



5 March 2018

Medicines Scheduling Secretariat
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2606

By e-mail: medicines.scheduling@tga.gov.au

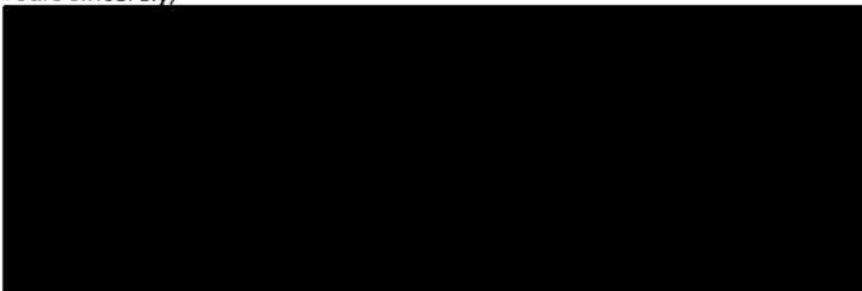
**Re: Scheduling delegates' interim decisions and invitation for further comment:
ACCS/ACMS, November 2017: Ibuprofen Schedule 2 and Schedule 3.**

We refer to the notice inviting further comment under subsection 42ZCZP of the Therapeutic Goods Regulations 1990 and would like to provide comment on the Delegate's Interim Decisions arising from the November 2017 meeting of the ACCS/ACMS. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

RB supports the Delegate's interim decision that the current Schedule 2 and Schedule 3 entries for ibuprofen remain appropriate. The reasons are summarised below and are consistent those outlined in RB's submission of 6 October 2017:

- There are no new safety concerns at OTC doses and duration;
- There is no evidence of excessive use, purchasing or harm through general sale or Schedule 2 availability;
- Recent review by the TGA and Overseas agencies have not identified any new safety concerns or risks;
- RB's Product Safety Update Reports (PSUR) found that the overall risk benefit of ibuprofen remains positive;
- Maintaining the current schedule provides benefits to accessibility to consumers.

Yours sincerely,



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