Public submissions on scheduling matters referred to the ACMS #23 meeting in March 2018

Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the Act) to amend the current *Poisons Standard* and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice. Such a notice relating to the scheduling proposals initially referred to the March 2018 meeting of the Advisory Committee on Medicines Scheduling (ACMS #23) was made available on the TGA website on 21 December 2017 and closed on 2 February 2018.

Public submissions received on or before 2 February 2018 are published here in accordance with regulation 42ZCZL of the Regulations. Also in accordance with regulations 42ZCZL of the Regulations, the Secretary has removed information that the Secretary considers confidential.

Under regulation 42ZCZN of the Regulations, the Secretary, after considering the advice or recommendation of the expert advisory committee, must (subject to regulation 42ZCZO) make an interim decision in relation to the proposed amendment. If the interim decision is to amend the current *Poisons Standard*, the Secretary must, in doing so, take into account the matters mentioned in subsection 52E(1) of the Act (including, for example, the risks and benefits of the use of a substance, and the potential for abuse of a substance) and the scheduling guidelines as set out in the *Scheduling Policy Framework for Chemicals and Medicines* (SPF, 2015), available on the TGA website.

Under regulation 42ZCZP of the Regulations, the Secretary must, among other things, publish (in a manner the Secretary considers appropriate) the scheduling interim decision, the reasons for that decision and the proposed date of effect (for decisions to amend the current *Poisons Standard*, this will be the date when it is expected that the current *Poisons Standard* will be amended to give effect to the decision). Also in accordance with regulation 42ZCZP of the Regulations, the Secretary must invite the applicants and persons who made a submission in response to the original invitation under paragraph 42ZCZK(1)(d), to make further submissions to the Secretary in relation to the interim decisions by a date mentioned in the notice as the closing date, allowing at least 10 business days after publication of the notice. Such a notice relating to the interim decisions of substances initially referred to the March 2018 meeting of the Advisory Committee on Medicines Scheduling (ACMS #23) will be made available on the TGA website on 7 June 2018, closing on 5 July 2018. Public submissions received on or before this closing date are will be published on the TGA website in accordance with regulation 42ZCZQ.

Privacy statement

The Therapeutic Goods Administration (TGA) will not publish information it considers confidential, including yours/other individuals' personal information (unless you/they have consented to publication) or commercially sensitive information. Also, the TGA will not publish information that could be considered advertising or marketing (e.g. logos or slogans associated with products), information about any alleged unlawful activity or that may be defamatory or offensive.

For general privacy information, go to https://www.tga.gov.au/privacy. The TGA is part of the Department of Health and the link includes a link to the Department's privacy policy and contact information if you have a query or concerns about a privacy matter.

The TGA may receive submissions from the public on a proposed amendment to the Poisons Standard where there has been an invitation to the public for submissions on the proposal in accordance with the *Therapeutic Goods Regulations 1990*. These submissions may contain personal information of the individual making the submissions and others.

The TGA collects this information as part of its regulatory functions and may use the information to contact the individual who made the submissions if the TGA has any queries.

As set out above, the TGA is required to publish these submissions unless they contain confidential information.

If you request for your submission to be published in full, including your name and any other information about you, then the TGA will publish your personal information on its website. However, if at any point in time, you change your mind and wish for your personal information to be redacted then please contact the Scheduling Secretariat at medicines.scheduling@health.gov.au so that the pubic submissions can be updated accordingly.

Please note that the TGA cannot guarantee that updating the submissions on the TGA website will result in the removal of your personal information from the internet.

Please note that the TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

[redacted]

AFGC SUBMISSION

EXEMPTION FROM SCHEDULING OF DICLOFENAC GEL 2%

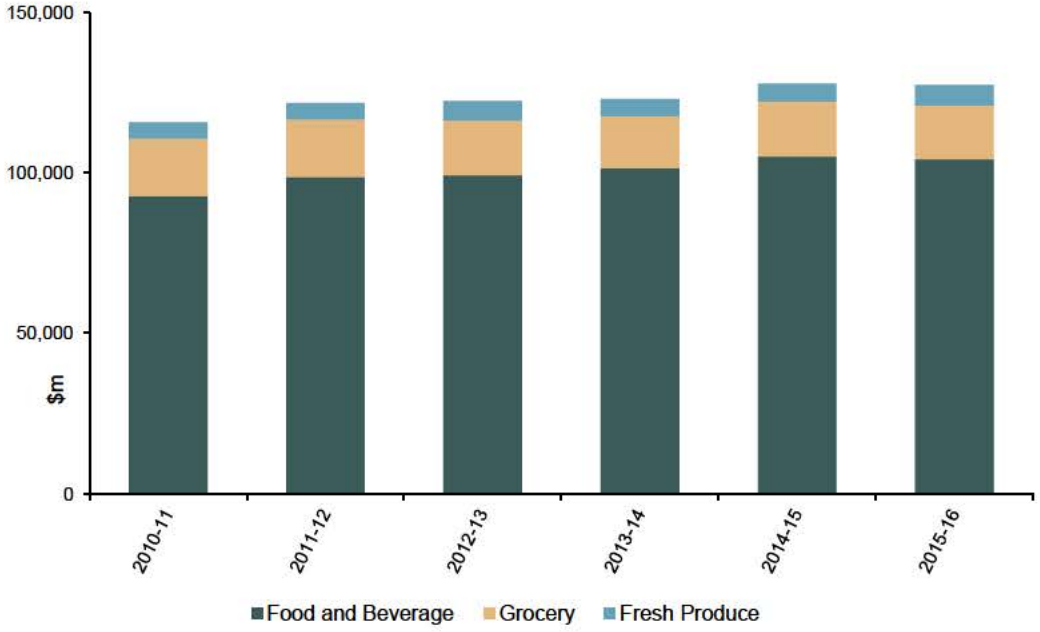
[redacted]

PREFACE

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, drink and grocery manufacturing industry.

The membership of AFGC comprises more than 180 companies, subsidiaries and associates which constitutes in the order of 80 per cent of the gross dollar value of the processed food, beverage and grocery products sectors.

Composition of the defined industry's turnover (2010-16)



With an annual turnover in the 2015-16 financial year of $127.4 billion, Australia's food and grocery manufacturing industry makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity.

Manufacturing of food, beverages and groceries in the fast moving consumer goods sector is Australia's largest manufacturing industry. Representing 32.4 per cent of total manufacturing turnover, the sector accounts for over one quarter of the total manufacturing industry in Australia.

The diverse and sustainable industry is made up of over 30,748 businesses and accounts for over $67.9 billion of the nation's international trade. These businesses range from some of the largest globally significant multinational companies to small and medium enterprises. Industry made $2.9 billion in capital investment in 2015-16 on research and development.

The food and grocery manufacturing sector employs more than 320,300 Australians, representing about 2.6 per cent of all employed people in Australia, paying around $17.3 billion a year in salaries and wages.

Many food manufacturing plants are located outside the metropolitan regions. The industry makes a large contribution to rural and regional Australia economies, with almost 40 per cent of the total persons employed being in rural and regional Australia. It is essential for the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies.

Australians and our political leaders overwhelmingly want a local, value-adding food and grocery manufacturing sector.

The AFGC provides this submission in response to the Therapeutic Goods Administration *Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018*.

The AFGC supports the removal from scheduling of Diclofenac gel 2% (diclofenac diethylammonium 2.32%) ("DDEA") in accordance with the submission from GlaxoSmithKlein (GSK). DDEA 2.32% has been marketed in Australia as a Schedule 2 product for over 3 years.

The AFGC strongly supports Australia's regulation of therapeutic goods in terms of its outcomes evidence basis, and it is therefore important for changes in that evidence base to be reflected in scheduling amendments. Scheduling will always be on the basis of evidence at a point in time, and just as evidence changes as new information or experience is gathered, so scheduling also must change to tighten the regulation in the case of products where the evidence identifies risks not previously fully known or considered, or to relax regulation where the evidence demonstrates levels of safety and use that previously were not available. It is essential for the credibility of the system that scheduling decisions go both ways: up-scheduling and down-scheduling based on the current state of the evidence reinforces that the system is both flexible and responsive to the emerging evidence base to deliver optimal regulatory outcomes for the Australian people.

The recent change in scheduling of codeine pain relief medicines is an example of the former – the AFGC considers DDEA 2.32% to be an example warranting the latter.

The AFGC has had opportunity to review the submission by GSK, and in particular notes the evidence that has emerged since DDEA 2.32% was last reviewed in May 2014. This evidence does seem to the AFGC to address the concerns raised by the Advisory Committee on Medicines Scheduling (ACMS) in that prior review relating to availability for wide community use, safety evidence from such wider use, the potential for confusion between 1% and 2% DDEA formulations and regulatory status in corresponding jurisdictions. The AFGC in particular highlights the availability of DDEA 2.32% for general sale in New Zealand – it does seem incongruous that New Zealanders have general access to this formulation when such general access is denied to the Australian population, and there are access and equity issues arising where a product can be sold only in pharmacies and not in supermarkets.

It is a well-known fact to the ACMS that removal from scheduling does not mean that a medicine becomes unregulated. Such a product will continue to be regulated by therapeutic goods regulation in relation to its manufacture, composition, packaging and advertising. The only change resulting from scheduling relates to how consumers access the product.

The AFGC supports the submission by GSK and recommends that the ACMS act in accordance with this new evidence and agree that DDEA 2.32% gel be removed from scheduling and made available for general sale.

[redacted]

Australian Self-Medication Industry Ltd.
ACN 607 233 116 ABN 55 082 798 952
Suite 2202, Level 22, 141 Walker Street,
North Sydney, NSW 2060
PO Box 764 North Sydney NSW 2059
Direct Ph: +61 2 9922 5111 | Fax: 61 2 9959 3693
Email: info@asmi.com.au | www.asmi.com.au

1 February 2018

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email to: medicines.scheduling@health.gov.au and to: chemicals.scheduling@health.gov.au

Dear Sir or Madam,

Notice inviting public submissions under subsection 42ZCZK/42ZCZL of the *Therapeutic Goods Regulations* 1990. Proposed Amendments to the Poisons Standard to be considered at the ACCS, ACMS and ACCS/ACMS Meetings, March 2018

We refer to the notice inviting public comment under Regulation 42ZCZK/42ZCZL of the *Therapeutic Goods Regulations* and would like to provide comment on two of the scheduling proposals that will be referred to the March 2018 meetings of the ACCS, ACMS and ACCS/ACMS.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI appreciates the opportunity to provide public comment in relation to ACCS, ACMS and ACCS/ACMS agenda scheduling proposals. We wish to address relevant matters under section 52E of the *Therapeutic Goods Act* 1989.

Please find enclosed, under cover of this letter, ASMI's comments in relation to the following scheduling proposals that will be considered by the ACCS, ACMS and ACCS/ACMS at the March 2018 meetings:

Diclofenac

> *To amend the Schedule 2 entry for diclofenac to increase the amount for exempt preparations for dermal use except when labelled for the treatment of solar keratosis from 1% to 2% or less of diclofenac.*

Fluticasone

> *A request has been made to amend the Schedule 2 entry for fluticasone to remove the limit of 200 actuations.*

[redacted]

Each of these agenda items is presented as a separate attachment.

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

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

Yours sincerely,

Steven Scarff
Regulatory and Legal Director

Agenda item 3 (ACMS) - Diclofenac

> *To amend the Schedule 2 entry for diclofenac to increase the amount for exempt preparations for dermal use except when labelled for the treatment of solar keratosis from 1% to 2% or less of diclofenac.*

Introduction

ASMI supports the proposal to amend the Schedule 2 entry for diclofenac.

The effect of the proposal would be to exempt diclofenac dermal preparations of up to 2% diclofenac from scheduling.

ASMI Comment

Dermal preparations containing 1% or less of diclofenac have been exempt from scheduling in Australia since February 2000. Diclofenac gel 2% has been marketed in Australia as a Schedule 2 product for over 3 years (date of first supply was June 2014).

Diclofenac gel 2% is unscheduled and approved for general sale in two major, comparable, markets – New Zealand (authorised July 2013) and the UK (authorised 2013).

Three recent Cochrane reviews, (Derry et al 2015, Derry et al 2016, and Derry et al 2017) provide high quality evidence showing a lack of systemic safety problems with topical non-steroidal anti-inflammatory drugs (NSAIDs) including diclofenac. Recent TGA reviews have also shown that topical diclofenac has a well-characterised and favourable safety profile.

ASMI understands that the safety profile of the 2% gel is comparable to that of 1% gel.

Diclofenac gel 2% is also supported by clinical efficacy data.

There is no evidence of dependence or abuse and intentional misuse is extremely rare.

ASMI understands that the Diclofenac 2% gel has been developed to provide the same total daily dose as is achieved with Diclofenac 1% gel but with less frequent daily applications (twice-daily for the former and four times daily for the latter). It is to be expected that less frequent application will lead to better adherence and so to better clinical outcomes.

ASMI understands that the indications for the 2% gel are the same as for the 1% gel as well as for other topical analgesics available for general sale in Australia.

While having two products on the market with different strengths of active might pose problems for consumers, we do not think that this will be the case with the dermal preparations of diclofenac, for the following reasons:

- Australian consumers already successfully navigate such an arrangement in relation to rubefacient products containing methyl salicylate.
- Labelling provisions (e.g. product name, label colour and directions for use) can all be used to effectively differentiate the products.

Scheduling factors

Up until recently, the Scheduling Policy Framework did not include factors for "exempt" or unscheduled medicines. This has now been rectified with the publication of the TGA's *Scheduling handbook: Guidance for amending the Poisons Standard* in December 2017.

From page 12 of the Scheduling Handbook:

> *Medicinal preparations exempted from scheduling must be determined to be able to be supplied, with reasonable safety, without any access to health professional advice.*
>
> *The term 'with reasonable safety' means:*
>
> - *the consumer is able to identify and self-manage the condition for which the medicine is intended without health professional input*
> - *the risk of the consumer confusing their condition with more serious diseases or conditions is very small*
> - *the risks to health from the medicine are small and can be managed with packaging and labelling. Risks to be assessed include, but are not limited to, risks from adverse reactions, drug/food interactions and contraindications*
> - *the risk of inappropriate use and misuse is negligible*
> - *there is little need to take any special precautions in handling*
> - *there is net public health benefit from wider availability for the consumer*

ASMI believes that diclofenac in dermal preparations of up to 2%, clearly meets the above description and that it is able to be supplied, with reasonable safety, without any access to health professional advice.

Conclusion

ASMI supports the scheduling proposal because:

- Topical diclofenac is a safe and effective analgesic.
- The safety profile of the 2% gel is comparable to that of 1% gel.
- Diclofenac 2% gel is unscheduled in New Zealand and in the UK.
- While the 1% gel and the 2% gel will be on the market at the same time (and for the same indications), the 2% gel offers less frequent dosing and should be easily differentiated from the 1% gel by way of labelling.
- The 2% gel can be supplied, with reasonable safety, without any access to health professional advice.

Agenda item 3 (ACMS) - Fluticasone

A request has been made to amend the Schedule 2 entry for fluticasone to remove the limit of 200 actuations.

Introduction

ASMI supports the proposal to amend the Schedule 2 entry for fluticasone.

The effect of the proposal would be to remove the upper limit on pack size for the Schedule 2 entry.

ASMI Comment

Fluticasone has been available in Australia for approximately 30 years, and has been the subject of numerous clinical studies. The safety and efficacy of the substance are therefore well characterised.

Fluticasone is indicated for the management of the symptoms of allergic rhinitis and other upper respiratory allergies. Allergic rhinitis is a chronic inflammatory condition of the nasal mucosa caused by an allergic reaction to substances in the air. The use of intranasal corticosteroids is recommended for the effective, long-term management of the symptoms of allergic rhinitis.

ASMI understands that 200 actuations corresponds to about 1.5 month's usage and that effective long-term management of allergic rhinitis typically involves longer periods of continuous use.

The proposal therefore has the potential to improve adherence.

The proposal to remove the actuation limit is also consistent with the schedule 2 entry for the intranasal corticosteroid mometasone (which contains no such upper limit). ASMI supports alignment of scheduling entries amongst intranasal corticosteroids.

In terms of the scheduling factors for S2 medicines, there is already a Schedule 2 entry for fluticasone, the question to be answered now is simply whether removing an upper limit on the number of actuations will change the applicability of the factors. In ASMI's view the scheduling factors for S2 medicines will still apply.

> Factor 1: The quality use of the medicine can be achieved by labelling, packaging, and/or provision of other information; however access to advice from a pharmacist is available to maximise the safe use of the medicine. The medicine is for minor ailments or symptoms that can easily be recognised and are unlikely to be confused by the consumer with other more serious diseases or conditions. Treatment can be managed by the consumer without the need for medical intervention. However, the availability of a pharmacist at the point of sale supports the consumer in selecting and using the appropriate medicine.
>
> *Applies regardless of pack size.*
>
> Factor 2: The use of the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low. Suitable for diagnosis and treatment by the consumer in the management of minor ailments.
>
> *Applies regardless of pack size, allergic rhinitis is a chronic condition.*

Factor 3: The use of the medicine at established therapeutic dosage levels is unlikely to produce dependency and the medicine is unlikely to be misused, abused or illicitly used.

There is no evidence of dependence, misuse or abuse.

Factor 4: The risk profile of the medicine is well defined and the risk factors can be identified and managed by a consumer through appropriate packaging and labelling and consultation with a medical practitioner if required.

Fluticasone has a well-established safety profile and a very low ADR rate.

Factor 5: The use of the medicine at established therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition.

Applies regardless of pack size.

Conclusion

ASMI supports the scheduling proposal because it will bring about alignment and consistency between scheduling entries for fluticasone and mometasone, and because it will be consistent with the scheduling factors for S2 medicines.

[redacted]

Consultation: Proposed amendments to the Poisons Standard - Advisory Committee on Medicines Scheduling meeting, March 2018

FEB
2018

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission on proposed amendments to the Poisons Standard being referred to the March 2018 meeting of the Advisory Committee on Medicines Scheduling for scheduling advice.

PSA's comments relate to proposed amendments to diclofenac and fluticasone.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 30,000 pharmacists[1] working in all sectors and locations.

PSA's core functions relevant to pharmacists include:

- providing high quality continuing professional development, education and practice support to pharmacists
- developing and advocating standards and guidelines to inform and enhance pharmacists' practice, and
- representing pharmacists' role as frontline health professionals.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

[1] Pharmacy Board of Australia. Registrant data. Reporting period: 1 October 2017 – 31 December 2017. At: http://www.pharmacyboard.gov.au/documents/default.aspx?record=WD18%2f24764&dbid=AP&chksum=%2fhTqAUMulEVk8XqLHBFjcg%3d%3d

[redacted]

Summary of PSA's position

Diclofenac *– PSA does not support the proposal to amend the Schedule 2 entry by extending the strength of exempt dermal preparations from 1% to 2%.*

Fluticasone *– PSA has no objections to the proposed amendment to remove the limit of 200 actuations from the Schedule 2 entry.*

Comments on specific substances

Diclofenac

Proposal to amend the Schedule 2 entry for diclofenac to increase the amount for exempt preparations for dermal use except when labelled for the treatment of solar keratosis from 1% to 2% or less of diclofenac.

The current entry in Schedule 2 for non-oral use of diclofenac is as follows:

- 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
- in transdermal preparations for topical use containing 140 mg or less of diclofenac.

In the Poisons Standard[2]:

- "dermal use" means application to the skin primarily for localised 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.

Thus, products for dermal use containing 1% or less of diclofenac are currently exempt from scheduling. These products are typically indicated for short term use (up to two or three weeks) for local symptomatic treatment of musculoskeletal inflammatory conditions (e.g. acute soft tissue injuries) or relief of pain in non-serious arthritis.

It has been reported[3] that topical diclofenac provides some therapeutic benefit for chronic osteoarthritis pain and that serious adverse events are uncommon.

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[2] Therapeutic Goods Administration. Poisons Standard February 2018. At: **https://www.legislation.gov.au/Details/F2018L00043/f48c5a61-92eb-4f2a-8eea-a47e68c96d7b**

[3] Derry S, Conaghan P, Da Silva JAP, Wiffen PJ, Moore RA. Topical NSAIDs for chronic musculoskeletal pain in adults. Cochrane Database of Systematic Reviews, 2016, Issue 4. Art. No.: CD007400. DOI: 10.1002/14651858.CD007400.pub3. At: **http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007400.pub3/pdf**

Studies[4,5,6] have been published where different topical formulations of diclofenac including the use of new pharmaceutical technology are examined. These are primarily aimed at enhancing treatment of local pain and inflammation and/or minimising any systemic effects.

Through initiatives of the Therapeutic Goods Administration (TGA), a full safety review of diclofenac was conducted in 2013 and a report[7] released in 2014. With regards to topical use of diclofenac, it was reported the efficacy of 1% and 3% diclofenac was well established but that research literature could not be located where the safety of topical 3% diclofenac was specifically examined. (The specific reference to 1% and 3% was based on the products available on the Australian Register of Therapeutic Goods.)

The TGA report noted that mandated Australian warning statements for topical 1% diclofenac are similar to those used in the UK but that USA product information for topical diclofenac contains much stronger warnings to the extent that it mirrors that of oral diclofenac. The report also emphasised that the (Australian) Product Information for topical 3% diclofenac makes reference to serious systemic side effects.

The safety review report concluded that, based on available information, the risk/benefit for topical diclofenac remains favourable and that there is paucity of evidence of serious systemic side effects. Nevertheless the TGA report recommended that:

> *…despite this relative lack of evidence it is recommended that the Consumer Medicine Information for topical diclofenac include warnings that systemic absorption is likely and that adverse cardiovascular events have been associated with oral diclofenac.*

Thus, the TGA's assessment and conclusions around topical diclofenac products suggest a conservative approach is warranted. Based on currently available information and evidence, PSA does not support extending the scheduling exemption for dermal diclofenac from 1% to 2%.

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[4] Altman R, Bosch B, Brune K, Patrignani P, Young C. Advances in NSAID development: evolution of diclofenac products using pharmaceutical technology. Drugs 2015; 75(8):859–77. At: **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4445819/pdf/40265_2015_Article_392.pdf**

[5] Nivsarkar M, Maroo SH, Patel KR, Patel DD. Evaluation of skin penetration of diclofenac from a novel topical non aqueous solution: a comparative bioavailability study. J Clin Diagn Res 2015; 9(12):FC11–13. At: **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4445819/pdf/40265_2015_Article_392.pdf**

[6] Derry S, Wiffen PJ, Kalso EA, Bell RF, Aldington D, Phillips T, Gaskell H, Moore RA. Topical analgesics for acute and chronic pain in adults – an overview of Cochrane Reviews. Cochrane Database of Systematic Reviews, 2017, Issue 5. Art. No.: CD008609. DOI: 10.1002/14651858.CD008609.pub2. At: **http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008609.pub2/epdf**

[7] Therapeutic Goods Administration. Safety review of diclofenac. v. 2.1. 2014;Oct. At: **https://www.tga.gov.au/sites/default/files/medicines-review-safety-diclofenac.pdf**

Fluticasone

Proposal to amend the Schedule 2 entry for fluticasone to remove the limit of 200 actuations.

The current entry in Schedule 2 for fluticasone is as follows:

> *FLUTICASONE in aqueous nasal sprays delivering 50 micrograms or less of fluticasone per actuation when the maximum recommended daily dose is no greater than 400 micrograms and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.*

Products containing fluticasone for short-term prophylaxis or treatment of allergic rhinitis in adults and children aged 12 years and over have been available in Australia without a prescription since 2001 and as Schedule 2 since 2003.

Intranasal corticosteroid sprays have high efficacy in controlling symptoms of allergic rhinitis and a good safety profile with minimal risk of systemic side effects due to their low bioavailability. They are well tolerated and PSA is not aware of any significant adverse events attributable to fluticasone nasal sprays since their inclusion in Schedule 2.

The primary goals of treatment of allergic rhinitis are to reduce symptoms, and to improve quality of life and daily functioning. Fluticasone-containing products (and other intranasal corticosteroids) are more effective than oral antihistamines for allergic rhinitis and is recommended for first-line therapy if symptoms are persistent and/or moderate to severe.[8]

The recommended dose of fluticasone nasal sprays is one or two sprays into each nostril once daily. In this dosage range, a product containing 200 actuations would provide for up to three months' therapy.[9]

PSA believes removal of the limit of 200 actuations from the Schedule 2 entry for fluticasone is not unreasonable given:

- the use of fluticasone nasal sprays for allergic rhinitis is reported to be safe and effective with very low incidence of adverse effects
- the delivery of 200 actuations at the current recommended dosage regimen provides for approximately three months' treatment while the Schedule 2 entry allows for up to six months' therapy.

Therefore PSA has no objections to the proposed amendment for fluticasone.

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[8] Sansom LN ed. Australian pharmaceutical formulary and handbook. 23rd edn. pp. 538–41. Canberra: Pharmaceutical Society of Australia; 2015.

[9] Sansom, op. cit., p. 311.

Submitted by:

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

Contacts:

Deb Bowden, Acting Chief Executive Officer

Kay Sorimachi, Director Policy and Regulatory Affairs
kay.sorimachi@psa.org.au

2 February 2018

[redacted]

PROPOSED AMENDMENTS TO POISONS STANDARD

ACMS Meeting March 2018

Comments by the Pharmacy Guild of Australia

1. **Diclofenac– Schedule 2 amendment**

2. **Fluticasone – Schedule 2 amendment**

Date January 2018
Contact [redacted]

National Secretariat
Level 2, 15 National Circuit, Barton ACT 2600
PO Box 310, Fyshwick ACT 2609
P: +61 2 6270 1888 • F: +61 2 6270 1800 • E: guild.nat@guild.org.au
www.guild.org.au

DICLOFENAC

Amend the Schedule 2 entry for diclofenac to the increase the amount for exempt preparations for dermal use except when labelled for the treatment of solar keratosis from 1% to 2% or less of diclofenac.

Overview

The Guild does not support this proposal. This proposal was considered by the ACMS in March 2014. At the time, both the ACMS and the Scheduling delegate considered the scheduling of diclofenac to be appropriate. The reasons cited in the decision included:

- 2 per cent formulation has not been available for wider community use
- A lack of evidence of safety from the wider use in the community
- Different dosing regimen from the current product, therefore access from a pharmacist is appropriate.[1]

The reasons cited in this decision remain relevant and as such the current scheduling should be retained.

Risks and Benefits associated with the use of the substance[2]

Polypharmacy with other NSAIDs

Concomitant administration of diclofenac gel with oral NSAIDs or aspirin may result in increased adverse NSAID effects.[3] 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. Guidelines for prescribing indicate only one non-aspirin NSAID should be used at any time.[4] Older consumers will be particularly at risk given the prevalence of osteoarthritis in this age group. There is also a risk these consumers are more likely to use topical NSAID preparations as well as an oral NSAID particularly with product labelling and advertisements promoting targeted relief of pain.[5]

Given the upscheduling of combination codeine products consumers will be seeking alternative products for relief of pain and we believe that consultation in a pharmacy would be appropriate to ensure quality use of medicines.

Dosage, formulation, labelling packaging and presentation of a substance[6]

Although advisory labels would outline to consumers the key differences with extended formulations and recommended dosages, the Guild has consistently argued that risk cannot be addressed by warning labels alone.

[1] Scheduling delegate's final decisions: ACMS July 2014 https://www.tga.gov.au/book/part-final-decisions-matters-referred-expert-advisory-committee-acms-1#diclo
[2] Therapeutic Goods Act 1989 – Sect 52E(a)
[3] Voltaren gel Prescribing Information -https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=9744
[4] Australian Medicines Handbook online - NSAIDs
[5] December 8 2017- 'ACCC takes Voltaren makers to court over 'misleading' arthritis pain relief claims' http://www.news.com.au/finance/business/manufacturing/accc-takes-voltaren-makers-to-court-over-misleading-arthritis-pain-relief-claims/news-story/f65e3fbf8adb67d62a92c671f7b616a9
[6] Therapeutic Goods Act 1989 – Sect 52E(d)

A 2017 study published in the Australian and New Zealand Journal of Public Health found almost a third consumers surveyed were unable to correctly identify the maximum daily dose for a common ibuprofen medicine and were unaware of some contraindications. Furthermore, fewer than half recognised potential side effects. The study also found that consumers who had not completed high school were significantly less likely to seek medical advice (when required) and significantly less likely to know when it was safe to take these products. The study concluded gaps in consumer knowledge, especially about the maximum daily dose, contraindications and potential side effects may be placing consumers at risk of experiencing adverse events.[7]

These findings would likely be replicated for other OTC NSAIDs and as such the risks are best mitigated with consumers having discussions regarding the safe and appropriate use of these medicines with pharmacy staff.

The dosage guidelines for 2 per cent diclofenac are also different than the 1 per cent concentration with the 2 per cent concentration being applied half as often.[8] Having potentially two types of unscheduled products available at different strengths increases the risk of medicine overuse and the aforementioned risks.

Summary

The Guild does not support this proposal and believes the current scheduling should be retained.

[7] Mullan, J., Weston, K.M., Bonney, A., Burns, P., Mullan, J. and Rudd, R., 2017. Consumer knowledge about over-the-counter NSAIDs: they don't know what they don't know. Australian and New Zealand journal of public health, 41(2), pp.210-214

[8] Australian Medicines Handbook online - Diclofenac

FLUTICASONE

Amend the Schedule 2 entry for fluticasone to remove the limit of 200 actuations.

Overview

The Guild does not object to this proposal.

The Guild notes other corticosteroids entries for similar indications such as seasonal allergic and perennial rhinitis have the following wording:

> BECLOMETASONE in aqueous nasal sprays delivering 50 micrograms or less of beclometasone per actuation when the maximum recommended daily dose is no greater than 400 micrograms and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.
>
> BUDESONIDE in aqueous nasal sprays delivering 50 micrograms or less of budesonide per actuation when the maximum recommended daily dose is no greater than 400 micrograms and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.
>
> MOMETASONE in aqueous nasal sprays delivering 50 micrograms or less of mometasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms for the prophylaxis or treatment of allergic rhinitis for up to six months in adults and children 12 years of age and over.
>
> TRIAMCINOLONE in aqueous nasal sprays delivering 55 micrograms or less of triamcinolone per actuation when the maximum recommended daily dose is no greater than 220 micrograms, for prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

We note that the indications for the above substances are as follows:

> BECLOMETASONE
> Short-term prophylaxis (up to 6 months), treatment of allergic rhinitis in adults, children ≥12 yrs
>
> BUDESONIDE
> Seasonal, perennial allergic rhinitis prevention, treatment. Treatment of nasal polyps
>
> MOMETASONE
> Prophylaxis or treatment of allergic rhinitis for ≤ 6 mths in adults, children ≥ 12 yrs
>
> TRIAMCINOLONE
> Allergic rhinitis, short-term treatment (3-6 mths)

We also note that the Therapeutic Guidelines entry for Intranasal corticosteroids state the following[9]

> Intranasal corticosteroids are particularly useful for more severe allergic rhinitis. They are more effective than oral antihistamines and are especially effective for congestive symptoms. Systematic analyses also indicate significant reduction of ocular symptoms.

[9] https://tgldcdp.tg.org.au/viewTopic?topicfile=rhinitis-rhinosinusitis&guidelineName=Respiratory#toc_d1e70

> It is important to explain to patients that intranasal corticosteroids do not relieve symptoms at the time of use; their role is to prevent symptoms. They usually start relieving symptoms within a few days but a minimum trial of a month is needed to establish efficacy.
>
> To reduce the likelihood of systemic adverse effects, use the minimum dose needed to control symptoms. Tailor the duration of treatment to the patient's symptoms and any drug adverse effects. Intranasal corticosteroid treatment may need to be continued for lengthy periods, even for many years.

Given the advice that treatment may need to be continued for lengthy periods "even for many years" the inclusion of a maximum number of actuations may be unnecessary and be related to the expiry date of the particular formulation after opening. An inspection of the product's information documents provide the following advice on expiry dates:

> **Beconase Allergy and Hayfever 12 Hour® (beclometasone)**
> Storage Store below 30° C. Shelf life of 2 years. Protect from light, do not refrigerate. This preparation should be discarded 3 months after first using the spray.
>
> **Rhinocort® (budesonide)**
> Storage Rhinocort Hayfever Nasal Spray has a shelf life of 2 years and should be stored in temperatures not exceeding 30° C. Do not freeze.
>
> **Nasonex® (mometasone)**
> Storage Store Nasonex Aqueous Nasal Spray 0.05% below 25° C. Do not freeze.
>
> **Telnase® (triamcinolone)**
> Storage Store below 25° C. The bottle should be discarded after 120 actuations or within two months of starting treatment.

We note that triamcinolone has a recommendation to discard contents after 120 actuations but there is no primary pack limitation in the SUSMP entry. On the other hand beclometasone should be discarded after 3 months but given that the dose is 2 sprays each nostril bd (=4 per day) and a maintenance dose of 1 spray each nostril bd (=2 per day) one would assume that if used as directed a primary pack would last from 50 to 100 days and there may therefore be little to discard.

The Guild suggests that if there is no clinical justification for the inclusion of *"containing 200 actuations or less"* in the beclometasone and budesonide entries then for the sake of consistency it could be removed to reflect the mometasone and triamcinolone entries. Alternatively if there is a justifiable clinical reason that nasal corticosteroids should be supplied in packs of not more than 200 acutations then it should be added to mometasone and triamcinolone. The Guild is not aware of any clinical data to suggest one or the other.

Summary

The Guild does not oppose this proposal but for consistency would recommend all the entries for nasal corticosteroids be reconsidered.

[redacted]

AusCann Group Holdings Ltd
ACN 008 095 207
57 Shenton Avenue
Joondalup WA 6027
AUSTRALIA

2 February 2018

Advisory Committee on Medicines Scheduling

Therapeutic Goods Administration

medicines.scheduling@health.gov.au

Proposed Amendments to the Poisons Standard (Medicines):
Entries for cannabidiol, cannabis and tetrahydrocannabinols

EXECUTIVE SUMMARY

1. We suggest amending the cannabidiol entry under schedule 4 as follows, rather than as proposed under the TGA consultation paper:

   Schedule 4
   CANNABIDIOL in preparations for therapeutic use in which:
   a. the total cannabinoid content of the preparation is comprised of at least 98% cannabidiol; and
   b. the total cannabinoid content of the preparation includes only those cannabinoids naturally found in cannabis and may include tetrahydrocannabinol; and
   c. the preparation only includes compounds naturally found in cannabis, and/or excipients.

2. We also suggest that tetrahydrocannabinols be cross referenced to cannabidiol in the Index of the Poisons Standard to provide further clarity on the proposed amendments to Appendix K and Schedule 8.

DETAILED RESPONSE

Schedule 4 Cannabidiol entry

We believe that the key area of confusion is in respect to the cannabidiol content of the preparation, versus its proportion to other cannabinoids. Interpretations have included 98% of the preparation must be cannabidiol in contrast to 98% of the total cannabinoids in the preparation must be cannabidiol.

We also suggest that the proposed amended wording in the TGA consultation paper, outlined below, introduces some additional ambiguity:

CANNABIDIOL in preparations for therapeutic use in which:

a. cannabidiol comprises at least 98 per cent of the total cannabinoid content of the preparation; and
b. any *other* cannabinoids present are only those naturally found in cannabis, and are present only as *unavoidable impurities* in the cannabidiol component of the preparation.

The use of the word '*other*' in point b implies that the cannabidiol itself may not be subject to the requirement of being 'naturally found in cannabis'. This may be the intention of the TGA.

The introduction of the term '*unavoidable impurities*' with regards to other cannabinoids present introduces ambiguity and subjectivity in what, under point a, had been a quantitative measure – that is, that cannabinoids other than cannabidiol can only represent up to 2% of the total cannabinoid content.

Although it is self-explanatory that tetrahydrocannabinol is a cannabinoid, and therefore could be included in the total cannabinoid content, explicit reference to it in the cannabidiol entry would assist in comprehension of the proposed amendments to the tetrahydrocannabinol entries in Appendix K and Schedule 8.

Amendments to Appendix K and Schedule 8

The amendments excluding cannabis and tetrahydrocannabinols from Appendix K and Schedule 8 when 'included' or 'specified' in Schedule 4 makes sense.

It may not be clear however, how or where tetrahydrocannabinols are 'included' or 'specified' in Schedule 4.

This can be addressed by specifically making reference to tetrahydrocannabinol in the cannabidiol entry, and also by cross referencing tetrahydrocannabinols to cannabidiol in the Index of the Poisons Standard.

ABOUT AUSCANN GROUP

AusCann is an Australian based company that was incorporated in September 2014 with the aim of producing and providing high quality, economical and clinically validated cannabinoid medicines to patients. It is bringing together leading expertise and operations across all aspects of the medicinal cannabis value chain and has built a strong team of experts and partners with international connections. Partners include Canopy Growth Corporation, the largest producer of medicinal cannabis globally; DayaCann, the only licensed medicinal cannabis grower in Chile; and Tasmanian Alkaloids, one of the largest producers and exporters of alkaloid raw material in the world. AusCann has been issued a medical cannabis licence, and a licence to manufacture by the Office of Drug Control.

Thank you for the opportunity to provide comment on the proposed amendments.

Yours sincerely,

Elaine Darby
Managing Director