Consumer Healthcare Products Australia

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18 May 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, June 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 June 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 ibuprofen scheduling proposal. 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

Ibuprofen

> *To amend the Schedule 2 entry to include … divided preparations, each containing 400 mg or less of ibuprofen in a primary pack containing not more than 12 dosage units, when labelled not for the treatment of children under 12 years of age.*

Introduction

CHP Australia supports the proposal to amend the Schedule 2 entry for ibuprofen.

CHP Australia Comments

History of use

Ibuprofen has been available in Australia since the early 1970's.

In May 1995, ibuprofen in 200 mg divided doses was rescheduled from S3 to S2 (with controls over pack size and total daily dose). In June 2003, ibuprofen in 200mg divided doses was exempted from scheduling (with controls over pack size and total daily dose).

Following a February 2006 decision, ibuprofen in 400mg divided doses was rescheduled to S3 (with controls over packs sizes and children's dosing). The scheduling of 400mg ibuprofen has remained unchanged since that time (expect for its inclusion in Appendix H in October 2017.

Ibuprofen 200mg has been available in Australia as an OTC medicine for more than 30 years, and in grocery for more than 15 years

The safety profile of ibuprofen is well established following the many years of market experience with this medicine. Ibuprofen has a wide margin of safety and low toxicity following overdose.

Ibuprofen 400mg is currently available from pharmacies allowing consumers to obtain advice when required, the scheduling proposal under consideration would not change this.

Risks

OTC ibuprofen (at doses ≤ 1200 mg/day) is well tolerated and when taken as directed has a favourable safety profile.

The maximum daily dose for S2 400mg ibuprofen will remain the same as for 200mg ibuprofen and the proposed pack size limit of 12 tablets represents 4 days' supply of

the 400mg product (whereas the current S2 pack size limit for the 200mg product – 100 doses - represents over 16 days' supply). The scheduling proposal therefore does not pose any additional safety risk from this point of view.

The safety profile associated with the short-term use of ibuprofen 400mg and 200mg are essentially the same.

Benefits / Purpose

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) used as an analgesic, antipyretic, and anti-inflammatory.

Over-the-counter (OTC) ibuprofen is indicated for relief of pain and discomfort associated with headache, back pain, muscle pain, period pain, dental pain, cold & flu and fever. These products are intended for short term use.

The approved indications for ibuprofen 400mg are the same as those for ibuprofen 200mg which are available as Unscheduled and S2 medicines. These indications are easily recognised by consumers, are unlikely to be confused with more serious conditions and are appropriate for self-selection within pharmacy.

The 400mg product offers the following benefits over the 200mg product:

- A 400mg dose is more effective and provides longer lasting pain relief than a 200mg dose
- The 400mg product offers the convenience of a single unit dose (especially important for those patients who have difficulty swallowing)

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

The proposed pack size of 12 dosage units, represents 4 days' therapy for patients taking the maximum dose (3 dosage units per day).

The dosing of the 400mg product is different to that for the 200mg product and TGA approved labelling has been used in the marketplace to clearly distinguish between the two products and thereby address the risks posed by confusing the two products.

Potential for abuse of a substance

Like all other NSAIDs, ibuprofen is not known to have the potential for abuse.

The potential for misuse is negligible.

Scheduling factors

The AHMAC *Scheduling Policy Framework*[1] sets out the following scheduling factors for Pharmacy Medicines (Schedule 2):

1. 1The quality use of the medicine can be achieved by labelling, packaging, and/or provision of other information; however access to advice from a pharmacist should be available to maximise the safe use of the medicine.

2. The use of the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low.

3. The use of the medicine is very unlikely to produce dependency (at either the established therapeutic dose or supratherapeutic doses) and the medicine is very unlikely to be misused, abused or illicitly used.

4. The risk profile of the medicine is well defined and the risks can be identified and managed by a consumer through appropriate packaging and labelling, including consultation with a health professional if directed by labelling.

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.

In our view, the proposed amendments to the Schedule 2 entry for ibuprofen clearly meet the requisite scheduling factors.

Conclusion

CHP Australia supports the proposed amendment to the Schedule 2 entry for ibuprofen based on:

- The requisite scheduling factors
- The risks and benefits of the 400mg ibuprofen dose (both *per se* and in comparison to the 200mg product)
- The S2 pack size being limited to 12 dosage units (i.e. 4 days therapy for patients taking the maximum dose)
- The likely benefits of providing the public with wider access to the 400mg product
- The use of the TGA approved product labels to clearly distinguish between the 200mg and the 400mg products

[1] https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals