



15th July 2013

OTC Medicines Regulatory Process Review
Therapeutic Goods Association
PO Box 100
Woden
ACT 2606
Australia

<mailto:OTCBPRconsultationpaper@tga.gov.au>

Consultation Response: OTC Medicine N2 Monograph Proposal for Ibuprofen, Aspirin and Paracetamol. Version 1.0, July 2013

Reckitt Benckiser (RB) appreciates the opportunity to provide comment on this consultation.

RB is unsure about the benefits of the proposed N2 OTC Monograph application route to industry.

RB supports a trial period for the three monographs and a full assessment of its benefits however we question the readiness of potential sponsors to submit applications within the 12 month period.

We are concerned and disappointed about the exclusion of New Zealand from the N2 Monograph application route. We are of the view that every opportunity to align regulatory processes and requirements across both countries should be made a priority to help facilitate the development and success of the joint agency, ANZTPA. We urge the TGA to develop joint monographs in the future if the trial of this application route is successful.

RB would appreciate clarity from the TGA regarding the timeframes and confirmation of the list of actives for the next phase of monograph development.

Lastly RB would like to confirm their alignment with the views of both the Australian Self Medication Industry (ASMI) and the New Zealand Self Medication Industry (NZSMI) on this consultation.

We look forward to hearing the outcomes of this initiative.

Yours sincerely

Reckitt Benckiser Pty Ltd