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10 February 2020
The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

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

Dear Sir or Madam,

Notice inviting public submissions under regulation 42ZCZK of the *Therapeutic Goods Regulations* 1990. Proposed Amendments to the Poisons Standard to be considered at the ACMS Meeting, March 2020

We refer to the notice inviting public comment under Regulation 42ZCZK of the *Therapeutic Goods Regulations* and would like to provide the following comments on the scheduling proposals referred to the March 2020 of the ACMS.

CHP Australia is the leading voice and industry body for **manufacturers and distributors of consumer healthcare products**, which includes non-prescription medicines. We strive to advance consumer health through **responsible Self Care** and were previously known as the Australian Self Medication Industry (ASMI). Our key priorities for the industry include **improving health literacy**, **growing the consumer healthcare products industry** and **increasing access to medicines** where appropriate.

CHP Australia appreciates the opportunity to provide public comment in relation to the ACMS agenda. Please find enclosed, under cover of this letter, CHP Australia's comments in relation to the Flurbiprofen, Rizatriptan, Melatonin, Adapalene and Nicotine scheduling proposals. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

As an industry representative, CHP Australia 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,

Steve Scarff
Regulatory and Legal Director

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Flurbiprofen

> *To exempt from scheduling, flurbiprofen in preparations for topical oral use when in divided preparations containing 10 mg or less of flurbiprofen per dosage unit when … not labelled for the treatment of children 12 years of age or less; and … in a primary pack containing not more than 16 dosage units.*

Introduction

CHP Australia supports the proposal to exempt from scheduling certain flurbiprofen preparations.

CHP Australia Comments

History of use

Flurbiprofen lozenges have been available in Australia since 2001 (as Schedule 3) and since 2003 they have been available as a Schedule 2 medicine.

The NDPSC last reviewed the safety of Flurbiprofen lozenges in 2010 (at meetings #58[1] and #59[2]) and since that time there has been no significant change in the safety profile of flurbiprofen lozenges, with no safety issues emerging and only six reports of adverse events included on the TGA's Database of Adverse Event Notifications (DAEN).

Risks

The systemic exposure to flurbiprofen from a lozenge format is minimal and significantly lower than alternative oral analgesics.

The potential risk of rare idiosyncratic allergic reactions is addressed by the mandatory label warning statements that apply to all NSAIDs, with the following warnings already required to be included on the labelling of flurbiprofen lozenges:

> "Do not use if you are allergic to [name of substance] or other anti-inflammatory medicines.", and
>
> "If you get an allergic reaction, stop taking and see your doctor immediately."

Flurbiprofen lozenges have an excellent safety profile, with a very low reporting rate of adverse events and no new safety concerns/signals emerging since the NDPSC reviews of 2010.

[1] https://www.tga.gov.au/sites/default/files/ndpsc-record-58.pdf

[2] https://www.tga.gov.au/sites/default/files/ndpsc-record-59.pdf

[redacted]

Benefits / Purpose

Clinical trials have confirmed that the pain relief provided by flurbiprofen lozenges is clinically meaningful.

Flurbiprofen lozenges are a low-dose topical analgesic and anti-inflammatory medicine for the relief of pain, swelling and inflammation associated with sore throats.

The use of flurbiprofen lozenges exposes the painful and inflamed mucosal region of the throat to the analgesic and anti-inflammatory actions of flurbiprofen while minimising systemic exposure.

Sore throat is a common condition, generally self-limiting, which develops quickly.

Sore throat can be easily identified and self-managed by consumers.

Lozenges are the most commonly used dosage form for the management of sore throats and most people who experience sore throats will self-manage their condition, nevertheless sore throat remains one of the top 10 reasons for visiting a GP.

Providing the public with wider access to a lozenge with both analgesic and anti-inflammatory activity therefore has the potential to improve the self-management of sore throats, to reduce the burden on healthcare professionals and to improve health-related quality of life.

Dosage, formulation, labelling, packaging and presentation of a substance;

The proposed limited pack size of 16 dosage units, represents 2 days' therapy for patients taking the maximum dose (8 lozenges per day)

Potential for abuse of a substance;

Like all other NSAIDs, flurbiprofen is not known to have the potential for abuse. The potential for overdose is negligible.

Products containing flurbiprofen for the symptomatic relief of sore throats have been available in Australia since 2001. There has been no evidence of misuse, abuse or illicit use to date and no reports of such in the TGA's Database on Adverse Event Notifications.

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Scheduling factors

The TGA's *Scheduling handbook, Guidance for Amending the Poisons Standard* (V1.1 July 2019 – at page 12 of 30[3]) lists the principles for "exemption of a particular medicinal preparation to allow supply from general sales outlets (such as supermarkets)". The Handbook indicates that 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 Handbook then goes on to state that 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

In our view, the proposed exemption from scheduling for flurbiprofen clearly meets this definition of "with reasonable safety".

Conclusion

CHP Australia supports the proposed exemption from scheduling based on:

- The factor's outlined in the TGA's Scheduling Handbook
- The minimal systemic absorption of flurbiprofen lozenges
- The pack size being limited to 16 dosage units (i.e. 2 days therapy for patients taking the maximum dose of 8 lozenges per day)
- The established efficacy of topical flurbiprofen
- The favourable safety profile of flurbiprofen lozenges, and
- The likely benefits of providing the public with wider access to the lozenges

[3] https://www.tga.gov.au/sites/default/files/scheduling-handbook-guidance-amending-poisons-standard.pdf

Rizatriptan

In 2018, the TGA established a multi-stakeholder Scheduling Working Group[4]. This Group examined (among other things) the then new Scheduling Policy Framework, the various scheduling reforms and the Schedule 3 advertising reforms.

Of relevance here, the Working Group also considered the identification of candidates for potential consideration for down-scheduling ('switching') from Schedule 4 to Schedule 3. The driver for this change to the SPF was to facilitate better access to medicines and support appropriate self-care. At that time, the Working Group noted that similar stakeholder groups had provided advice of this type to regulators in UK, Ireland, Denmark and Singapore.

The Working Group acknowledged that while they could assess the potential of products for down-scheduling and identify factors to be considered and how risks could be best mitigated, a formal application would still be required to initiate consideration of individual substances for rescheduling.

At the request of the Working Group convenor, ASMI (as CHP Australia was known at the time) compiled a list of switch candidates that were S4 in Australia, but already available without a prescription in at least one comparable international jurisdiction.

Rizatriptan was on the list of switch candidates provided by ASMI.

On this basis (and noting the reasons put forward by the applicant), CHP Australia:

- Supports the proposal to establish a Schedule 3 entry for Rizatriptan.
- Supports the inclusion of Rizatriptan in Appendix H.
- Supports the proposal to establish an Appendix M entry for Rizatriptan.

[4] https://www.tga.gov.au/scheduling-news

[redacted]

Melatonin

In 2018, the TGA established a multi-stakeholder Scheduling Working Group[5]. This Group examined (among other things) the then new Scheduling Policy Framework, the various scheduling reforms and the Schedule 3 advertising reforms.

Of relevance here, the Working Group also considered the identification of candidates for potential consideration for down-scheduling ('switching') from Schedule 4 to Schedule 3. The driver for this change to the SPF was to facilitate better access to medicines and support appropriate self-care. At that time, the Working Group noted that similar stakeholder groups had provided advice of this type to regulators in UK, Ireland, Denmark and Singapore.

The Working Group acknowledged that while they could assess the potential of products for down-scheduling and identify factors to be considered and how risks could be best mitigated, a formal application would still be required to initiate consideration of individual substances for rescheduling.

At the request of the Working Group convenor, ASMI (as CHP Australia was known at the time) compiled a list of switch candidates that were S4 in Australia, but already available without a prescription in at least one comparable international jurisdiction.

Melatonin was on the list of switch candidates provided by ASMI.

On this basis (and noting the reasons put forward by the applicant), CHP Australia:

- Supports the proposal to establish a Schedule 3 entry for Melatonin.
- Supports the inclusion of Melatonin in Appendix H.
- Supports the proposal to establish an Appendix M entry for Melatonin.

[5] https://www.tga.gov.au/scheduling-news

[redacted]

Adapalene

In 2018, the TGA established a multi-stakeholder Scheduling Working Group[6]. This Group examined (among other things) the then new Scheduling Policy Framework, the various scheduling reforms and the Schedule 3 advertising reforms.

Of relevance here, the Working Group also considered the identification of candidates for potential consideration for down-scheduling ('switching') from Schedule 4 to Schedule 3. The driver for this change to the SPF was to facilitate better access to medicines and support appropriate self-care. At that time, the Working Group noted that similar stakeholder groups had provided advice of this type to regulators in UK, Ireland, Denmark and Singapore.

The Working Group acknowledged that while they could assess the potential of products for down-scheduling and identify factors to be considered and how risks could be best mitigated, a formal application would still be required to initiate consideration of individual substances for rescheduling.

At the request of the Working Group convenor, ASMI (as CHP Australia was known at the time) compiled a list of switch candidates that were S4 in Australia, but already available without a prescription in at least one comparable international jurisdiction.

Adapalene was on the list of switch candidates provided by ASMI.

On this basis (and noting the reasons put forward by the applicant), CHP Australia:

- Supports the proposal to establish a Schedule 3 entry for Adapalene.
- Supports the inclusion of Adapalene in Appendix H.
- Supports the proposal to establish an Appendix M entry for Adapalene.

[6] https://www.tga.gov.au/scheduling-news

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Nicotine

Tobacco use continues to have a major impact on public health in Australia and remains the leading cause of preventable disease and early death (smoking-related diseases kill more than 20,000 people every year[7]). Despite a significant decline in prevalence over the last few decades approximately 2.5 million Australians continue to smoke daily.[8]

In our view, tobacco control requires a comprehensive, population-wide approach that encompasses the regulation of products which may promote the uptake or continuation of smoking. In such a context, CHP Australia remains concerned at the potential introduction to the Australian market of additional forms of tobacco such as the Heated Tobacco Products – HTPs – referred to in the scheduling proposal which lack independent research on their long-term effects on health[9,10].

We note that the WHO Information Sheet on Heated Tobacco Products[11] states that:

> [HTPs] *"contain the highly addictive substance nicotine (contained in the tobacco), which makes HTPs addictive"*
>
> *"Currently, there is no evidence to demonstrate that HTPs are less harmful than conventional tobacco products."*
>
> [where some studies have claimed reductions in the formation of and exposure to harmful and potentially harmful constituents relative to standard cigarettes] *"… there is currently no evidence to suggest that reduced exposure to these chemicals translates to reduced risk in humans."*
>
> *"Currently, there is also insufficient evidence on the potential effects of second-hand emissions produced by HTPs."*
>
> *"Conclusions cannot yet be drawn about their ability to assist with quitting smoking (cessation), their potential to attract new youth tobacco users (gateway effect), or the interaction in dual use with other conventional tobacco products and e-cigarettes."*

In comparison, proven smoking cessation aids such as nicotine replacement therapies have been rigorously assessed for efficacy and safety and have been approved by the TGA for use as aids in withdrawal from smoking.

Caution should therefore be exercised before permitting public access to any new addictive product, without independent research and without a proven safety profile.

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[7] https //www acosh org/who-we-help/smoking-in-australia/

[8] https //www acosh org/who-we-help/smoking-in-australia/

[9] https //tobaccocontrol bmj com/content/28/5/582

[10] https //www bmj com/company/newsroom/heat-not-burn-smokeless-tobacco-product-may-not-be-as-harm-free-as-claimed/

[11] https //www who int/tobacco/publications/prod_regulation/heated-tobacco-products/en/