# FURTHER PUBLIC SUBMISSIONS ON THE PROPOSED AMENDMENTS TO THE POISONS STANDARD

### Regulation 42ZCZQ, 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 further public submission on the proposed amendments to the Poisons Standard. These submissions are in response to the delegates' interim decisions. The interim decision takes into account the original application, submissions received in any consultative phase and advice from the June 2012 Advisory Committee on Chemicals Scheduling (ACCS) #5, the Advisory Committee on Medicines Scheduling (ACMS) #6 and the joint ACCS and ACMS #2.

In accordance with the requirements of subsection 42ZCZQ of the Regulations these submissions have had 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 www.tga.gov.au/industry/scheduling-spf.htm.

Discrete submissions have been grouped by substance.

## LIST OF SUBMISSIONS

| Substance | Total number of public submissions |
|---|---|
| Tranexamic Acid | 1 |
| Ibuprofen in combination with phenylephrine | 2 |

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sir/Madam

**Public Comment Submission to the Delegate's Interim Decision under subsection 42ZCZP of the Therapeutic Goods Regulations 1990**

We refer to the notice published on 5 September 2012 of the Delegate's interim decisions under subsection 42ZCZP of the *Therapeutic Goods Regulations 1990*, inviting public submissions, with respect to certain substances, addressing a matter raised in section 52E of the *Therapeutic Goods Act 1989.*

[redacted] provided comments on **tranexamic acid** for consideration at the joint meeting of the ACMS and ACCS held in June 2012.

[redacted] has reviewed the Interim Decisions & Reasons for Decisions by the Delegate of the Secretary to the Department of Health and Ageing. Even though interim decisions relating to tranexamic acid impose a more restrictive control than what we proposed in our pre-meeting submissions, [redacted] we therefore support the Delegate's interim decisions.

We look forward to further advice from the ACMS and ACCS. [redacted]

Yours faithfully

[redacted]

18 September 2012

[redacted]

[redacted]

# 19 September 2012

# Comments [redacted] on the interim decision for combination products containing ibuprofen and phenylephrine

## Background

[redacted] notes the delegate's interim decision to exempt ibuprofen from scheduling when in divided preparations containing 200 mg or less of ibuprofen in fixed dose combinations with 5 mg or less of phenylephrine in packs containing not more than 25 units, when used for the treatment of adults and children aged 12 years and over.

## Comments

In opposing the initial proposal to exempt from scheduling combination products containing ibuprofen and phenylephrine, [redacted] provided a number of clinical and social reasons for retaining these products within Schedule 2 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). [redacted] believes that these points are all the more relevant in light of information published recently within the American Heart Association's journal 'Circulation'.[1]

Danish researchers investigated the incidence of death rates and non-fatal recurrent myocardial infarction (MI) associated with subsequent non-steroidal anti-inflammatory drug (NSAID) use in people who had experienced a first-time MI between 1997-2009. Having previously established that NSAIDs are harmful among patients with MI or heart failure and that the risk is prevalent even after short treatment periods, the Danish researchers further investigated risks associated with the time elapsed following an MI. The patient cohort was significant with over 43,000 people investigated. The conclusion of the investigation was 'that NSAID use among patients with first-time MI was associated with persistently increased risk of all-cause mortality and of a composite of coronary death or nonfatal MI, respectively, for at least 5 years thereafter. The results support previous findings that NSAIDs have no apparent safe treatment window among patients with MI. Further studies are warranted to evaluate the cardiovascular safety of NSAIDs, but at this point the overall evidence suggests advising caution in using NSAIDs at all times after MI'.

**The authors also advise that 'the results from the past decades have shown that the cardiovascular safety of pharmacotherapy can have massive implications, and**

[redacted]

[redacted]

**the risk-benefit ratio of all NSAIDs and the over-the-counter availability of non-selective NSAIDs such as diclofenac or ibuprofen in many countries should be reconsidered.'**

Applying these findings to the Australian setting, in 2009 there were 9,307 deaths from Acute MI[2]. Cardiovascular disease (CVD) accounted for 6% (475,200) of all hospitalisations in Australia in 2007-08. Of these, 34% were due to Coronary Heart Disease (CHD), which includes MI and angina, and 10.4% due to heart failure or cardiomyopathy.[3]

This is a significant number of people who are at risk of post-MI complications should they take a NSAID, of which ibuprofen is the most commonly used due to its increased availability and the fact that it is available in a large number of combination products. This risk is increased in the following circumstances:

- in combination with other cardio-active drugs (such as phenylephrine)
- taking higher doses of NSAID
- if used with other NSAIDs (e.g. other prescribed NSAID or non-prescription NSAID labelled for another indication)

Due to the multitude of brands and types of NSAIDs available, consumers are often unaware that different products contain the same or similar medicine. Consumers may inadvertently put themselves at greater risk of post-MI complications by taking one or more of these products at the same time without any access to health care professional intervention.

In considering the impact of these findings, it is important to note the following factors which we raised in our original submission:

- limitations with consumer health literacy mean that there are increased risks with relying solely on labelling and packaging to address safety concerns
    - more vulnerable patient groups (e.g. elderly) are particularly at risk as this group is more likely to have had a prior cardiac event
    - only 7% of Americans read the labels of non-prescriptions for warnings
    - a third of Americans would take more than the recommended dose of a non-prescription medicine
    - 36% of Americans are likely to take multiple non-prescription medicines when they have multiple symptoms
- consumers are often unaware of the adverse effect profile of NSAIDs
- there is no identified need for increasing access for this medicine combination through the grocery sector

In addition, since the initial proposal was considered by the ACMS, there is a report[4] from a large prospective analysis which identifies that regular use (greater than two times per week) of ibuprofen and acetaminophen (paracetamol) was associated with an overall 17 and 9 percent increase in the risk of hearing loss, respectively.

[redacted] is concerned that the ready availability of ibuprofen products without any access to healthcare professional intervention demonstrates a number of increased health risks, including:

- cardiovascular health
- kidney health and
- aural health

As more and more of these detrimental health outcomes are being identified with NSAID use, there may be a need to consider whether these so-called 'simple analgesics' should continue to have a scheduling exemption. In the meantime, [redacted] believes that proposals for future exemptions should not be supported, particularly for combination products.

# Conclusion

[redacted] believes that the new evidence provided with this recent Danish research, along with that provided in our original comments on this proposal, demonstrate the significant risks faced by a large number of people who have had a non-fatal MI who may inadvertently take a cold tablet containing ibuprofen and phenylephrine because they do not have access to pharmacist advice. We maintain that Schedule 2 is the more appropriate schedule for ibuprofen when combined with phenylephrine.

**Reference Sources:**

[1] Anne-Marie Schjerning Olsen, Emil L Fosbol, Jesper Lindhardsen et al; Long-Term Cardiovascular Risk of NSAID Use According to Time Passed After First-Time Myocardial Infarction: A Nationwide Cohort Study; Circulation; published online 10 September 2012
[2] http://www.abs.gov.au/ausstats/abs@.nsf/Products/C04DC24838AA01AACA2577F5000BBF89
[3] Australia's Health 2010; AIHW
[4] SG Curhan, J Shargorodsky, R Eavey; Analgesic use and the risk of hearing loss in women; Am J Epidemiol; 29 Aug 2012; http://www.ncbi.nlm.nih.gov/pubmed/22933387

[redacted]

[redacted]

19 September 2012

Medicines and Poisons Scheduling Secretariat
Therapeutic Goods Administration
MDP 88
GPO Box 9848
CANBERRA ACT 2601

Dear Sir/Madam

**Interim scheduling decision – ibuprofen in combination in phenylephrine**

[redacted] welcomes the opportunity to provide a submission on the interim scheduling decision for ibuprofen in combination with phenylephrine.

[redacted]

[redacted] notes that the delegate has made an interim decision to reschedule ibuprofen from Schedule 2 to unscheduled when in divided preparations containing 200 mg or less or ibuprofen in fixed dose combinations with 5 mg or less of phenylephrine in packs containing not more than 25 tablets.

[redacted] supports this interim decision. We have reviewed the reasons for this decision, and believe that the safety implications of exempting these products from scheduling have been given proper consideration. This decision will increase the accessibility of these products for consumers, and, as noted in the reasons for the delegate's decision, the wider availability of an additional combination product to alleviate cough and cold symptoms would be of public benefit.

[redacted] notes that two submissions relating to this decision raised concerns about the number of ibuprofen products currently available and the increased risk of inappropriate use. These concerns could be lessened through the implementation of proposed regulatory changes relating to the labelling of non-prescription medicines containing ibuprofen, as outlined in the Therapeutic Goods Administration's (TGA) *Medicine Labelling and Packaging Review Consultation Paper*. These changes would require non-prescription medicines containing ibuprofen to include a statement in bold on the front of their packaging that the product contains ibuprofen and advising the consumer to consult a doctor or pharmacist before taking other medicines for pain or inflammation.

[redacted]

[redacted] appreciates the opportunity to provide a submission on the interim decision. If you would like to discuss these comments in more detail, please contact [redacted]

Yours sincerely

[redacted]

[redacted]