

Complaint 04/08**Complainant:** GlaxoSmithKline Australia Pty Ltd (GSK)**Respondent:** Reckitt Benckiser Australia Pty Ltd (RB)**Complaint:** Trade and consumer advertising campaign for Nurofen for Children brand including Nurofen for Children Infant Drops. GSK complained against the advertising claim that Nurofen for Children, in terms of duration of action in respect of fever in children, "reduces fever for up to eight hours, which is up to two hours longer than children's paracetamol".**Alleged Breaches:**

GSK alleged the following breaches of the ASMI Code:

1. Clause 5.1.3: GSK cited Dover study that uses the currently approved doses of paracetamol and ibuprofen which demonstrated the equivalent antipyretic efficacy of ibuprofen 10mg/kg and paracetamol 15mg/kg. It was alleged that advertising claims are no longer current or accurate in light of the Dover study and, if left uncorrected, will mislead healthcare professionals and consumers as to the duration of action of ibuprofen and paracetamol.
2. Clause 5.1.4: GSK alleged that RB had access to but ignored the Dover Study in making its current claim and failed to provide it when requested by GSK to substantiate the claim.
3. Clause 5.2.2: The comparative claim "Nurofen for Children relieves discomfort of fever for up to eight hours, which is up to two hours longer than children's paracetamol" has been proven false in a direct head to head clinical trial comparing ibuprofen with paracetamol for fever relief in children (Dover Study).

Outcomes:

The ASMI Complaints Panel found:

1. That in the context of the approved Australian dosing regime, the Dover study does negate the advertised claim. The Panel took the view that it will not ordinarily be influenced by new evidence as it becomes available unless it has sufficient power and relevance to the claim being contested. The Dover study is the only study directly comparing the Australian approved dosages of the two products in the potential consumers to whom the advertisements were (indirectly) addressed, namely children and babies from 3 months. The Panel found the claim, in its slightly different forms, to be inaccurate and misleading, in moderate breach of clause 5.1.3 of the Code.
2. That the advertisements imply that children's paracetamol is ineffective in reducing fever beyond 6 hours. This was found to be a moderate breach of clause 5.2.2 of the Code.
3. That the Dover study demonstrated the equivalent antipyretic efficacy of ibuprofen 10mg/kg and paracetamol 15mg/kg at and up to 8 hours, and since this information was publicly known in 2006, the claim was not substantiated when made. This was found to be a moderate breach of clause 5.1.4 of the Code. RB provided its response in a timely fashion upon GSK's request for substantiation and was not found to be in breach of clause 5.1.4 of the Code. This aspect of the complaint was dismissed.

Sanctions: The Panel ordered Reckitt Benckiser to:

- a. Discontinue making such claims until they can be supported by clinical evidence
- b. Send to every pharmacist in Australia to whom the advertising and promotional material was likely to have been exposed a corrective letter
- c. Pay the following fines:
 - i. For the Moderate Breaches in relation to Nurofen for Children, compendious fine of \$20,000.

Complaint 05/08**Complainant:** Johnson & Johnson Pacific Pty Ltd (JJP)**Respondent:** GlaxoSmithKline Australia Pty Ltd (GSK)

Complaint: Advertising and trade promotion for Nicabate Patch and Click2Quit Program. JJP complained against the '30% more likely to quit' claim' in all its forms, with words to the effect: "30% more likely to quit with Click2Quit when used alongside Nicabate Patch and Click2Quit Program".

Alleged Breaches:

Johnson & Johnson Pacific alleged the following breaches of the ASMI Code:

1. Clause 5.1.4: GSK did not provide requested substantiation of the '30% more likely' claim and when substantiation was provided, two contradictory sets of data were provided which did not support the claim.

Outcomes:

The ASMI Complaints Panel found:

1. That even though GSK acted promptly in providing the clinical study titled "Efficacy Evaluation of Niquitin CQ committed Quitters Stop Smoking Plan Program", the study does not substantiate the claim. Accordingly, this was found to be a moderate breach of clause 5.1.4 of the Code.

Sanctions: The Panel ordered GlaxoSmithKline to:

- a. Discontinue the practice of advertising or otherwise communication of the '30% more likely to quit' claim until it can be supported by clinical evidence.
- b. To retrieve and destroy all promotional material containing any such claim within 10 weeks of the date of the Panel determination.

Complaint 06/08

Complainant: Johnson & Johnson Pacific Pty Ltd (JJP)

Respondent: GlaxoSmithKline Australia Pty Ltd (GSK)

Complaint: Advertising and promotional campaign for Nicabate Pre-QUIT patch directed towards consumers and healthcare professionals. JJP complained against the 'triples' claim: "Nicabate PRE-QUIT is clinically proven to triple the chance of quitting successfully compared to cold turkey.

Alleged Breaches:

Johnson & Johnson Pacific alleged the following breaches of the ASMI Code:

1. Clause 5.1.3 and 5.1.4: GSK stated that the claim was arrived at by multiplying two values for relative risk (RR); one being the RR of standard patch versus placebo (Cochrane Review rounded up to 1.7); and the other being the RR for pre-cessation NRT versus standard patch therapy (RR of 1.7). JJP alleged that the claim was misleading, inaccurate and does not reflect the body of evidence in its entirety as the substantiation provided by GSK neglected to use the 3 month data from the pre-cessation NRT study by Bullen *et al.* (2008).
2. Clause 5.1.4: GSK failed to provide all data used in the substantiation of the 'triples' claim, despite a specific request for it on a separate occasion. It was alleged that JJP was unable to sufficiently evaluate all data as GSK failed to provide a complete explanation of how they arrived at the values for Relative Risk used in their meta-analysis.

Outcomes:

The ASMI Complaints Panel found:

1. That there was no evidence before Panel of any clinical study of pre-cessation patch versus placebo or will power alone. The Panel found that the derived methodology of supporting 'triples' claim provided a robust estimate but did not establish that the result had been 'clinically proven' and for this reason the claim was misleading and had not been substantiated. This was found to be a moderate breach of clause 5.1.3 and 5.1.4 of the Code.
2. That GSK provided enough information to JJP to evaluate the validity of the 'triples' claim and was not in breach of this aspect of clause 5.1.4 of the Code. This aspect of the complaint was dismissed.

Sanctions: The Panel ordered GlaxoSmithKline to:

- a. Discontinue advertisements and publication of claims to the effect that Nicabate PRE-QUIT is clinically proven to triple the chance of quitting successfully compared to cold turkey until it can be supported by clinical evidence.
- b. Retrieve and destroy all material containing any such claim within 10 weeks of the date of Panel determination and to remove any such claim from any online postings.
- c. Send to every pharmacist in Australia to whom the advertising and promotional material was likely to have been exposed a corrective letter.
- d. Publish a corrective advertisement in the next available issue of Australian Pharmacist.