From:	r r
To:	Medicines Scheduling
Subject:	Invitation to comment on proposed amendments to the Poisons Standard being referred to the June 2020 meeting of the ACMS-ACCS meetings, with respect to IBUPROFEN SCHEDULING: [SEC=No Protective Marking]
Date:	Sunday, 19 April 2020 3:52:02 PM
Attachments:	public-submission-cover-sheet.docx

- **Dear Sir/Madam,**
- **I refer to the Invitation to comment on proposed amendments to the Poisons Standard being referred to the June 2020 meeting of the ACMS-ACCS meetings, with respect to IBUPROFEN SCHEDULING:**

  I wish the submit my comments as follows:
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- I agree with the statement that, since the rescheduling of all codeine based analgesics to Schedule 4, there has been a need to improve availability of OTC treatments to manage strong pain.
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- Also, I agree with the statement that the 400 mg double strength tablets are likely to be used by people seeking relief of stronger pain.
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- I note that Cochrane reviews have confirmed that the 400 mg dose is more efficacious than the 200 mg dose with equivalent tolerability.
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- In addition, a single dose of ibuprofen 400 mg has been clinically demonstrated to be as efficacious as the fixed combination of paracetamol/ibuprofen (500 mg/200 mg) (one tablet) one of the main Schedule 2 options for the relief of acute strong pain.
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- Therefore, I agree that Ibuprofen 400 mg is appropriate for inclusion in Schedule 2 as it has a superior risk-benefit profile to that of paracetamol, aspirin and diclofenac, as single agents, as well as paracetamol/ibuprofen combinations.
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- I also agree that Ibuprofen 400 mg is as effective as the combination analgesic and is a safer option as people are only exposed to one active ingredient that is as well tolerated as paracetamol and is safer than paracetamol in overdose situations.
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- I note and agree with concerns regarding paracetamol overdose in combination products (paracetamol/ibuprofen) was highlighted as a reason to maintain its current Pharmacy scheduling status at the November 2019 ACMS meeting.

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- Indeed, with respect to paracetamol, toxicity, specific concerns arise due to liver damage, arising from the metabolite NAPQ1, which decreases the liver glutathione, and directly damages cells in the liver.

  Since, as noted, approximately 1 in 6 customers of Australian pharmacies have difficulty swallowing oral medications, having the option to take one small 400 mg tablet will provide these people the benefit of taking fewer tablets to help manage their strong pain. For these people the benefit of taking fewer tablets is meaningful and is not adequately addressed by the current scheduling as swallowing difficulties are not commonly discussed.

  Finally, I, and others, have had long-standing concerns, which I have previously raised , regard the potential for renal toxicity of Ibuprofen and other NSAIDs,), especially in with a diuretic and an ACE or ARBs.(commonly-used antihypertensive combination medication.

  However, since this potential adverse renal effect is NOT DOSE-RELATED and there is cautionary labelling about NSAID, on non-prescription packs of Ibuprofen products, with regard to renal compromise, I believe it is appropriate to move Ibuprofen 400mg to schedule 2, with the presumption of pharmacist guidance to patients on any dose and usage concerns.

In summary, therefore, improving the availability of 400 mg ibuprofen by permitting self-selection as a Schedule 2 medicine should provide consumers with an effective and safe alternative option to relieve strong pain, whilst still having the advantage of of pharmacist guidance to patients on any dose and usage concerns