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The Secretary
Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
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Dear Sir/Madam

**Re: Consultation: Proposed amendments to the Poisons Standard - ACMS Meeting #31
Item 1.5 Ibuprofen**

Modified release ibuprofen has only recently become available as a non-prescription (OTC) medicine in Australia with the first product (Advil 12 Hour Extended Release Tablet - AUST R 306571) only having been launched in November 2019. The current Schedule 3 status for OTC modified release ibuprofen is appropriate to support the quality use of medicines given that its indication (for the relief of persistent pain) and format (modified release) differs from the standard immediate release ibuprofen more widely available.

As a new ibuprofen format, the role of the pharmacist is important to educate, determine suitability based on individual needs and to support its safe and effective use. Furthermore, the requirement for the provision of Consumer Medicine Information (CMI) ensures that there is access to written information beyond the product label to reinforce the pharmacist's advice.

In May 2020, two new Schedule 3 ibuprofen products were approved by TGA (Nurofen 12 Hour - AUST R 335682 and ARW Ibuprofen Long Lasting 300 - AUST R 335681), each containing 300mg ibuprofen in a modified release format. Whilst not appearing to be within scope of the current application to amend the Schedule 2 entry for ibuprofen to include pack sizes of not more than 12 dosage units each containing 400 mg or less, the proposed wording of the schedule entry would also capture these 300 mg modified release formats recently approved by the TGA. Given the limited time modified release ibuprofen has been available as an OTC medicine in Australia, it is important that these remain S3.

When assessing the proposed amendments to the Poisons Standard for ibuprofen at the June ACMS meeting, GSK requests the Committee and Delegate consider any implications for modified release formulations such that these remain within Schedule 3.

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