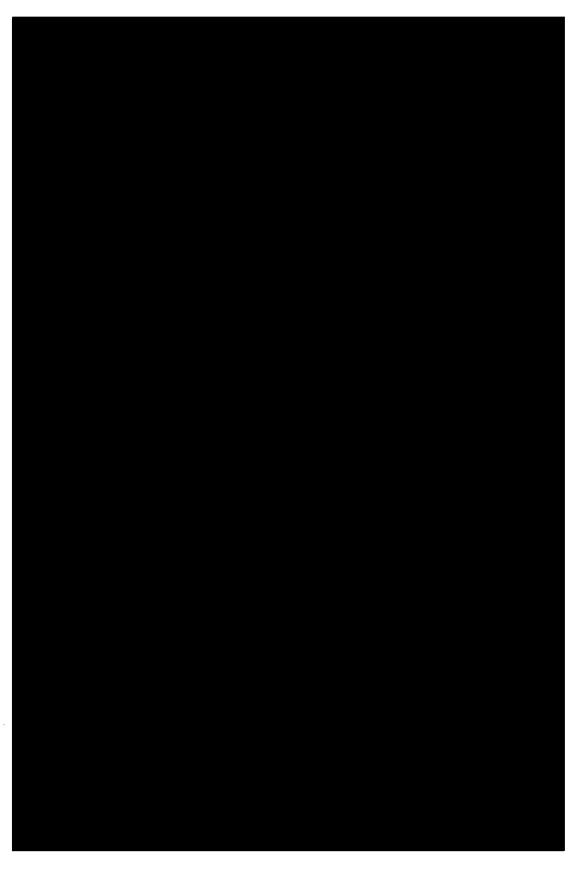
# Advisory Committee for Medicines Scheduling Meeting of 24 - 25 October 2012

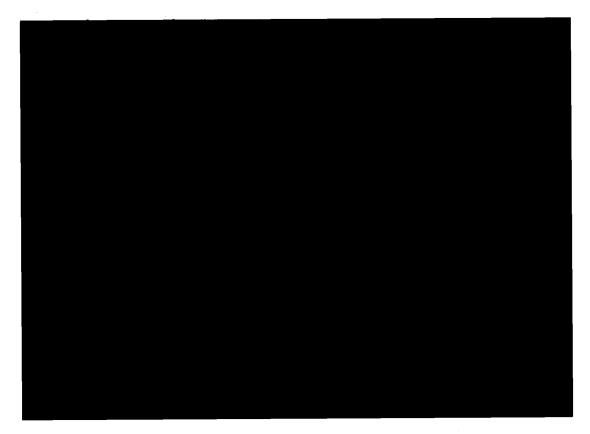
Comments by to the proposed amendments referred by the delegate for scheduling advice

Closing date for submission – 12 September 2012

# Background

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 24 – 25 October 2012.





# **Comments on Proposed Amendments**

has considered the proposed amendments to the SUSMP of relevance to with particular reference to Section 52E(1) of the Therapeutic Goods Act 1989 and the current Scheduling Policy Framework<sup>9</sup>. We provide comments for the following proposed amendments in line with the rationale for our position provided above:

- 1. Chloramphenicol
- 2. Diclofenac
- 3. Pantoprazole
- 4. Paracetamol when combined with ibuprofen
- 5. Vitamin D
- 6. Hydrogen peroxide and carbamide peroxide

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

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

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

<sup>&</sup>lt;sup>4</sup>http://www.guild.org.au/Guild\_Training/Pharmacy+Assistants+Training/A+Career+in+Pharmacy/Ask+Assess+Advise.page

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

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

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

<sup>9</sup> NCCTG Scheduling Policy Framework for Medicines and Chemicals – Effective date 1 July 2010

1. Chloramphenicol – Proposal to reschedule chloramphenicol for ophthalmic use from Schedule 3 to Schedule 4.

The decision to list chloramphenicol in Schedule 3 was carefully considered by the National Drugs and Poisons Scheduling Committee (NDPSC) in October 2009 and again by the ACMS in February 2011. Stands behind the decision taken by the NDPSC and supported by the ACMS in listing chloramphenicol as a Schedule 3 medicine.

It is difficult to provide specific commentary on this proposal without understanding the reasons behind it. We are aware of an anecdotal report of alleged inappropriate supply by pharmacists which have resulted in the near-loss of sight for a patient. While acknowledging the seriousness of the case, we are unaware whether this is an isolated event or to what extent the adverse health outcomes definitively relate to the pharmacist intervention. While we agree that the supply of any medicine that results in adverse health outcomes is to be avoided as much as possible, we believe that reversing the decision to allow greater consumer access to chloramphenicol eye products with the assistance of a pharmacist is a retrograde action.

We have previously put forward the following points and we believe these remain relevant:

- Topical [ocular] chloramphenicol is generally well tolerated, and adverse effects such as hypersensitivity, burning, and stinging sensations are uncommon<sup>10</sup>.
- Community pharmacy is often the first place that patients with conjunctivitis go for assistance. Pharmacists currently triage patients with conjunctivitis on a regular basis to determine the appropriate course of action.
- Pharmacists currently refer patients to the GP where there are complications or where the pharmacist is unsure or concerned
- Chloramphenicol is the gold standard against which new antibiotic eye drops are compared and will be effective against nearly all cases of acute bacterial conjunctivitis in adults and children who present in the pharmacy<sup>11</sup>.
- There are potential savings to both the Medical Benefits Scheme (MBS) and Pharmaceutical Benefits Scheme (PBS).
- Patients have quicker and easier access to effective treatment for the treatment of minor bacterial eye infections.
- A protocol has been developed by the Pharmaceutical Society of Australia (PSA) to assist pharmacists with the appropriate and responsible supply of chloramphenicol.
- Pharmacists have familiarity with supplying non-prescription antibiotic eye products such as Bleph 10<sup>®</sup> (sulfacetamide) and Brolene<sup>®</sup> (propamidine).

In addition to these, we would also like the committee to consider the following points:

• Do reports of inappropriate supply by pharmacists definitively demonstrate that adverse outcomes are due to the pharmacist's intervention? While does not condone pharmacy practice that encourages a pharmacist to shirk their professional responsibilities, without the full knowledge of the complaints or

complainants, it is difficult to assess to what degree a pharmacist may or may not be at fault.

With the anecdotal report of which we are aware, we understand the issue was with a pharmacist supplying chloramphenical eye products to a person with contact lenses. While this is contrary to recommendations in the pharmacy protocol, we do not know to what extent the pharmacist was aware that the person used contact lenses. We do not know whether the pharmacist enquired or what they were told. The unfortunate health outcome may have been a result of the consumer not understanding or following the pharmacist advice.

- Decisions to re-schedule should not be based on isolated reports:
  - O Is there an increase in the extent of adverse outcomes reported from pharmacist supply of chloramphenicol?
  - o Is the extent of adverse outcomes reported significantly more than that from prescribed supply by medical practitioners?
- In 2011, as part of the Mystery Shopper program under QCPP, 166 pharmacies had been randomly assessed on the non-prescription supply of chloramphenical and had performed well, achieving one of the highest random assessment scores for a medicine supply.<sup>12</sup>

Rather than reversing the scheduling decision for chloramphenicol, would like consumers to continue to have access to a safe and effective non-prescription medicine when used appropriately. This can be achieved through more effort being put into education and supporting pharmacists and consumers in the use of Schedule 3 medicines. Should retaining chloramphenicol in Schedule 3 be supported, it would be appropriate to review the pharmacy protocol and consider the need for additional training programs. would be pleased to work with relevant professional bodies, including ophthalmological organisations, to ensure community pharmacy is appropriately trained and resourced.

A common complaint from pharmacists is that consumers have a feeling of entitlement to access Schedule 3 medicines because they are available without a prescription. would be pleased to also work with other relevant bodies to assist in managing consumer expectations so that they have a greater understanding that pharmacists must ask questions to assess whether the supply of a Schedule 3 medicine is both safe and appropriate.

### Position

With consideration of the above factors, does not support the proposal to reschedule chloramphenicol from Schedule 3 to Schedule 4.

<sup>10</sup> Lam RF, Lai JSM, Ng JSK et al; Topical chloramphenicol for eye infections; HKMJ Vol 8 No 1 Feb 2002; 44-47

<sup>&</sup>lt;sup>11</sup> Marvyn Elton; The Pharmaceutical Journal (Vol 274) 11 June 2005; 725-728

<sup>&</sup>lt;sup>12</sup> Quality Improvement in Pharmacy, The 2012 Report to the National Coordinating Committee on Therapeutic Goods; The Pharmacy Guild of Australia; 31 March 2012

#### ACMS - October 2012

2. Diclofenac – Proposal to amend the Schedule 2 entry for diclofenac when presented in a transdermal delivery system for topical use (containing 140 mg or less).

While diclofenac is readily available in preparations for both oral and topical use, is unsure whether this proposal relates to 'transdermal use' or 'topical use' as defined within the SUSMP. The primary difference in the application is the intention of systemic effect with 'transdermal use' versus localised effect with 'topical use'.

is not aware of any diclofenac transdermal delivery system proposed for supply in Australia and has not been approached to discuss the introduction of this new delivery system. If the intent is for a transdermal application with systemic effect, then we believe this should be scheduled to facilitate access to advice from a health care professional. While pharmacists can familiarise themselves with clinical product information for Schedule 3 medicines, products listed in Schedule 2 should ideally be supported by training and information resources for pharmacy assistants. We are unaware of any formal discussion with the pharmacy sector regarding professional support in the form of training, information or professional resources for either pharmacists or pharmacy assistants.

Although the 'topical use' of diclofenac is relatively safe, without knowing what transdermal system is proposed, we cannot yet consider the pharmacokinetics and comment on potential risks or extent of possible systemic side-effects.

We note a recent study<sup>13</sup> compared oral diclofenac (150 mg per day) against a transdermal diclofenac patch (100 mg per day) for post-operative pain control. This study demonstrated similar efficacy between the two delivery systems and observed greater patient comfort and less systemic side-effects with the transdermal patch. However, the transdermal patch in this study was used for systemic rather than local pain control.

With this in mind and given the lack of consultation regarding potential support for the pharmacy sector, believes that Schedule 3 would be the more appropriate schedule for a new delivery system. Given that low-dose oral diclofenac is listed in Schedule 2 and topical diclofenac is generally exempt from scheduling, a proposal for listing in Schedule 2 may be supported in the future when we have a greater understanding about any proposed product/s and the level of commitment to supporting and resourcing the pharmacy sector.

### <u>Recommendation</u>

With consideration of the above factors, recommends a Schedule 3 entry for diclofenac when formulated for transdermal use.

<sup>&</sup>lt;sup>13</sup> Comparison of transdermal diclofenac patch with oral diclofenac as an analgesic modality following multiple premolar extraction in orthodontic patients: A cross over efficacy trial; H Bhaskar, P Kappor & Ragini; Contemporary Clinical Dentistry, v1(3); Jul-Sep 2010

3. Pantoprazole – Proposal to amend the Schedule 3 entry for pantoprazole 20 mg to increase the maximum allowable pack size from 14 to 28 dosage units.

does not support the proposal to increase the pack size for pantoprazole when included in Schedule 3. We also note the repetitiveness of these proposals for proton pump inhibitors (PPI) as a similar proposal for omeprazole was considered by the ACMS in July 2012 and was not supported.

maintains the same position for pantoprazole as it did for omeprazole and believes it applies to PPIs as a category:

- We support the availability of PPIs as Schedule 3 medicines, requiring pharmacist intervention to ensure their safe and appropriate use.
- We believe any proposal to increase the non-prescription pack size of PPIs is contrary to the intent of listing PPIs in Schedule 3 to facilitate consumer access for short-term relief of acute heartburn and gastro-oesophageal reflux disease (GORD) symptoms.
- Larger packs of pantoprazole are available as prescription only medicines and packs of 30 of the 20 mg and 40 mg strengths are subsidised on the PBS. Consumers requiring larger quantities or continuous therapy should be encouraged to consult a prescriber for review and assessment.

does not believe there is any public benefit in providing larger pack sizes of PPIs without a prescription. We believe in fact that this could significantly impact on consumers seeking medical review for more chronic symptoms. It would also make monitoring by pharmacists more difficult, particularly as supply of Schedule 3 medicines are not recorded.

Where individual circumstances justify the clinical need, a pharmacist can supply two packs of 14 in a single transaction. However, consumer requests for multiple packs would prompt questions from a pharmacist to assess the circumstances and consider whether medical referral is warranted.

While there may be some small financial benefit for consumers to have a double treatment pack available, this may be off-set by the fact that non-prescription purchases cannot be recorded on a person's Safety-Net, particularly impacting high PBS users with GORD.

### Recommendation

recommends that Schedule 3 is appropriate for PPIs, including pantoprazole, for packs of up to 14 days supply, and larger pack sizes should remain as Schedule 4.

### ACMS - October 2012

4. Paracetamol when combined with ibuprofen – Proposal to reschedule paracetamol 500 mg when combined with ibuprofen 200 mg from Schedule 3 to Schedule 2 for pack sizes of 12 units or less.

Proposal to also include Schedule 3 paracetamol when combined with ibuprofen in Appendix H.

supports both proposals, with consideration of the following points:

- The use of paracetamol in combination with a non-steroidal anti-inflammatory (NSAID) has been demonstrated to provide additive pain-relief. The availability of a combination product provides consumers and clinicians with an effective and cost-effective product that:
  - o simplifies the dosage schedule for both active ingredients
  - o improves adherence
  - o improves efficacy without increasing adverse effects
  - o decreases adverse effects without loss of efficacy
- Although having relatively safe profiles, the relative risk of these medicines, particularly in combination<sup>16</sup>, warrants consumers having access to advice and support from a pharmacist. This is achieved by inclusion within either Schedule 2 or Schedule 3 of the SUSMP.
- believes that small packs of 12 units of an ibuprofen/paracetamol combination product meet the criteria for Schedule 2 as defined within the Scheduling Framework.
  - O The quality use of the product and management of identified risks can generally be achieved by labelling and packaging and information provided by a pharmacy assistant, while the pharmacist is available for referral if required.
  - O The use of paracetamol and ibuprofen, either alone or in combination, is relatively safe when taken within their recommended dosage range for short-term pain relief.
  - O Neither paracetamol nor ibuprofen have any significant abuse potential, and the availability of a combination analgesic in Schedule 2 may also assist in reducing the reliance many patients have had to date on combination analgesics containing codeine.
- Under current scheduling arrangements, small packs containing either paracetamol or ibuprofen as a single active ingredient are exempt from scheduling and larger pack sizes included in Schedule 2 of the SUSMP.
  - Although ibuprofen can cause upper gastrointestinal side-effects and should be avoided in people with aspirin-induced asthma, the greatest risks with an ibuprofen/paracetamol combination product are:
  - o the potential for cardiovascular harm from the use of NSAIDS
  - o the potential for adverse effects on renal function from the use of NSAIDs
  - o the potential for adverse effects on liver function from inadvertent overdosage on paracetamol by taking different paracetamol containing products at the same time

While these risks are greater for people with chronic conditions taking other medicines which may interact with ibuprofen and/or paracetamol as well as more vulnerable population groups such as the elderly, they can be ameliorated

through appropriate warnings on the pack and by facilitating access to health professional advice when required.

• The availability of a safe and effective ibuprofen/paracetamol combination product in Schedule 2 would provide consumers with greater access to effective medicines for the treatment of pain and fever in self-diagnosed self-limiting conditions.

As with any Schedule 2 medicine, pharmacy assistants will need suitable training to ensure they can adequately triage patients and refer to the pharmacist when appropriate. This has been exemplified in the UK with training available to pharmacy assistants for the product Nuromol<sup>®17</sup>. would be pleased to collaborate with the sponsor and other relevant bodies to assist in developing and providing appropriate training and practice resources to the pharmacy sector.

- pelieves packs of an ibuprofen/paracetamol combination product in quantities greater than 12 units meet the criteria for Schedule 3 as defined within the Scheduling Framework.
  - O Patients requiring ongoing treatment of painful or inflamed conditions benefit from the intervention of a health professional such as a pharmacist to assess the situation and ensure there are no complications that would warrant medical review.
  - O Listing larger pack sizes in Schedule 3 also provides an opportunity for the pharmacist to ensure that the medicine remains effective for the condition being treated and is being used appropriately. The pharmacist can also check that the patient is not doubling up on other paracetamol based products or suffering adverse effects from ibuprofen use.
- also believes that should ibuprofen/paracetamol combination products remain in Schedule 3 for all pack sizes, pharmacists are well prepared to manage analgesic requests, including product based requests that would result if the products were able to be advertised directly to consumers.

supports the proposal for the inclusion of small packs of 12 units of ibuprofen/paracetamol combination products in Schedule 2. believes Schedule 3 is appropriate for larger pack sizes to facilitate pain management in consultation with a health care professional. If the decision is to maintain the current schedule status of Schedule 3 for all pack sizes, supports the inclusion of ibuprofen/paracetamol combination products in Appendix H.

Position

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<sup>&</sup>lt;sup>14</sup> HF Miranda, MM Puig, JV Prieto, G Pinardi; Synergism between paracetamol and nonsteroidal anti-inflammatory drugs in experimental acute pain; Pain 121 (2006) 22-28; <a href="www.elsevier.com/locate/pain">www.elsevier.com/locate/pain</a>

 $<sup>^{15}</sup>$   $\overline{\text{AF}}$  Merry, RD Gibbs, J Edwards et al; Combined acetaminophen and ibuprofen for pain relief after oral surgery in adults: a randomized controlled trial

<sup>16</sup> Therapeutic Guidelines - Analgesic; Paracetamol; Sept 2007

<sup>17</sup> http://www.nuromol.co.uk/?

5. Vitamin D – Proposal to a new Schedule 3 entry to allow a weekly dose of Vitamin D up to 175 micrograms (7000IU) per recommended dose.

Proposal to also include Schedule 3 Vitamin D in Appendix H.

does not support either proposal.

Although more research is needed for conclusive evidence, low vitamin D has been linked to multiple sclerosis, diabetes (type1 and type 2), various types of cancers (particularly colon cancer), heart disease, mental health conditions including schizophrenia, worse outcomes in stroke, altered immunity and other autoimmune diseases. <sup>18</sup>

Vitamin D is synthesised in the skin on exposure to UV light. The people most at risk of low vitamin D levels are those with limited sun exposure, such as frail or elderly people (particularly those with limited mobility), people who wear extensive covering clothing for religious and cultural reasons, people who avoid sun exposure for cosmetic or health reasons and people who are hospitalised or institutionalised for long periods. The need for vitamin D supplementation varies as does the dosage amount required and the duration for supplementation.

There is a lot of conflicting information being provided to health care professionals as well as consumers. The introduction of a vitamin D product requiring only weekly dosing has many advantages, including:

- simplified dosage schedule
- o improved adherence
- o simplified packing requirements for dose administration aids

But there are also risks, such as:

- o inadvertent overdose from taking the medicine daily instead of weekly
- o poorer adherence from forgetting to take the weekly dose

If a weekly dosage vitamin D product was available as a Schedule 3 medicine, would like to see appropriate training and professional support resources for pharmacists. As we are unaware of any formal discussion with the pharmacy sector regarding proposed professional assistance, we are reluctant to support the proposal and we cannot advise the committee of any intent for sector support.

Without knowing the background for this proposal, cannot justify the need for a high-dose weekly vitamin D product without prescription. Those people who would most benefit are likely to be on multiple medicines and routinely seeing a prescriber, therefore access is unlikely to be a significant issue.

### Recommendation

With the scant background information available to us, recommends that Schedule 4 remains the appropriate schedule for high-dose vitamin D medicines with a weekly dose schedule.

<sup>18</sup> http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Vitamin D

6. Hydrogen peroxide and carbamide peroxide – Proposal to exempt teeth whitening products containing 3% or less of hydrogen peroxide and 9% or less of carbamide peroxide from schedule.

Proposal for teeth whitening products containing between 3% - 6% of hydrogen peroxide and between 9% - 18% of carbamide peroxide to be only legally accessible from a registered health practitioner. Patients to be permitted to use these products 'at home' only after consultation with their registered health practitioner.

Proposal for teeth whitening products containing more than 6% hydrogen peroxide and more than 18% carbamide peroxide be legally accessed by registered health practitioners.

supports the intent of these proposals, but has concerns with how they are implemented. We note that 'dental bleaches' and 'dental whiteners' are not regarded as therapeutic goods<sup>19</sup> and Schedules 2, 3 and 4 of the SUSMP are designed for 'medicines' which are defined as poisons for therapeutic use in the SUSMP.

Some pharmacies provide in-pharmacy teeth whitening services, subject to relevant legislation and professional standards. supports pharmacies providing in-pharmacy teeth whitening services as long as:

- the service is supervised by a pharmacist or appropriately qualified person following clearly defined procedures and protocols which address assessment, documentation, informed consent and infection control and
- the service is provided in a designated treatment area within the pharmacy

also notes that with over 90% of community pharmacies participating in QCPP, there is an expectation for pharmacies to have quality assurance procedures in place for all in-pharmacy services. Believes that all tooth whitening service providers should be adequately trained and have appropriate quality assurance processes in place.

recognises that good dental health relies on the advice and support of a dentist. Appropriate guidelines for teeth whitening can ensure community pharmacy is an appropriate referral point to a dentist when necessary. Teeth whitening is a cosmetic service and is not a substitute for good dental hygiene.

is aware of the safety issues identified by the Australian Competition and Consumer Commission (ACCC) and their recommendation that DIY teeth whitening kits containing products with concentrations in excess of 6% hydrogen peroxide or 18% carbamide peroxide are unsafe and should not be supplied to consumers.<sup>20</sup>

A variety of teeth whitening preparations containing carbamide peroxide or hydrogen peroxide in varying concentrations are available without prescription for self-administration, including via the internet. One website<sup>21</sup> identified the following products promoted for sale via the internet:

PRODUCT	Available Strengths	
PRODUCI	Carbamide Peroxide	Hydrogen Peroxide
Nite White ACP	10%, 16% & 22%	
Nite White Turbo ACP		6%
Day White ACP	38%	6%, 7.5% & 9.5%
Colgate Visible White		6%
SDI Polanight	10% & 16%	
SDI Poladay	35%	3%, 7.5% & 9.5%
Zoom Weekender Kit		6%
Opalescence PF	10%, 15%, 20% & 35%	
Opalescence Oh!	10%, 15%, 20% & 35%	
Dr Collins All White	10%, 16% & 22%	
Opalescence Treswhite Supreme		
Plus White Whitening Gel	·	6%
White and Bright	10%, 16% & 22%	

In addition to this, there are a number of tooth whitening pastes/gels available through pharmacies and supermarkets within common branded product ranges such as Sensodyne<sup>®</sup>, Colgate<sup>®</sup> or Macleans<sup>®</sup>. It is unaware to what extent these may also be impacted as it is difficult to access information about active ingredients, even from company websites. Consideration should still be given to any potential impact on these products as part of the review.

Currently, tooth whitening products containing 3-6% hydrogen peroxide or 9-18% carbamide peroxide are in Schedule 5 of the SUSMP, and products containing greater amounts are in Schedule 6. The safe and proper use of these products is managed through packaging and labelling arrangements. has serious concerns with relying solely on packaging and labelling information to manage the safe and proper use of medicines and other potentially risky products. We have previously noted that many consumers will read limited amounts of label information, if at all. A US survey indicated that 34% of Americans read the label for the active ingredient when they buy a non-prescription medicine for the first time and 22% read the label for instructions when they use non-prescription medicines for the first time. <sup>22</sup> If this translates to potentially dangerous cosmetic products such as tooth whiteners, this is cause for major concern.

### **Position**

agrees in-principle that the sale of tooth whitening products should be accompanied by accurate and objective advice from qualified personnel. However, the level of qualification needs to be determined. We would like to understand more what is meant by the term 'registered health practitioner' and how access would be restricted if not utilising Schedules 2, 3 and 4 of the SUSMP before we can support the proposals as presented.

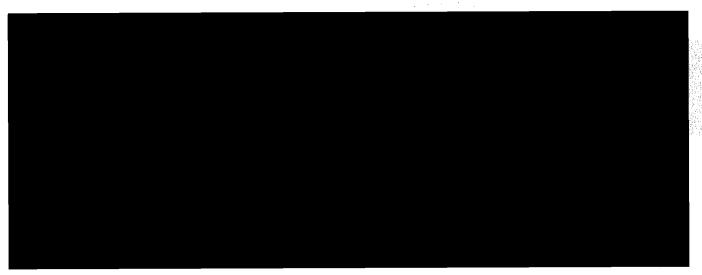
1111.

<sup>&</sup>lt;sup>19</sup> Therapeutic Goods (Excluded Goods) Order No.1 of 2011; 1 June 2011; <a href="http://www.tga.gov.au/industry/legislation-excluded-goods-order-1101.htm">http://www.tga.gov.au/industry/legislation-excluded-goods-order-1101.htm</a>

<sup>&</sup>lt;sup>20</sup> http://www.accc.gov.an/content/index.phtml/itemId/1021472 [accessed May 2012]

<sup>&</sup>lt;sup>21</sup> http://www.teethwhitening.com.au/ [accessed May 2012]

<sup>&</sup>lt;sup>22</sup> Op Cit Attitudes and beliefs about the use of over-the-counter medicines



### **Purpose**

makes this submission in relation to items referred by the Delegate for scheduling advice to the October 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS).

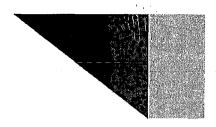
### Recommendations

ы	ovides the following recommendations to the ACMS.
-	·
1.	strongly advocates for more detail to be made available in the pre-meeting notices

- strongly advocates for more detail to be made available in the pre-meeting notices, similar to
  the level of information currently being provided by the New Zealand Medicines Classification
  Committee. This will promote greater transparency and enable potential respondents to provide
  due consideration of proposed rescheduling changes.
- 2. **Chloramphenicol**. does not support the proposal to reschedule chloramphenicol for ophthalmic use from Schedule 3 (S3) to Schedule 4 (S4).
- 3. **Diclofenac.** suggests the definition of "transdermal use" in the *Poisons Standard 2012* requires amendment.
- 4. **Mometasone**. does not support the proposal to reschedule mometasone for topical use (0.1% or less in packs of 30 g or less, for adults and children 12 years and over) from S4 to S3.
- 5. **Pantoprazole**. does not support the proposal to amend the S3 entry for pantoprazole 20 mg to increase the maximum allowable pack size from 14 to 28 dosage units.
- 6. Paracetamol with ibuprofen. supports the inclusion of paracetamol 500 mg when combined with ibuprofen 200 mg in pack sizes of 12 units or less in Schedule 2 (S2).
- 7. does not support the inclusion of paracetamol when combined with ibuprofen in Appendix H.
- 8. **Hydrogen peroxide and carbamide peroxide**. suggests that the second part of the proposal requires amendment around the use and context of "registered health practitioner" so that the responsibilities of pharmacists can be clarified.



### Specific comments



### Chloramphenicol

believes a scheduling change to chloramphenicol for ophthalmic use from S3 to S4 is not warranted. Some of the reasons are outlined below.

- Chloramphenicol remains a safe and effective option for the treatment of acute bacterial
  conjunctivitis. Consumer access through pharmacist intervention confers advantages in allowing
  therapy to be commenced as early as possible.
- No increase in significant or atypical adverse events has been reported to the Therapeutic Goods Administration (TGA) since chloramphenicol was rescheduled from S4 to S3 in May 2010.
- Is not aware of any new information or evidence on any problems associated with increase in resistance.
- guidance document on the provision of chloramphenicol as a *Pharmacist only medicine* has been well accepted by pharmacists and is being used appropriately to support practice.
- receives comments on the guidance document from time to time and these will be considered as part of the quality assurance and improvement processes associated with these documents. For example, some issues where advice could be strengthened or supplemented in the document or other strategies that could be suggested include:
  - additional detail on the reason for referral of children under two years of age although
    this advice is currently referenced, has become aware that the source document is
    no longer readily available;
  - referral of consumers who wear contact lenses;
  - o information around requests for off-label use for example, pharmacists often encounter consumers who request the product for use in the ear; and
  - appropriate communication messages and strategies for example, pharmacists routinely encounter parents of infants who are not willing to accept the advice that medical referral is required because, anecdotally, childcare centres will not provide care unless treatment has been commenced on chloramphenicol.
- does not support the proposal to reschedule chloramphenicol for ophthalmic use from S3 to S4.

### **Diclofenac**

notes the inclusion of the following definitions in the Poisons Standard 2012:

"Transdermal use" means application to the skin primarily for systemic effect.

"Topical use" means application of a poison for the purpose of producing a localised effect on the surface of the organ or within the tissue to which it is applied.

The use of a transdermal drug delivery system to achieve a localised effect is not yet common although it is available, for example with local anaesthetics. Transdermal patches of diclofenac are reportedly available overseas. The purpose of some of these products appears to relate to the systemic effects. A product for acute pain relief is also available and a report cites that the diclofenac transdermal patch "exerts its pharmacologic effects through localized accumulation at the application site rather than from systemic absorption".

These examples highlight that the current definitions in the Poisons Standard may need to be reviewed and revised. For example, it may be logical or appropriate for the mode of application to be separated from the intended outcome (systemic vs. localised effect) in the definition.

In relation to the proposed rescheduling application, further information is required for to be able to provide due consideration of relevant issues. For example, if the transdermal drug delivery system is designed to produce a localised effect, what is the level of systemic absorption and therefore potential side effects and drug interactions? Potential cardiovascular or gastrointestinal risks associated with the use of nonsteroidal anti-inflammatory drugs will be influenced by the desired effect (systemic or local) but it is not possible to assess this with the level of detail of information provided.

reiterates its view that the lack of access to information, apart from the brief statement provided in the meeting notice, is a significant barrier in providing proper consideration of the scheduling proposals. We do not believe it is appropriate that those who wish to provide feedback through the public consultation process are denied access to more specific, non-confidential information and left to speculate on what the fundamental objective and possible outcomes of the proposal may be. We do not believe this constitutes due process and significantly disadvantages those who are invited to respond.

strongly advocates for greater transparency and would support a process similar to that which currently operates for the Medicines Classification Committee in New Zealand.

### Mometasone

Topical corticosteroids are widely available and used primarily for their anti-inflammatory effects in the management of many dermatological conditions. The efficacy and potential adverse effects of topical preparations depend on factors such as: potency of corticosteroid; concentration of preparation; product formulation; application method, frequency and duration; patient's age; site of application; and nature and extent of the skin disorder.

Within a four level classification (mild, moderate, potent and very potent), mometasone (0.1% as furoate) is regarded as a 'potent' corticosteroid.<sup>4</sup> Mild corticosteroids are readily available and intermittent therapy is recommended. Side effects can generally be minimised or avoided by correct use of the product.

<sup>&</sup>lt;sup>1</sup> U.S. National Library of Medicine, National Institutes of Health. MedlinePlus. Diclofenac transdermal.

Patel KN, Patel HK, Patel VA. Formulation and characterization of drug in adhesive transdermal patches of diclofenac acid. Int J Pharm Pharm Sci 2012;4(1):296–9.

Moody ML. Topical medications in the treatment of pain. Pain Medicine News Special Edition 2010 Dec;15–21.

Sansom LN, ed. Australian pharmaceutical formulary and handbook. 22nd edn. Canberra: Pharmaceutical Society of Australia; 2012. pp. 157–9.

However, the risk of adverse effects and possibility of rebound on cessation of treatment increases with increasing potency of the corticosteroid.

For some dermatological conditions, inital treatment will warrant a potent corticosteroid (e.g. mometasone). These situations would generally involve a consultation with, and a prescription from, a GP or dermatologist. Generally, both the potency of corticosteroid and frequency of use should be reduced as the condition improves and prolonged use is not recommended. Where chronic use is necessary, this would be under medical advice with appropriate supervision or monitoring.

Over-the-counter (OTC) availability of mometasone will enhance consumer access, however this is not thought to provide any advantage for chronic use as appropriate approvals through the Pharmaceutical Benefits Scheme would be more cost-effective. wider availability of a potent corticosteroid may lead to prolonged or inadvertent inappropriate use by consumers and has the potential to result in adverse outcomes. This is not in the best interests of patient safety.

In summary does not support the proposal to reschedule topical mometasone from S4 to S3.

### **Pantoprazole**

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In relation to the proposal to amend the S3 entry to increase the maximum allowable pack size from 14 to 28 dosage units, reiterates the following points we have made in previous submissions.

- The provision of a 14-day pack size is consistent with the general recommendation for initial therapy<sup>5</sup> and would be adequate for the consumer's response to treatment to be assessed in the first instance. Referral is recommended if long term use or a higher dose is required.
- Referral for further investigation is recommended if two weeks of continuous therapy has failed to adequately control symptoms, if symptoms recur following an initial course of therapy, or if the consumer exhibits any alarm symptoms.<sup>6</sup>
- believes vigilance is warranted with the use of PPIs generally as there have been reports of an increased rate of community-acquired pneumonia and a two- to three-fold increase in risk of *Clostridium difficile* infection. While these possible adverse effects are likely to be more pertinent with the use of PPIs at higher doses and/or long term, the risk of *C. difficile* infection may be a noteworthy caution given reports of an increase in rate overseas and evidence of a new strain of *C. difficile* in Australia.

In summary, does not support the proposal to amend the maximum allowable pack size for S3 pantoprazole to 28 dosage units.

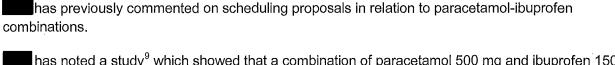
<sup>&</sup>lt;sup>5</sup> Sansom, *op. cit.*, pp. 513–6.

Sansom, *op. cit.*, pp. 570–3.

National Prescribing Service. Pharmacy practice review: a counselling and action resource. Quality use of prescription PPIs. April 2009.

Stuart RL, Marshall C. Clostridium difficile infection: a new threat on our doorstep. Med J Aust 2011;194:331–2.





has noted a study<sup>9</sup> which showed that a combination of paracetamol 500 mg and ibuprofen 150 mg provided superior pain relief (after oral surgery) to paracetamol or ibuprofen alone. We also noted the inherent safety profile of each substance is well established.

In considering paracetamol 500 mg in combination with ibuprofen 200 mg, overall believes the Factors for Pharmacy Medicines listed in the Scheduling Policy Framework are appropriately met.

A combination product however, carries a wider spectrum of precautions and potential side effects or interactions. In addition, there are many other products widely available to consumers with one of these active ingredients. This presents many more opportunities for inadvertent duplication of the ingredients and therefore a risk of adverse outcomes.

The potential for serious side effects arising from the use of paracetamol and ibuprofen are well recognised and ways to minimise adverse outcomes are regularly being explored. For example, the *TGA* medicine labelling and packaging review has proposed the inclusion of an additional warning statement on packets of medicines containing paracetamol (Recommendation 1.6). A similar, separate recommendation was included for ibuprofen-containing medicines (Recommendation 1.7).

The National Prescribing Service (NPS: Better choices, Better health) has also provided a focus on educating consumers about knowing the active ingredients of their medicines and checking before taking medicines so that they do not "double up" on the same ingredient through different products.

Given this environment, believes it is preferable to restrict any additional Appendix H listings at this time for paracetamol and ibuprofen.

In summary, supports the inclusion of paracetamol 500 mg when combined with ibuprofen 200 mg in S2 for pack sizes of 12 units or less, however, S3 Appendix H listing is not supported.

## Hydrogen peroxide and carbamide peroxide

believes the three part proposal on the scheduling of hydrogen peroxide and carbamide peroxide is likely to be associated with the recent clarification issued by the Australian Competition and Consumer Commission (ACCC) on the safety of self-administered teeth whitening products. <sup>10</sup> Essentially the ACCC's position is that do-it-yourself teeth whitening products containing concentrations of more than 6% hydrogen peroxide or more than 18% carbamide peroxide are unsafe for use by consumers in their home.

<sup>&</sup>lt;sup>9</sup> Merry AF, Gibbs RD, Edwards J, et al. Combined acetaminophen and ibuprofen for pain relief after oral surgery in adults: a randomized controlled trial. Br J Anaesth 2010;104(1):80–8.

Australian Competition and Consumer Commission. Product safety bulletin: Safety of do-it-yourself (DIY) teeth whitening products for at home use. 2012; Jul.

understanding is that the first and third parts of the scheduling proposal covering lower and higher concentration products, respectively, would appropriately reflect information contained in the ACCC bulletin.

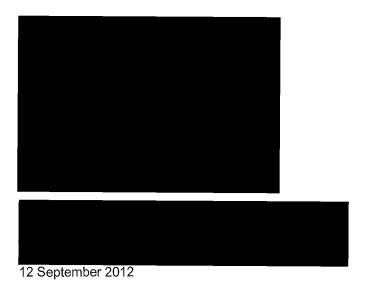
The second part of the proposal in the scheduling notice states the following.

Proposal for teeth whitening products containing between 3% - 6% of hydrogen peroxide and between 9% - 18% of carbamide peroxide to be only legally accessible from a registered health practitioner. Patients to be permitted to use these products 'at home' only after consultation with their registered health practitioner.

Under the Australian Health Practitioner Regulation Agency, pharmacists are included as 'registered health practitioners'. The first sentence above, therefore, seems logical since some pharmacist proprietors may choose to supply teeth whitening products (for at home use) through their pharmacy business and this would be permitted within the relevant concentration ranges.

However, the second part of the sentence is not clear to particularly around what would constitute a "consultation with their registered health practitioner" given this could capture a multitude of dental and non-dental health practitioners. For example, it could mean 'a consultation or service provided by a registered dental practitioner in a dental practice' or it could refer to 'the provision of information by a pharmacist to the consumer in a pharmacy premises'.

would suggest more specific wording is required so that unambiguous advice can be communicated to pharmacists regarding their responsibilities as proprietors, <sup>11</sup> managers or staff if home-use teeth whitening products are supplied through their pharmacy.



<sup>&</sup>lt;sup>11</sup> Pharmacy Board of Australia. Guidelines on responsibilities of pharmacists when practising as proprietors. 2010; Dec.

11<sup>th</sup> September 2012

The Secretary Scheduling Secretariat GPO Box 9848 CANBERRA ACT 2601 SMP@health.gov.au

Re: Invitation for public comment - ACMS and ACCS meetings, October 2012
2. Proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling (ACMS)

the Advisory Committee on Medicines Scheduling (ACMS)
does not have access to the documentation supporting the proposed changes or the specific reasons for the proposed changes; therefore offers the following general comments regarding the scheduling proposal for chloramphenicol for ophthalmic use and paracetamol combined with ibuprofen.
strongly supports the need for the appropriate use of antibiotics and in doing so reduce the risk of emergence of antimicrobial resistance. Hence, we would generally support the restriction of access to antibiotics to prescription only by a suitably qualified health professional. However, believe there is benefit to the broader community if chloramphenical eye drops remain in Schedule 3. When used in line with TGA approved indications these products offer an effective treatment with minimal risk and we believe this treatment option should remain available after consultation with a pharmacist. Returning these products to Schedule 4 will potentially increase demand on GP services and delay treatment in consumers who live in areas with extended waiting times for GP appointments.
In contrast is concerned that a combination product that contains two medicines with well documented adverse effects and frequently irreversible effects (paracetamol and ibuprofen) that are known to be used in appropriately by consumers will be made more easily accessible. In does not believe that a smaller pack size reduces the risk of using any medicine and would not support the rescheduling of this combination product to Schedule 2.