ASMI Complaints Panel Determination 02/14

Meeting held on December 9, 2014

GlaxoSmithKline Consumer Healthcare Australia Pty Ltd ("GSK")
v.
Reckitt Benckiser (Australia) Pty Limited ("RB")

Nurofen Zavance "Headache" marketing campaign

1. After some informal communications between the parties, GSK initiated this complaint formally by letter dated November 7, 2014. RB responded formally by letter dated November 21, 2014 and GSK referred the complaint to ASMI on November 24, 2014. RB contends that the complaint includes new matters not raised in the informal complaint resolution process, many of which would have been able to be resolved without the necessity for the ASMI Panel's intervention.

2. GSK complains that claims made in an advertising campaign for Nurofen Zavance breach the ASMI Code of Practice 2013 (ASMI Code) and the Therapeutic Goods Advertising Code (TGAC). The campaign comprises 3 television commercials ("TVCs"), a You Tube advertisement, a consumer website, a digital advertising display, bus shelter advertising, a print advertisement and a range of point of sale material (all directed to consumers); and 3 items contained in a show bag provided to pharmacy assistants at the Pharmacy Assistant National Conference held on October 16 – 18, 2014.

3. In particular, GSK says RB has not complied with prior rulings of the Complaints Resolution Panel ("CRP") nor with orders by the TGA delegate made in CRP Complaints 2011-06-001, 2012-08-010 and 2012-10-024. Those rulings and orders, but not the advertisements with respect to which they were made, have been provided to the Panel in the present complaint.

4. RB says that, save in one minor respect, the advertising campaign complies with the provisions of the ASMI Code and the TGAC raised by GSK. RB says the orders of the Delegate overruled the CRP in important respects and that RB has complied with the Delegate's orders.

"**Targets pain" claims**

5. The TVCs differ only in their imagery, as follows:

> [Rotating back, head and neck image]
> Everything in the body is connected.
> [Muscles in neck and head highlighted]
> That's why when you feel the pain of a headache the source of the pain may be the muscles in your neck and head.
> [Nurofen Zavance pack]
> So if you want fast relief try Nurofen Zavance.

[Orange target flies from pack to image of body torso where it moves up to the head]
To relieve your headache fast at the source of pain
[Image of lady/man rubbing temples]
Nurofen Zavance. Targets headaches at the source of the pain faster.
[Footage of lady playing with a child/lady jogging/male auctioneer completing a sale]
Text on screen:
Target headaches at the source of pain faster
vs Standard Nurofen

6. Targeting claims in other consumer advertisements include:

   (a) For fast pain relief, try Nurofen Zavance to relieve your headache at the source of the pain. Not only is it absorbed up to twice as fast as standard Nurofen, it targets the source of pain by working both at the site of pain in the body and on pain signals that reach the brain [Website];

   (b) Did you know the source of headache pain may be the muscles in your neck and head? Target headaches at the source of pain faster vs Standard Nurofen [Digital Display];

   (c) Target headaches at the source of pain faster vs Standard Nurofen. [Bus Shelter Advertisement and Point of Sale Material]; and

   (d) The most common type of headache could be caused by the muscles in your neck and head. So the next time you feel the pain of a headache try Nurofen Zavance. It targets the source of pain quickly to relieve your headache, helping you get on with your day pain free. [Print Advertisement].

7. As described by GSK, Nurofen Zavance is depicted in the TVCs to be the target device (the same as that on the Nurofen Zavance pack). The target device is shown to enter the body via the stomach and travel up the body (with a small amount of diffusion) until it reaches the source of the pain (neck and head muscles). Here the target device is depicted to be working on the muscles of the head and neck before it comes to rest at the temple. Once it reaches the temple, the highlighted muscles disappear, suggesting that the pain has been relieved.

8. GSK says the TVC clearly depicts the Nurofen target moving towards an area of pain in order to relieve it. This is signalled by the brightening of the Nurofen target device. Taken in concert with the prominent final headline "*target headaches at the source of pain faster*", GSK contends that a reasonable consumer would conclude that Nurofen travelled specifically to the area of the body affected by the pain, would not travel to other parts of the body and would only have an effect on that painful part of the body. Hence the advertisement very clearly represents that, in the context of headaches, the advertised product (Nurofen Zavance) goes straight to the source of the pain. This breaches the Delegate's order in Complaint 2011/06/001 and the undertaking given by RB not to use any

representations that implied that, in the context of headaches, Nurofen goes straight to the source of pain.

9. In relation to point of sale advertisements, GSK says consumers having seen one of the TVCs and the Bus Shelter Advertisement would be left with the impression that Nurofen Zavance targets headaches at the source of pain. When they go to the supermarket to buy a pain reliever they are faced with an array of products on shelf, where the point of sale material reinforces the messages from the TVC and the Bus Shelter Advertisement. It is in this context, in which the Nurofen Zavance headache-specific advertising has been placed *in situ* with other Nurofen products, that the advertising claims become misleading and in contravention of the Delegate's order, because there is no mention that Nurofen Zavance can work on pain at any other site.

10. GSK says that, taken as a whole in the context of a consumer shopping in-store, the advertising campaign represents that one Nurofen product is for targeting headaches whilst other Nurofen products are for other types of pain. There is nothing in any of the "headache" advertising that clearly indicates that Nurofen Zavance can be used for the same purposes as or is interchangeable with other forms of Nurofen, which is the determination of the TGA Order issued on 9 May 2014. Accordingly, RB has not complied with the prior rulings of the CRP nor the Delegate's Orders and is again in breach of TGAC section 4(2)(c) by representing that, in the context of headaches, only Nurofen Zavance can target headaches at the source of pain.

11. RB says its TVC campaign complies with the Delegate's order by representing the action of the product through the body as travelling on a zigzagging path, leaving product spreading out and dissolving through the body in its wake as well as Nurofen "targets", which it leaves behind as the product travels to the source of pain. An ordinary consumer would understand that the product does not travel straight to the source of pain and that it diffuses within the body. As recognised by GSK in the complaint, there is no single target depicted in the TVC. To the contrary, the Nurofen "targets" target multiple areas in the neck and head before acting to relieve the pain. The voiceover reinforces the fact that Nurofen works more generally by opening with the statement that: "*Everything in the body is connected*" and closing with the statement: "*so if you want fast relief try Nurofen Zavance*". A consumer would more readily interpret the visuals and voiceover as meaning that Nurofen could act on multiple areas than at a single site or source of pain.

12. As to the point of sale advertisements, RB says advertising located near or including references to a standard supermarket shelf layout is not advertising in relation to other products. Nor is it advertising featuring a comparison to other products. RB submits there is no basis for suggesting that the location or inclusion of references to a shelf layout in the advertising cited in the complaint import a claim that, in the context of headaches, only Nurofen Zavance can target headaches at the source of pain.

Panel consideration

13. In considering this complaint, the Panel has had regard to the decisions of the CRP and to the orders of the Delegate. It notes in particular the comments of the CRP in paragraph 43 of its determination in Complaints 2012-08-010 and 2012-10-024 that, at least in some senses, products containing ibuprofen could be regarded as in fact providing targeted relief from pain; that a claim that the advertised product "goes straight to the source of pain" would not be acceptable as it would be misleading; and that the appropriateness of such claims would need to take into account the effect of the claim when combined with other elements of an advertisement.

14. As this Panel noted in its August 3, 2009 determination in *Wyeth v. RB* concerning Nurofen Zavance, the Panel needs to determine how each advertisement, taken as a whole and in the context in which it is presented, including the circumstance that each is a part of a campaign, would be likely to be understood by the class of consumers likely to be affected by it (ie. people seeking painkillers), including the astute and the gullible, the intelligent and the not so intelligent, the well educated and the poorly educated, acting reasonably.[1] Likewise, the conformity of an advertisement with the TGAC should be assessed in terms of its probable impact upon the reasonable person to whom the advertisement is directed.[2]

15. The Panel considers that all of the TVCs and other consumer advertisements in question containing "targets pain" claims would represent to consumers, acting reasonably, that an object or goal of Nurofen Zavance is to relieve headache pain by affecting its source, such as the muscles in the neck and head.

16. Further, the Panel considers that none of the advertisements would be understood by consumers, acting reasonably, as representing that Nurofen Zavance:

    - goes straight to the source of the pain;
    - would not travel to parts of the body unaffected by headache pain; or
    - would have effect only on that painful part of the body.

17. The Panel does not accept that the point of sale advertising at issue here, which compares Nurofen Zavance for headache with Standard Nurofen, when placed in-store near other Nurofen products, would be understood by consumers, acting reasonably, as representing that one Nurofen product is for targeting headaches whilst other Nurofen products are for other types of pain nor that, in the context of headaches, only Nurofen Zavance can target headaches at the source of pain.

[1] *Parkdale Custom Built Furniture Pty Ltd v Puxu Pty Ltd* [1982] HCA 44 and *Taco Co of Australia v Taco Bell Pty Ltd* [1982] FCA 136.

[2] TGAC 3(2).

18. Accordingly the Panel finds that the "targets pain" claims, in the contexts in which they have been made in this campaign, do not breach the ASMI Code or the TGAC.

Fast acting claims

19. GSK says RB has made several claims relating to the "fast" action of Nurofen Zavance which are not substantiated by scientific data and are therefore in breach of ASMI Code Clause 5.1.3 as well as TGAC sections 4(1)(b), 4(2) (c) and 4(5).

20. GSK says the claim "*Nurofen Zavance targets headaches at the source of the pain faster*" is qualified in each case by "*Vs standard Nurofen*", which qualification is either unreferenced or referenced only to *Schachtel et al 1996*.[3] Such a qualification should be used only if it has been demonstrated to be true. However, *Schachtel et al 1996* compared the clinical effectiveness of standard ibuprofen to that of paracetamol in patients with tension-type headache. Since sodium ibuprofen (the ingredient in Nurofen Zavance) was not tested, the reference does not support the claim. The same comment applies to the print advertisement claim "*It targets the source of pain quickly to relieve your headache"*, since this claim is also referenced only to *Schachtel et al 1996*.

21. GSK says much data has been amassed to determine whether an analgesic formulation that is absorbed faster (pharmacokinetic data) also provides faster and better pain relief.[4] A recent review of this topic has found that, in general, this principle holds true when the data from different fast acting ibuprofen formulations (arginine, lysine and sodium salts) are pooled together.[5] However, these authors caution that the pooling of fast-acting formulations into groups could have been "*overly simplistic*".

22. In contending that the "faster" claim is not supported by the body of scientific literature comparing time to onset of meaningful pain relief with sodium ibuprofen versus standard ibuprofen, GSK summarises three published studies[6],[7],[8] which

[3] Schachtel BP, Furey SA, Thoden WR. Nonprescription ibuprofen and acetaminophen in the treatment of tension-type headache. *J Clin Pharmacol* 1996 December; 36(12):1120-1125.
[4] Moore RA, Derry S, Straube S, Ireson-Paine J, Wiffen PJ. Faster, higher, stronger? Evidence for formulation and efficacy for ibuprofen in acute pain. *Pain* 2014 January;155(1):14-21.
[5] Ibid.
[6] Brain P, Leyva R, Doyle G, Kellstein D. Onset of Analgesia and Efficacy of Ibuprofen Sodium in Postsurgical Dental Pain: A Randomized, Placebo-Controlled Study versus Standard Ibuprofen. *Clin J Pain* 2014 August 27.
[7] Norholt SE, Hallmer F, Hartlev J, Pallesen L, Blomlof J, Hansen EJ, Fernandes N, Eriksson L, Pinholt EM. Analgesic efficacy with rapidly absorbed ibuprofen sodium dihydrate in postsurgical dental pain: results from the randomized QUIKK trial. *Int J Clin Pharmacol Ther* 2011 December;49(12):722-729.
[8] Schleier P, Prochnau A, Schmidt-Westhausen AM, Peters H, Becker J, Latz T, Jackowski J, Peters EU, Romanos GE, Zahn B, Ludemann J, Maares J, Petersen B. Ibuprofen sodium dihydrate, an ibuprofen formulation with improved absorption characteristics, provides faster and greater pain relief than ibuprofen acid. *Int J Clin Pharmacol Ther* 2007 February;45(2):89-97.

examined post-surgical dental pain and two clinical trial reports[9],[10] which found that onset of pain relief with sodium ibuprofen in tension-type headache was not significantly faster than with standard ibuprofen. The only clinical trial showing a statistically significant faster onset of meaningful pain relief with sodium ibuprofen was in relation to dental pain, a type of pain not related to the muscles in the head and neck. GSK says the conclusion from this dental pain study is that only 10-20% of patients will experience pain relief earlier with sodium ibuprofen versus standard ibuprofen.[11] That is, the majority of patients (80-90%) will obtain no benefit above that of standard ibuprofen.

23. GSK says the claim in the Pharmacy Assistant materials *"Recommend Nurofen Zavance for fast-acting pain relief"* is not supported by the referenced publication, *Moore et al 2014*,[12] which reported a rapid reduction of pain intensity with sodium ibuprofen versus standard ibuprofen in the first hour associated with better overall pain relief and longer lasting analgesia in patients with acute pain following third molar extraction but stated that confidence about this result for third molar extraction should not be extrapolated to all acute pain conditions and that it needs replication in other acute pain settings, such as other post-surgical pain, in acute pain from other causes, and independently in conditions like tension headache or migraine.

24. RB submits that the parties are in agreement that Nurofen Zavance provides better and faster pain relief than standard Nurofen. GSK's suggestion that the pooling of data could have been overly simplistic is not an appropriate basis for abandoning the conclusions of the study (GSK Ref.4). RB's claim reflects the existing body of clinical evidence and the validity of extrapolating the dental pain model to support efficacy in other pain conditions such as headache is widely accepted (citing GSK Ref.6, GSK Ref. 7, Regulatory authorities generally and EMEA Guidelines). Accordingly there is no basis for a specific pain study to support the "faster" claim given that it is widely accepted that the extrapolation model used by RB is clinically acceptable and relevant for other pain states. The reservation expressed in *Moore et al 2014* (Ref.12) on this point is not reflective of the methodology's broader acceptance in the scientific and regulatory community.

25. RB says the base ibuprofen molecules found in Nurofen Zavance 256mg sodium ibuprofen salt and standard Nurofen 200mg ibuprofen acid are equivalent. The solubilised ibuprofen in Nurofen Zavance provides the same therapeutic effect as the equivalent solubilised ibuprofen in standard Nurofen. The difference between the two formulations arises from the different solubility profiles: the Nurofen Zavance ibuprofen salt formulation is much more soluble and dissolves more

[9] Pfizer. Study Evaluating A Novel Ibuprofen Formulation In Episodic Tension-Type Headache. http://clinicaltrials.gov/show/NCT01077973; 2012. Report No.: ClinicalTrials.gov Identifier: NCT01077973.
[10] Pfizer. Ibuprofen Sodium Tension Headache Study. http://clinicaltrials.gov/ct2/show/NCT01362491?term=01362491&rank=1; 2014. Report No.: ClinicalTrials.gov Identifier: NCT01362491.
[11] Schleier P et al, supra.
[12] Moore RA, Derry S, Straube S, Ireson-Paine J, Wiffen PJ. Validating speed of onset as a key component of good analgesic response in acute pain. *Eur J Pain* 2014 May 22.

quickly in the stomach than the equivalent Nurofen standard acid formulation, with pharmacokinetic studies indicating that this leads to the faster absorption. Accordingly, the *Schachtel* paper, which studies the effect of 200mg ibuprofen acid, is applicable to the equivalent 256mg ibuprofen salt. In principle any efficacy data on ibuprofen acid are fully applicable to ibuprofen salt.

26. RB says *Moore et al 2014* (GSK Ref.4) confirms that the equivalent ibuprofen salt formulations reach median maximum plasma concentrations faster, provide significantly better analgesia, with a less frequent need for additional analgesia, indicating longer lasting pain relief than the equivalent ibuprofen acid. Individual patient data analysis in dental pain indicates a strong correlation between more rapid reduction of pain intensity and better overall pain relief. In combination with *Moore et al 2014* (GSK Ref.4), *Schachtel* provides adequate clinical support for the faster claim. For the avoidance of doubt however, RB says it is prepared to amend the references in the advertising to include the *Moore et al 2014* (GSK Ref.4) paper.

27. RB says the body of scientific literature does support the "faster" claim, both because extrapolation of the dental pain model to support efficacy in other pain conditions such as headache is valid and widely accepted and because the claim is supported by the published studies.

28. The *Schleier* study (GSK Ref.7) demonstrated that ibuprofen sodium produced significantly greater and faster pain intensity reduction compared to ibuprofen acid and that onset of pain relief occurred significantly earlier with ibuprofen sodium compared to ibuprofen acid in the post-dose period from 10-45 minutes. Pain intensity reduction by 50% was also 30 minutes earlier with ibuprofen sodium compared to ibuprofen acid.

29. In the *Norholt* study (GSK Ref.6), although "faster" was not demonstrated in relation to the primary endpoint, it was demonstrated on secondary endpoints. At page 725 the authors state: *"The first signs of pain relief occurred significantly earlier (by 6 min; p=0.004) in the ibuprofen sodium dihydrate than in the conventional ibuprofen group".* At page 726, the authors comment that, in the patients' diary assessments, pain relief occurred faster in the ibuprofen sodium dihydrate than in the conventional ibuprofen group, with significant differences at 15 and 30 min post-analgesic administration ($p<0.001$) and ibuprofen sodium dihydrate started reducing pain intensity at 15 min after administration.

30. RB says the unpublished and non-peer reviewed studies referenced by GSK (GSK Refs.8 and 9) are not appropriate evidence to support or disprove any claim and do not form part of the body of scientific evidence relevant to assessing a claim.

31. RB concedes that *Moore et al 2014* (GSK Ref.4) further clarifies the basis upon which the claims are made and is prepared to incorporate this reference in materials going forward.

Panel consideration

32. Despite the reservation expressed by the authors of *Moore et al 2014* (GSK Ref.4), the Panel considers that the validity of extrapolating the dental pain model to support efficacy in other pain conditions such as headache is widely accepted as "*the key model for the evaluation of analgesics intended for the treatment of mild-moderate pain": Schleier* (GSK Ref.7), citing *Averbuch and Katzper 2000, CHMP 2002.*

33. Further, the Panel notes the finding in *Moore et al 2014* (GSK Ref.4) that: "In *acute pain following third molar extraction, faster acting analgesic formulations provide earlier onset of pain relief, better overall pain relief, and a lesser need for additional analgesia, indicating longer lasting pain relief".* Accordingly the Panel accepts the published and peer reviewed *Moore et al 2014* (GSK Ref.4), *Schleier* (GSK Ref.7) and *Norholt* (GSK Ref.6) studies as supporting the "faster" and "quick" relief claims for Nurofen Zavance versus standard Nurofen in headache.

34. The Panel does not accept that the results of unpublished and non-peer reviewed studies should displace the results of published and peer-reviewed studies when assessing advertising claims.

35. However, *Schachtel* (GSK Ref.1) studied standard ibuprofen versus paracetamol in headache. It did not compare ibuprofen sodium with standard ibuprofen. Accordingly, although the Panel is satisfied that Nurofen Zavance has been shown to relieve pain faster than standard Nurofen, the *Schachtel* study does not support that claim. The Panel finds that, in citing this study as the sole reference to support the claim, RB has breached ASMI Code Clause 5.1.3 and TGAC section 4.2(c) by representing, misleadingly, that it does. The Panel finds this to be a Minor Breach of the ASMI Code.

Pain free claim

36. GSK says the print advertisement claims that "*It [Nurofen Zavance] targets the source of pain quickly to relieve your headache, helping you get on with your day pain free.*" The only reference material cited is the *Schachtel* study (GSK Ref.1), which does not provide data on the efficacy of sodium ibuprofen and cannot possibly be used to support a claim that patients will be "pain free" after taking sodium ibuprofen. Moreover, based on the data reported in the *Schachtel* study, complete pain relief (pain free) status was not achieved in 100% of the participants who received standard ibuprofen. The claim is not substantiated by the scientific data. Accordingly, RB is in breach of ASMI Code Clause 5.1.3 and TGAC sections 4(1)(b), 4(2)(c) and 4(5). Moreover TGAC, section 4(2)(g) does not permit the use of claims that imply that a product is a certain, guaranteed or sure cure.

37. RB says the "pain free" claim is merely an attempt to convey the concept of analgesia, as is GSK's "pain is gone" claim for Panadol. The *Schachtel* study showed that the great majority in the ibuprofen treatment group reported no pain

by 4 hours and that the patients in the ibuprofen treatment group achieved complete relief faster than patients in the paracetamol treatment group.

Panel consideration

38. The Panel considers the claim "*It [Nurofen Zavance] targets the source of pain quickly to relieve your headache, helping you get on with your day pain free*" simply conveys to consumers that Nurofen Zavance acts quickly to relieve headache pain and contributes towards achieving complete relief. It does not represent that one dose will last an entire day, nor is there an implied representation that it is a certain, guaranteed or sure cure.

39. As GSK noted, the *Schachtel* study, which evaluated standard ibuprofen, not sodium ibuprofen, versus paracetamol, found "*Significantly more participants experienced complete relief with each active treatment compared with placebo (63% of those receiving ibuprofen at 400 mg, 34% of those receiving acetaminophen [paracetamol] at 1000 mg and 7% of those receiving placebo; p<0.001)*".

40. Since the base ibuprofen molecules found in sodium ibuprofen and ibuprofen acid are equivalent, with the difference between the two being the enhanced solubility of the sodium product, the Panel considers that the *Schachtel* study supports the claim. There is no breach of the ASMI Code or the TGAC.

Claims of superior efficacy versus paracetamol

41. The Pharmacy Assistants materials contain the following claims relating to the superior efficacy of standard Nurofen over paracetamol in the relief of tension-type headaches:

    • Nurofen is superior to paracetamol for treating tension-type headache.
    • Nurofen has been shown to be significantly more effective than paracetamol at treating TTH ($p<0.01$)
    • More people achieve complete relief at 2 hours from TTH with Nurofen than with paracetamol ($p<0.01$)
    • Over 95% of people achieved complete relief from TTH with Nurofen
    • More people achieve complete relief from TTH with Nurofen than with paracetamol.

42. GSK says in each instance the claim has been referenced solely to the *Schachtel et al 1996* study. Whilst the cited data appear to have been accurately extracted from the reference paper, the material is misleading because it does not take into account the available body of evidence on this topic, which GSK identifies as *Schachtel et al 1996* and a study by RB(UK), study NL9701. Both of these studies provide data of head-to-head comparisons of ibuprofen 400mg and paracetamol 1000 mg in tension-type headache.

43. GSK says recent guidelines have suggested that in trials evaluating analgesics for use in tension-type headache, the measure "pain free at 2 hours" is clinically

relevant and should be the primary efficacy measure in clinical studies (GSK Ref.14). Despite their similar study design, in contrast to *Schachtel et al 1996*, the NL9701 study showed no difference between paracetamol and ibuprofen in terms of the proportion of patients' pain free at 1 hour or 2 hours. GSK contends that RB has selectively chosen to dismiss their own clinical trial data and rely instead on the *Schachtel et al 1996* study because it suits their purposes in making a directly comparative claim.

44. GSK says RB has made a claim which does not reflect the body of scientific evidence. Accordingly, the superior efficacy in tension-type headache claim is in breach of ASMI Code Clauses 5.1.3 and 5.2.2 and TGAC sections 4(1)(b), 4(2)(c) and 4(5).

45. GSK says this is not the first time that GSK has been able to provide evidence of RB-sponsored data that directly conflicts with claims being made by the company. ASMI Complaint 04/08 of July 17, 2008 found in favour of GSK in respect of data from the Dover study, a study sponsored by RB but not accounted for when RB made directly comparative advertising claims in favour of its Nurofen for Children product over paracetamol.

46. GSK also claims that a YouTube video makes an implied and misleading representation that Nurofen Zavance is superior to paracetamol in headache or tension-type headache, by means of a clear image showing the "Nurofen Zavance headache claim" on-shelf collateral placed over a shelf containing Panadol/paracetamol packs. The reference displayed on the screen is *Schachtel et al 1996*. RB has made a claim which does not reflect the body of scientific evidence. Accordingly, the superior efficacy in tension-type headache claim is in breach of ASMI Code Clauses 5.1.3 and 5.2.2 and TGAC sections 4(1)(b), 4(2)(c) and 4(5).

47. As to the Pharmacy Assistant material, RB says the *Schachtel* reference demonstrates that ibuprofen is significantly different from paracetamol both in terms of pain intensity difference and pain relief ratings ($p<0.01$). The great majority of patients in the ibuprofen treatment group reported no pain by 4 hours, and the patients in the ibuprofen treatment group achieved complete relief faster than patients in the paracetamol treatment group ($p<0.001$). Study NL9701 was not designed to demonstrate non-inferiority to paracetamol; there were significant differences between groups for gender and mean weight and height; headaches at baseline were moderate to severe, and inclusion/exclusion criteria might not have been inappropriate [*sic*]. This study is not published and has not been peer reviewed. This study therefore provides a lower level of evidence than the *Schachtel* study. On this basis, RB submits the *Schachtel* reference is the only relevant study upon which to base a claim of superior efficacy compared to paracetamol and therefore the claim is consistent with and reflective of the body of scientific evidence.

48. As to the YouTube video, RB says a consumer without GSK's special interest would be unlikely to notice the pack of Panadol on the shelf behind the actress. The marketing collateral on shelf in the background of the advertisement is out of

focus and unable to be read. It is quite unlikely that a consumer would freeze frame and sharpen the picture so as to understand the comparison the collateral at point of sale is alleged to be making. Accordingly, RB denies this allegation.

Panel consideration

49. As to the Pharmacy Assistant material, the Panel has already stated that the results of unpublished and non-peer reviewed studies should not displace the results of published and peer-reviewed studies when assessing advertising claims. In this regard the Panel notes that the Dover study was a published study.[13] Accordingly, the *Schachtel* study, which GSK concedes supports the claims of superiority of Nurofen Zavance over paracetamol set out above, constitutes the body of relevant scientific evidence. There is no breach of the ASMI Code or the TGAC.

50. As to the YouTube video, the Panel accepts that there is an out of focus but recognizable pack of Panadol on shelf in the background, next to multiple packs of Nurofen Zavance. The shopper describes tension-type headache and chooses Nurofen Zavance from a shelf having the pack of Panadol next to it. If freeze framed, the *Schachtel et al 1996* study is visible as the last of five references.

51. The Panel does not accept that the video represents to a consumer acting reasonably, who would be unlikely to freeze frame the video, that Nurofen Zavance is superior to paracetamol. Even if it does, as the Panel has stated in paragraphs 39 and 40, the *Schachtel et al 1996* study supports this claim. There is no breach of the ASMI Code or the TGAC.

Unsolicited sampling

52. GSK says at the recently convened Pharmacy Assistant National Conference held on the Gold Coast, 16-18 October 2014, RB personnel who are not qualified healthcare professionals provided to Pharmacy Assistants a show bag which contained a sample pack of 4 Nurofen tablets. This constitutes the direct supply of unsolicited samples to consumers, in breach of ASMI Code Clause 5.1.2 and TGAC section 4(8).

53. RB denies the allegation, saying there is no prohibition on sampling in ASMI Code Clause 5.1.2, the Explanatory Notes to which refer to distribution of samples to the public as an advertising or promotional technique which may be considered inappropriate and contrary to the provisions of the TGAC because it may be likely to persuade consumers to use a product which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser.

[13] Autret-Leca E, Gibb IA, Goulder MA. Ibuprofen versus paracetamol in pediatric fever: objective and subjective findings from a randomized, blinded study. *Curr Med Res & Opin* 2007 September; 23(9):2205-2211.

54. RB submits that a sample pack provided to Pharmacy Assistants at a Pharmacy Assistant conference containing 4 tablets of Nurofen is not likely to persuade consumers to use a product which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of the purchaser. The Pharmacy Assistant National Conference was open only to Pharmacy Assistants, who are far better placed than the general public to be aware of and understand the role and correct manner of administration of common analgesic products such as Nurofen.

55. RB says the wording of the third bullet point in Explanatory Note to ASMI Code 5.1.2 specifically refers to the distribution of samples *to the public*. This was deliberate, as can be seen by the contrast to the wording of the previous bullet point which refers to sales assistants and healthcare professionals. The intention here is not to capture the persons referred to in the second bullet point of the Explanatory Note to clause 5.1.2. TGAC section 4(8) refers to advertisements offering a sample of therapeutic goods. No such advertisement was conducted by RB and the complaint does not specify any advertisement offering a sample. Accordingly, no breach of section 4(8) of the TGAC can be made out.

Panel consideration

56. While Pharmacy Assistants are to be considered consumers when assessing advertisements directed to them, there is no advertisement in question here. The Explanatory Notes to ASMI Code 5.1.2 distinguish between "distribution of samples to the public" and "Promotion to sales assistants". The Panel considers that the distribution of a sample pack of 4 Nurofen tablets to Pharmacy Assistants at a conference which is not open to the general public would not be likely to persuade consumers to use a product which may not be needed or a larger quantity than is sufficient to meet the reasonable needs of a purchaser. Accordingly there is no breach of TGAC section 4(8). The ASMI Code does not prohibit unsolicited sampling. There is no breach of the ASMI Code.

Conclusion

57. In paragraph 35 the Panel has found a Minor Breach of the ASMI Code by RB in citing *Schachtel* (GSK Ref.1) as the sole reference in support of the "faster" and "quick" relief claims for Nurofen Zavance versus standard Nurofen in headache. RB, in its formal response, has accepted this was a breach and has undertaken to cite, in addition to *Schachtel,* the *Moore et al, 2014* study in any future advertising of the claim.

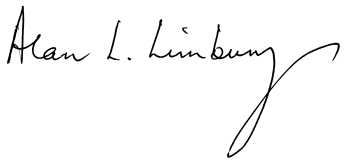
58. In light of this undertaking, the Panel imposes no sanctions.

59. RB has submitted that the Panel should assess each of GSK's allegations separately and consider whether they should be characterised as having been generated as a competitive tool. While the sampling claim and GSK's assertions as to how the YouTube video would be understood appear to the Panel to be completely untenable, and while many of GSK's allegations should have been able to be resolved by discussion between the parties, the Panel is not prepared

to find that this complaint has been used simply as a competitive tool, contrary to ASMI Code Clause 9.4.2.1.

60. Nevertheless, in relation to ASMI Code Clause 9.4.2.2, the Panel considers that, having regard to the dismissal of all GSK's allegations, save in relation to one Minor Breach which does not affect the substance of the advertised claim involved, GSK should reimburse 100% of ASMI's out-of pocket expenses.

Dated: December 24, 2014.
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.