ASMI COMPLAINTS PANEL FINAL DETERMINATION
Meeting held May 8, 2012

Glaxo Smith Kline Consumer Healthcare ("GSK") v. Reckitt Benckiser Pty Limited ("RB")

Nurofen for Children advertising.

1 GSK complains that Point of Sale material in pharmacies and a television advertisement for Nurofen for Children ("NfC") breached the ASMI Code of Practice ("the Code") and the Therapeutic Goods Advertising Code ("TGAC"), with which members are required to comply pursuant to the Code, section 4.3.1.

2 The claims of which GSK complains are as follows:

Point of sale material ("POS")	**mums told us they prefer nurofen because: "I found it great for teething."** ("the Mums Prefer Claim").
Television commercial ("TVC")	**"I switched to Nurofen for Maria's teething, as I just found it worked better."** **"Discover why more mums are switching to Nurofen for Children."**

Testimonial-based claim

3 GSK says supporting data for the Mums Prefer Claim provided by RB in response to a request from GSK included three statutory declarations by mothers who use NfC, none of which contained the direct quote **"I found it great for teething",** in breach of the Code section 5.1.4.

4 RB relies on the statutory declaration of one particular mum dated 3 February 2012, which says "it worked very well", "worked better for her", "nothing else seemed to work as well" and she "was surprised at how well it worked" for teething and teething pain. RB contends that these phrases indicate that, for her, it could be said that NfC was great for teething.

5 RB also relies on a recently transcribed market survey focus group of mothers conducted on 14 June 2011, (not provided to GSK in response to its initial request) in which Julie says "yes I find it [Nurofen] great for teething," Richelle says "yeh I find it [Nurofen] great for teething", and Angela agrees. RB contends that this evidence substantiates the Mums Prefer Claim.

Panel consideration

6 The Mums Prefer Claim: "**mums told us they prefer nurofen because: "I found it great for teething"** represents that more than one mum actually spoke those words. None of the statutory declarations provided by RB in response to GSK's request substantiates this representation, in breach of the Code, section 5.1.4.[1]

7 It is unnecessary to decide whether the transcript of extracts of the market survey focus group of mothers conducted on 14 June 2011 substantiates the representation because it was not provided to GSK without delay upon request, in further breach of the Code, section 5.1.4.

Teething Claims

Comparator not immediately clear

8 GSK says the TVC portrays a mum talking to the camera, saying **"*I switched to Nurofen for Maria's teething, as I just found it worked better*"**. This and the Mums Prefer Claim (together "Teething Claims") are comparative in that they claim that mums have either switched to NfC (from something else) or expressed a preference for NfC (over something else) for teething because it works better. However, it is not clear with what NfC is being compared or upon what basis it is being compared, in breach of the Code section 5.2.2.

9 RB says the Code (in the explanatory note to section 5.2.2) suggests only that, in some cases, such a technique ***may*** (emphasis added) be considered inappropriate and contrary to the provisions of the Code, however GSK have failed to demonstrate how the Teething Claims are unclear and therefore how they constitute a breach of section 5.2.2.

10 RB says there is no lack in clarity in the comparator in the Teething Claims, which refer to a switch from, or a preference for NfC relative to the other available products in the product category for childhood teething problems.

11 RB says neither of the Teething Claims breaches section 5.2.2. Whilst the claims do refer to a relative preference by a user for NfC, they do not identify nor purport to describe another product, or show the non-prescription consumer healthcare products of a competitor as broken or defaced, inoperative or ineffective. Any comparison made reflects the anecdotal and individual experiences of genuine and typical users of NfC and does not purport to describe any products of a competitor as a whole.

Panel consideration

12 In using the "hanging comparatives" inherent in the words "prefer", "switched" and "better", without clarifying with what those comparisons are made, the advertisements would be understood by reasonable consumers as representing that NfC is being compared with (to use RB's words) "the other available products in

[1] Because determinations of the Panel are published on the ASMI website, the declarants are not identified here.

the product category for childhood teething problems". However, the advertisements do not describe or show the non-prescription consumer healthcare products of a competitor as broken or defaced, inoperative or ineffective. There is no breach of the Code, section 5.2.2.

13 The Panel suggests to ASMI that, in any Code revision, the explanatory note to section 5.2 might be better placed as an operative provision or as a note appurtenant to section 5.1.3.

Comparator most likely to be paediatric paracetamol

14 GSK says the substantiating data provided to it by RB included National Pharmacy Value ($) Scan Data which shows the market-leading brand of children's analgesic products just prior to the airing of the TVC to be Children's Panadol, followed by NfC, followed by a number of other paracetamol-based brands. GSK contends that the claims of "switching" and "prefer" would be interpreted by the consumer to mean that the mums in the NfC advertisements had previously used a paracetamol-based paediatric analgesic product and now they choose to use NfC because it works better than paracetamol. RB has provided no scientific data to substantiate this superior efficacy claim, in breach of the Code, section 5.1.4.

15 RB submits that "the relative reference point" for the Teething Claims is "the other available products on the market" (including any other ibuprofen products, paracetamol products and other products which contain other analgesics such as codeine, anaesthetics or any other relevant active ingredients). Brands other than Nurofen and Panadol constitute a not insignificant portion of the market.

Panel consideration

16 As stated in paragraph 12, because no comparator product is identified, reasonable consumers would understand that the comparison is with all other teething products readily available on the market, including the market leader, Children's Panadol. Accordingly, the Teething Claims would be understood by consumers as representations by RB that NfC works better than any other teething products readily available on the market. RB did not provide substantiation without delay upon request for the representation that NfC works better than any other teething products readily available on the market, let alone all of them, in breach of the Code, section 5.1.4.

Lack of scientific support data to prove superior teething efficacy of Nurofen

17 GSK says the body of evidence does not support the claim that NfC (ibuprofen) will work better than paracetamol for infants with teething pain. Hence the claim is not substantiated and does not reflect the body of scientific evidence, in breach of the Code section 5.1.3 and the TGAC sections 4(1)(b), 4(2) (a), 4(2) (c) and 4(5). Further, the consumer testimonial "*I switched to Nurofen for Maria's teething, as I just found it worked better*", is not supported by the body of the

scientific literature so does not illustrate a typical case, in breach of TGAC section 4.7.

Code 5.1.3

18 RB says GSK incorrectly assumes that RB has made a comparative claim against paracetamol products. Neither advertisement provides general "information or medical claims" about NfC or any other product. The Teething Claims are expressions of individual mothers' opinions regarding how the product works *for them* (emphasis added), not claims of efficacy for NfC or ibuprofen over paracetamol. RB says that at no stage has it made a general or specific comparison between NfC and paracetamol based paediatric analgesics, or ibuprofen (generally) as compared with paracetamol based paediatric analgesics. Hence RB says it is not required to provide any comparative studies of ibuprofen versus paracetamol as substantiating evidence.

Panel consideration

19 The Panel has found that reasonable consumers would understand the advertisements to make the medical claim that NfC works better than all other teething products readily available on the market, including the market leader, Children's Panadol. The Panel accepts that the body of scientific evidence does not establish that NfC (ibuprofen) will work better than paracetamol for infants with teething pain. RB has not contended otherwise. Accordingly the claim is misleading, in breach of the Code, section 5.1.3.

TGAC 4(1)(b)

20 RB denies breach of this section, which requires that advertisements for therapeutic goods *contain correct and balanced statements only and claims which the sponsor has already verified,* saying the only claims it has made relate to individual anecdotal experiences of particular mothers who have used NfC. One of the statutory declarations supports the claim of the mother featured in the TVC saying, *"I switched to Nurofen for Maria's teething, as I just found it worked better"* as well as the claim *"mums told us they prefer Nurofen because: "I found it great for teething"".* The latter claim is also supported by the survey evidence.

Panel consideration

21 A claim made in an advertisement by someone other than the advertiser cannot be verified simply by demonstrating that the person made the claim. The advertiser has the responsibility of substantiating the claim itself. Hence it is beside the point to show, as RB has attempted to do, that the claims in these advertisements represent the genuinely held opinions of one or more of the mums in question. Having failed to substantiate the claim that NfC works better than all other teething products readily available on the market, RB is in breach of section 4(1)(b) of the TGAC.

TGAC 4(2)(a)

22 RB denies breach of this section, which requires that advertisements for therapeutic goods must not: *be likely to arouse unwarranted and unrealistic expectations of product effectiveness*, saying GSK has not provided any evidence or other submissions to support its claim of breach. NfC is a known product that relieves pain and is indicated on the ARTG Register accordingly. None of the claims made in any of the advertising material exaggerates the product effectiveness beyond the known indications of the product.

Panel consideration

23 The representation that NfC works better than all other teething products readily available on the market is likely to arouse in consumers an expectation that the representation is true. Since this is not supported by the body of scientific evidence, that expectation is unwarranted and unrealistic. Accordingly RB is in breach of section 4(2)(a) of the TGAC.

TGAC 4(2)(c)

24 RB denies breach of this section, which requires that advertisements for therapeutic goods must not: *mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions,* saying at no stage in the NfC advertising campaign is a specific comparison of efficacy made between either NfC or ibuprofen as compared with paracetamol based paediatric analgesics, so consumers are unlikely to be mislead into such a belief.

Panel consideration

25 Although no express reference is made to paracetamol based paediatric analgesics, the advertisements, by using the "hanging comparisons" inherent in the words "prefer", "switched" and "better", without identifying the comparator, represent that NfC works better than all other teething products readily available on the market, including Children's Panadol. Since the body of scientific evidence does not support this, the advertisements mislead directly or by implication, in breach of section 4(2)(c) of the TGAC.

TGAC 4(5)

26 RB denies breach of this section, which requires comparative advertising to: *be balanced and must not be misleading or likely to be misleading, either about the therapeutic goods advertised or the therapeutic goods, or classes of therapeutic goods, with which it is compared. Points of comparison should be factual and reflect the body of scientific evidence. Comparisons should not imply that the therapeutic goods, or classes of therapeutic goods, with which comparison is made, are harmful or ineffectual.* RB says the NfC advertising campaign does not specifically compare NfC or ibuprofen with paracetamol based paediatric analgesics. The advertisement shows an individual recounting [her] personal experience with the product. This is not misleading because it is supported by evidence that the individual mothers referred to in the advertisements did find that Nurofen was great for teething.

Panel consideration

27 For the reasons given in paragraph 21, the fact that the individual made the statement is irrelevant. RB has failed to show that the comparison is factual and reflects the body of scientific evidence, in breach of section 4(5) of the TGAC.

TGAC 4.7

28 RB denies that the claim "*I switched to Nurofen for Maria's teething as I just found it worked better"* is in breach of this section of the TGAC, which provides that: *Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.* RB says the claim is documented and supported by a mum's statutory declaration and is not misleading because it represents her individual anecdotal experience and is not a statement of comparison with paracetamol based paediatric analgesics. The significant market share of NfC (as evidenced by the scan data provided to GSK) indicates that NfC is preferred by a significant proportion of consumers. Hence that mum's experience is by no means atypical.

29 RB also relies on unit share information (not previously provided to GSK) in respect of the NfC product and other children's products which, it says, shows an increase in unit share for the NfC products only in the 12 month period up to 12 February 2012. Hence there has been no breach of section 4(7) of the TGAC.

Panel consideration

30 It is misleading for the testimonial to represent, as it does, that NfC works better than all other teething products readily available on the market, including Children's Panadol, because that representation is not supported by the body of scientific evidence. Further, the testimonial is not typical because it is not clear from the volume scan data that NfC is preferred by a significant proportion of consumers nor that people are switching to NfC. In the period from September 25, 2011 to February 12, 2012 unit share for NfC declined while increasing for Panadol. Accordingly the testimonial is in breach of section 4(7) of the TGAC.

Lack of scientific support data: Switching Claim

31 The TVC ends with a voice-over statement saying **"Discover why more mums are switching to Nurofen for Children"** ("Switching Claim"). GSK says this and the Mums Prefer Claim in the POS are designed to encourage consumers to switch to NfC and 'discover' for themselves the better efficacy that other mums have experienced as a result of switching.

32 GSK says the value share data provided by RB in response to GSK's request does not support a 'switching' or 'preference' claim. Any increase in value ($) share could be due to a price increase or to new mums entering the market and starting off using Nurofen for Children for all conditions requiring a Children's analgesic/antipyretic treatment not just to treat teething issues.

33 Further, GSK says the information provided in the statutory declarations does not support the claim that mums (plural) are switching to Nurofen. At best, it shows only one mum switching to Nurofen for Children for her daughter's teething pain. Accordingly, RB has failed to substantiate the Switching Claim, in breach of the Code section 5.1.4 and TGAC section 4(1)(b).

34 RB relies on National Pharmacy Scan Data by volume, which it provided in response to the formal complaint, and which RB says indicates increased market share for NfC and a corresponding decrease in the other brands shown. RB also says the claim does not refer to or imply, nor would it be understood by a reasonable consumer to refer to, a switch from paracetamol paediatric analgesics in general or Children's Panadol in particular.

35 In the context of the TVC as a whole, the Switching Claim is a standalone statement, not limited to switches for teething pain, because 3 mothers are featured, each with discrete and different stories about their experiences with NfC. The statutory declarations provide evidence that "[two] more mums [plural] are switching to NfC".

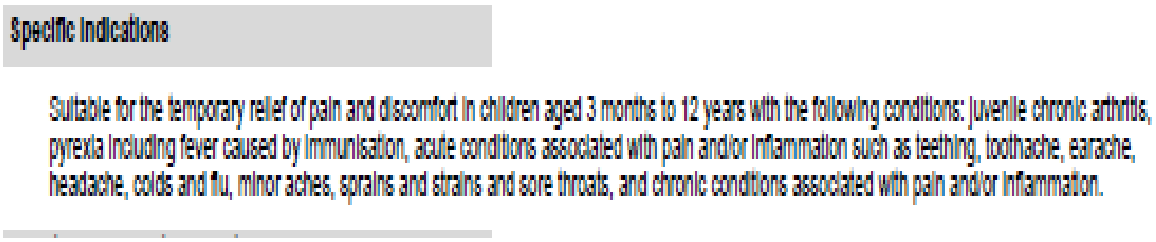
Panel consideration

36 The Panel considers that reasonable consumers would understand from the Switching Claim that mums in significant numbers are switching to NfC from other paediatric analgesics readily available on the market, not necessarily from all of them. Although they may not know that Children's Panadol is the leading brand, they would know it as a very popular brand and accordingly many consumers would be likely reasonably to conclude that some mums are switching from Children's Panadol.

37 RB does not argue before the Panel that the value scan data it provided in response to GSK's request for substantiation supports the Switching Claim and the Panel finds that it does not. As indicated in paragraph 30, the Panel does not regard the volume scan data provided in response to GSK's formal complaint as establishing switching to NfC from Children's Panadol. The evidence of switching in two statutory declarations is insufficient to support the Switching Claim as it is likely to be understood by reasonable consumers. Accordingly the claim, when made, had not been substantiated, in breach of the Code, section 5.1.4 and TGAC section 4(1)(b) and evidence of substantiation was not provided without delay upon request, in breach of the Code, section 5.1.4.

Misleading by omission

38 GSK says both the POS material and the TVC refer only to "***teething***". The ARTG entry for Nurofen for Children states it is indicated for the relief of pain and/or inflammation associated with teething:



39 The statutory declaration provided by the mother talking about "teething" in the television commercial states "*I switched to Nurofen for Maria's teething **pain** because it worked better for her*." (emphasis added).

40 In making the "teething" claims, RB has chosen to omit the word 'pain', which acts as a qualifier in the statutory declaration and which is supported by the approved indication for the product. This omission has the potential to mislead consumers into believing that NfC "works better" in any or all of the symptoms that might be associated with teething. Given that Australian research has shown that parents continue to harbour a number of false beliefs about the signs and symptoms of teething, with as many as 70% attributing fever to teething and in the context of a TVC, which also discusses fever, RB has promoted the belief that NfC "works better" in other symptoms, such as fever, that parent's commonly attribute to teething. This raises additional concerns in relation to the appropriate use of medicines as the scientific literature is very clear that high temperature in young children should not be attributed to teething and should be investigated.

41 In these circumstances, GSK says the claims are not an accurate reflection of the testimonial and suggest that NfC may be used to manage other symptoms associated with teething and not just pain, beyond the approved indication for this product. Accordingly, RB has breached the ASMI Code section 5.1.3 and TGAC Sections 4(1) (a) and (b), 4(2)(a), and 4(2)(c) .

42 RB denies extending the advertising beyond the approved indication for the product, since "pyrexia" is the medical term for fever. The ARTG entry for NfC states that the product is indicated for *"pain and discomfort in children aged 3 months to 12 years with pyrexia … acute conditions associated with pain and/or inflammation such as teething…"*. The advertising of NfC is consistent with this entry and it is irrelevant that "teething" is unqualified by "pain" in the advertisements, which do not imply that teething causes fever.

43 Because NfC is indicated for treatment of pyrexia (fever) in children, its use in relation to fever does not constitute inappropriate use of medicines (whether or not a parent wrongly believes fever to be caused by teething).

44 One of the statutory declarations refers to both "teething" and "teething pain" and says that "it worked very well", "better for her", "nothing else seemed to work as well" and that she was "surprised at how well it worked". Given that NfC is indicated for pain, inflammation and fever, RB says the Mums Prefer Claim accurately reflects that testimonial.

Panel consideration

45 Since the approved indications for NfC include pyrexia as a stand alone condition, the omission of the word “pain” from the advertised claims for teething is not misleading or likely to mislead reasonable consumers. The advertising does not go beyond the approved indications and the reference to fever does not constitute inappropriate use of medicines. Since one of the statutory declarations refers to both "teething" and "teething pain" the references in the advertisements to “teething” without the word “pain” do accurately reflect that testimonial. Accordingly the Panel finds no breach of the Code or the TGAC.

Categories of breach

46 The breach of the Code, section 5.1.4 found in paragraph 6 is Minor. All of the other breaches found to have been established are Moderate since they are likely to impact on the perceptions of the consumer regarding the efficacy of NfC and other products used for the symptomatic relief of children’s pain and fever, including paracetamol.

Sanctions

47 On the material before the Panel, the Panel has considered the factors set out in the Code, section 9.1.3, as follows:

- *Whether publication has ceased*; and
- *Whether steps have been taken to withdraw the material published.*
  RB says the campaign involving the POS for NfC will come to an end with relevant stores being instructed to remove the POS for NfC, including the Mums Prefer Claim, after 7 May 2012. The Panel does not know whether broadcast of the TVC has ceased. The Panel notes that in relation to the POS material, RB has had the full benefit of its campaign.

- *Whether corrective statements have been made.*
  No corrective statements appear to have been made.

- *Whether the breach was deliberate or inadvertent.*
  It is clear the wording of the advertisements was deliberately chosen. As to whether the breach was deliberate, the Panel considers that, having regard to the breaches mentioned below, RB deliberately sought to sail as close to the wind as it thought it could but that it did not deliberately breach the Code. In this regard the Panel considers that, to base a campaign on the testimonials of (at most) 7 people does not establish that their experience is typical.

- *Whether the Member that is the subject of the complaint has previously breached the Code.*

On July 17, 2008, RB was found by this Panel to have breached the Code in claiming that NfC and Nurofen for Children Infant Drops reduce fever for up to 2 hours longer than children's paracetamol.

On 3 August, 2009, RB was found by this Panel to have breached the Code in claiming that Nurofen Zavance works twice as fast as other painkillers.

On August 26, 2010, RB was found by this Panel to have breached the Code in claiming that NfC offers more time without fever in the first four hours than paracetamol.

- *Whether there were or are safety implications.*
  There are no safety implications

- *Whether the perceptions of healthcare professionals or consumers have been or will be affected.*
  The perceptions of consumers are likely to have been and will be affected.

48 The Panel requires RB:

(a) to give an undertaking in writing to the Executive Director of ASMI to cease publication forthwith in any media, until it can be supported by clinical evidence, of any representation, express or implied, to the effect that Nurofen for Children is more effective than other teething products readily available on the market, including Children's Panadol;

(b) to ensure that the Point of Sale material that is the subject of this complaint is removed from exposure to consumers within 30 days and to notify the Executive Director of ASMI that this has been done; and

(c) to pay a fine of $10,000 for the Moderate Breaches found by the Panel.

49 The Panel makes no determination to alter the usual operation of section 8.4.2.2 of the Code.

50 Attention is drawn to sections 9.2.6 and 10.1 of the Code.

Dated: May 27, 2012

For the ASMI Complaints Panel

Alan L. Limbury

Chairman

Note: although this is called a Final Determination, each party has a right of appeal to the Arbiter. If no appeal is lodged this determination will be published on the ASMI website once the time for lodging an appeal has expired. If there is an appeal, the Arbiter's determination will be published on the ASMI website together with this determination. Until publication on the website, parties and their representatives should maintain the privacy of these proceedings.