ASMI COMPLAINTS PANEL FINAL DETERMINATION
Meeting held August 24, 2010

Johnson & Johnson Pacific Pty Limited ("JJP") v. GlaxoSmithKline Australia Pty Limited ("GSK")
4mg Nicabate Minis lozenge TVC.

1. JJP complains that a TVC for GSK's 4mg Nicabate Minis lozenge breached clauses 5.1.3 and 5.2.2 of the ASMI Code of Practice ("the Code").

The advertisement

2. JJP describes the advertisement as follows:

> "The advertisement depicts the hopeful but hapless quitter subject to the agitations of nicotine cravings. The Nicabate Mini Lozenge is the answer, the advertisement shows. It "*dissolves in minutes*" and the cravings are visibly relieved. The advertisement highlights the contrast between the small size of the lozenge and its beneficial impact in that "*they dissolve in minutes to release their full dose of therapeutic nicotine three times faster than Nicabate gum*". This claim is presented both in voice-over, and in the superimposed words "*Nicabate 4mg Lozenge releases full dose of therapeutic nicotine three times faster than Nicabate gum*". This claim is reinforced by two additional superimposed statements, in yellow capital letters: *DISSOLVES IN MINUTES. RELEASES 3 X FASTER THAN NICABATE GUM*
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> When the quitter does not light a cigarette, the screen turns red and the "cravings" become agitated, run around, jump and yell. The quitter then shakes the Mini Lozenge pack and the "cravings" calm and look at the pack. The screen then changes from red to blue as the Mini lozenge pack is lowered over the "cravings" who immediately become less agitated. The voiceover concludes that the Mini Lozenge delivers "calm" and "control" and is the tool to "quit - one cigarette at a time".

The Complaint

3. JJP says the TVC conveys a clear message of alleviating nicotine cravings that is very fast to immediate and is highly superior to NRT gum. Specifically, the TVC conveys a message of 3 times faster speed of craving relief. Importantly, nothing in the TVC clarifies that the message conveyed relates only to the speed of release of nicotine into the mouth, and does not relate to speed of craving relief offered by the Nicabate Mini Lozenge. Although reference is made to a particular brand of gum (GSK's Nicabate gum), the message conveyed is highly

superior speed of craving relief, specifically 3 times faster speed of craving relief, than that of alternative products, including all NRT gum.

4. JJP says the available data relate to speed of dissolution and release of the dose into the mouth and there are no data about speed of craving relief. Consumers are interested in the speed of craving relief (and would not care about speed of dissolution and speed of dose release unless it told them something about craving relief). The TVC itself makes clear that speed of craving relief is what the hopeful quitter wants and needs. There is no evidence to support the claim that speed of craving relief is proportionate to speed of dissolution or speed of dose release. In the absence of relevant substantiation, the message is misleading. Accordingly, JJP says the messages are in breach of section 5.1.3 of the Code. The comparison is also in breach of section 5.2.2 of the Code as it portrays NRT gums to be ineffective.

5. JJP says that even if it is found that only a narrower comparison is conveyed to consumers, ie a comparison with only Nicabate gum and not other NRT gum products, GSK does not have the required substantiation. Furthermore, the words "dissolves in minutes" fail to clarify that the product does not relieve cravings three times faster than other NRT gum products.

6. JJP refers to decision No.2010-02-30 dated 28 April, 2010 of the Complaints Resolution Panel (CRP), on a TVC that JJP says is not the same but, on the key issue here, is very similar. In that matter:

    (a) the TVC was for the same advertised product and adopted the same distinctive animated sequence of quitter in need of help from agitated cravings for nicotine;

    (b) the TVC made a similar claim, ie that the Nicabate Mini Lozenges "release their full dose of therapeutic nicotine three times faster than gum";

    (c) the CRP found that the TVC was in breach of the *Therapeutic Goods Advertising Code* (TGAC), on the basis that the message conveyed by the TVC was that the product alleviated cravings three times faster than NRT gum products, and this message was unsubstantiated.

7. JJP contends that the following observations of the CRP are entirely apt in relation to the very similar aspects of the TVC the subject of the present complaint:

    > 31.”A statement that is true in a narrow or technical sense may nonetheless be misleading, lack balance, or be likely to arouse unwarranted and unrealistic expectations in relation to a product's

effectiveness. The Panel was satisfied that the words *"Nicabate Mini 4mg lozenges release their full dose of therapeutic nicotine 3 times faster than gum"* would arouse in any reasonable consumer an expectation that the lozenges product would have an effect three times sooner than a competing gum product."

32."Moreover, other contextual elements ... were, in the Panel's view, likely to reinforce such an interpretation on the part of consumers. The Panel noted that the television advertisement, for example, conveyed an impression that control of cravings was immediate - the advertisement's protagonist replaced a cigarette with a lozenge and appeared to experience immediate craving relief. The 'one cigarette at a time' motif running through [the TVC] suggested that relief was immediate. These contextual elements, in the Panel's view, directed consumers minds to the speed of craving relief, and not merely to the speed with which nicotine was released, making consumers likely to connect the 'three times faster' claim with the speed of craving relief. "

The Response

8. GSK's formal response included informal correspondence between the parties, contrary to section 8.4.1.1 of the Code. The Panel has ignored this.

9. GSK says, by way of background, that JJP first raised concerns in April 2009 with the *claim 'Nicabate Minis 4mg releases its full dose of therapeutic nicotine three times faster than gum'.* In May 2009 GSK agreed to use the qualifying statement '*speed of release does not infer speed of craving relief*' with that claim. In December 2009 JJP expressed the view that the use of the qualifying statement did not change the likely interpretation of this claim by a reasonable consumer. GSK disagreed**.**

10. In February 2010 JJP complained to the CRP in relation to the use of the claim *Nicabate Minis 4mg releases its full dose of therapeutic nicotine three times faster than gum*' with the qualifying statement *'speed of release does not infer speed of craving relief'* . The CRP determined that in its view, the qualifying statement would need to be as prominent as the main claim in order for this specific claim to be adequately balanced and not misleading.

11. In the current complaint JJP mentions that GSK has not provided technical support demonstrating the correlation between the time it takes for nicotine to be completely released from the product and the absorption of nicotine. This was also raised by JJP with the CRP (CRP determination points 12 - 13), however the CRP chose not to comment in its determination.

12. GSK says paragraphs 31 and 32 of the CRP determination are not presented in full context, as the CRP agreed at paragraph 28 that technically the claim

"*Nicabate Minis releases its full dose of therapeutic nicotine three times faster than gum"* can be regarded as true.

13. GSK says its intent has always been to communicate the convenience benefit (10 minutes versus 30 minutes use by the consumer) in a compelling way. Accordingly, following the CRP determination, GSK changed the claim to *'they may be small but they dissolve in minutes to release their full dose of therapeutic nicotine three times faster than Nicabate gum'*("The Claim").

14. In GSK's view the inclusion of the words '*they may be small'* (visual characteristic of the product); '*they dissolve in minutes*' (functional and convenience characteristic); and changing the comparison to '*Nicabate Gum*" add further context to The Claim and make it clear that The Claim is about the products' speed of dissolution in relation to Nicabate Gum specifically. GSK decided to make the comparison specific to Nicabate gum to eliminate any potential perceived, direct or implied comparison with Nicorette gum or any other NRT gum.

15. GSK says communicating a point of difference, that is, convenience and speed of dissolution between Nicabate Minis (4mg) and Nicabate gum is important as Nicabate Minis were developed as a result of research which showed that smokers expressed dissatisfaction with how long it takes to use existing oral dose NRT products (typically 30 minutes). To address this dissatisfaction, Nicabate Minis were specifically designed to be small, presented in a convenient format and to dissolve quickly in the mouth (typically 10 minutes for the 4mg variant) therefore releasing their dose of nicotine more quickly (three times more quickly) than other oral dose formats such as gum.

16. GSK says JJP has inaccurately interpreted the messages conveyed within the TVC and has not provided any evidence to support its allegations in relation to the alleged implied messages. The TVC for Nicabate Minis is promoting the benefit of 'reduce to quit' as a quitting strategy. There is nothing within the TVC which explicitly refers to craving relief. More specifically, the TVC for Nicabate Minis is an animation designed to engage the conflicted quitter who may be thinking about quitting. It depicts the dilemma experienced by a smoker faced with the notion that quitting smoking means giving up all cigarettes at once. The opening line of the *TVC 'You may be thinking about not smoking but your brain has other ideas*' clearly communicates the dilemma faced by many smokers thinking about quitting. The introduction of Nicabate Minis in the TVC communicates that there is no need to fear quitting as it doesn't mean giving up all cigarettes at once. Nicabate Minis is promoted as a convenient product to use in a 'reduce to quit fashion' so that smokers can quit one cigarette at a time, helping to eliminate the fear and anxiety which can be associated with giving up all at once.

17. In addition to helping smokers to quit one cigarette at a time, Nicabate Minis are also easy and convenient to use as they do not require 30 minutes of use (chew and park) such as Nicabate gum. As noted above, the mini lozenges dissolve completely in 10 minutes releasing all their nicotine on dissolution. Hence the use of The Claim within this TVC communicates the convenience of 10 minutes use for Nicabate Minis versus 30 minutes use for Nicabate gum in the context of helping anxious smokers who are not ready to quit abruptly to quit one cigarette at a time.

18. As for the messages conveyed by the TVC, GSK says The Claim relates to the functional and convenience characteristics of the product. Importantly, as Nicabate gum does not dissolve but instead 'releases' its nicotine through the chewing action of the quitter, it is impossible to state simply that Nicabate Minis dissolves three times faster than Nicabate gum. Consequently, the words *'releases three times faster than Nicabate Gum'* were used to communicate this benefit in comparison to Nicabate Gum. There is no reference to craving relief within The Claim or the TVC as viewed by the consumer. The TVC refers to quitting one cigarette at a time, which is an approved indication for use for this product and also a reason why consumers would choose Nicabate Minis over other forms of NRT which generally promote abrupt quitting programs.

19. Consequently, GSK says it strongly believes that The Claim is not misleading and does not in any way directly or by implication;

    - communicate that Nicabate Minis relieve cravings three times faster than all other forms of NRT;
    - communicate that Nicabate Minis relieve craving faster than all branded NRT gum; or
    - portray NRT gum to be ineffectual.

20. GSK says the reason why it has not provided to JJP data demonstrating the correlation between the time it takes for nicotine to be completely released from the product and the absorption of nicotine is that the claim being communicated by GSK to consumers is expressing the length of time taken for the 4mg Nicabate Mini lozenge to dissolve thereby releasing its nicotine, and for Nicabate gum to be chewed thereby releasing its nicotine. GSK is not making any claims related to the rate of absorption.

21. GSK says that even if The Claim were considered an implied craving relief claim, it is supportable by the following:

    - there are no published data of which GSK is aware to show that 4mg NRT gum relieves cravings in less than 15 minutes. The only study available which specifically addresses craving relief with NRT gum is a study by *Shiffman et al (2003)* which concludes that NRT gum begins to relieve cravings in 15 minutes.

- in comparison 4mg Nicabate Minis are bioequivalent to 4mg Nicabate lozenge which have been shown to relieve cravings in 5 minutes: *Durcan et al (2004)*.

22. JJP has not provided any data to support its allegation that GSK is not able to support craving relief claims (if they were explicitly or implicitly made). In addition, if data demonstrating that Nicorette gum relieves (or even begins to relieve) cravings at the same time as Nicabate Minis did exist, GSK is sure that JJP would have provided these data in support of its allegation.

23. GSK denies that The Claim communicates that Nicabate Minis relieve cravings three times faster than all other forms of NRT or all branded NRT gum, and denies that the claim portrays NRT gum to be ineffectual.

24. GSK disagrees with JJP's assertion that consumers would only be interested in craving relief and would not care about dissolution of the product, saying JJP has provided no evidence supporting this opinion. GSK says if consumers were only interested in craving relief there would be no benefit in launching innovations in NRT unless they delivered faster craving relief than other NRT products already on the market. In addition, if JJP truly held this opinion it would not have a number of different NRT formats available on the market. Quite clearly, JJP knows that consumers choose different NRT formats based on their individual quitting needs or styles. Hence consumers would be interested in a mini lozenge which was packaged in a convenient format and which required only 10 minutes use.

25. GSK says functional claims such as the one communicated for Nicabate Minis are commonly used in the OTC environment in particular, when the point of difference between products within the category are the functional characteristics of these products which may appeal to consumers. By way of example, the current Nurofen Zavance TVC communicates the claim '*Nurofen Zavance is absorbed up to twice as fast as standard Nurofen'*. There is no qualifying statement (prominent or otherwise) that the claim does not relate to pain relief even though this product is used for pain relief and this is portrayed in the TVC. In addition, advertising for Advil by way of a TVC and outdoor media communicates that *'Advil is absorbed 30% faster than Nurofen capsules'* again there is no qualifying statement that the claim does not relate to pain relief. This is an acceptable means of communicating functional benefits of products and consumers are accustomed to receiving these messages. It would be in the best interest of industry to maintain the ability to communicate these functional claims in a responsible and balanced manner.

26. GSK's says this Formal Complaint by JJP is premature and potentially vexatious as JJP has not raised the concerns outlined within it, in relation to The Claim informally with GSK.

Panel consideration

27. In constituting the Panel for this Complaint, the Executive Director of ASMI ensured that the consumer representative had not participated in the determination of CRP decision No.2010-02-30.

28. In addressing the question whether this TV advertisement is in breach of the ASMI Code, which is defined in section 1 to include the TGAC unless the context otherwise requires, the Panel needs to determine how the advertisement, taken as a whole and in the context in which it is presented, including the circumstance that it is a television commercial, would be likely to be understood by the class of consumers likely to be affected by it (ie. people thinking of quitting smoking), including the astute and the gullible, the intelligent and the not so intelligent, the well educated and the poorly educated, acting reasonably[1]. The intention of the advertiser is irrelevant[2], save that if it were to be found that there was an intention to mislead, the conclusion might be drawn more readily that this had been achieved[3].

29. The approach to be adopted is helpfully set out in *Energizer Australia Pty Limited v Gillette Australia Pty Limited* [2001] FCA 1887 at paragraph 53:

> "53 Generally as to the implications and incidents of television advertising, the following extracts from the judgment of a Full Court in *Pacific Dunlop Ltd v Hogan* (1989) 23 FCR 553 provide guidance. At 569, Sheppard J (who was in dissent in the result) made the following general observation:
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> > *"Although the television advertisement was shown frequently, its duration was only 30 seconds. When it was shown, it was shown without warning and, no doubt, as one of a batch of advertisements during advertising breaks between programmes or in the course of particular programmes. The opportunity which viewers had to see the advertisement was a fleeting one. It appeared momentarily on their screens. That is so in the case of most television advertising which must, perforce, be quite transitory. Indeed, that is why advertisers, such as the agency here, seek to "grab" or "hook" viewers by using material which so attracts their attention, that they are held for sufficiently long to see the product which is being*

[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] *Hornsby Building Information Centre Pty Ltd v. Sydney Building Information Centre Ltd* (1978) 140 CLR 216 at 223.

[3] *Twentieth Century Fox Film Corp. v. South Australian Brewing Co Ltd* (1996) 66 FCR 451.

advertised. This is particularly important when one bears in mind that viewers become distracted during advertising breaks by conversation, looking at reading material or leaving the room to attend to household chores and the like."

And at 583, Burchett J, one of the majority, said as follows:

"However, the ultimate conclusion whether the advertisement was likely to mislead should not depend upon precisely that analysis which would be sufficient for an advertisement appearing only in print... for the kind of representation constituted by the display of the trademark... The advertisement here in question uses the still relatively new technology of television..."

Subsequently at 585 and 586, his Honour added the following general observations:

"Such an advertisement is not analysed like a crossword puzzle. It comes as a caller upon a family relaxing in the evening.

...

... the vagueness of the suggestion conveyed in this case is not sufficient to save it. The vagueness is not incompatible with great effectiveness. It would be unfortunate if the law merely prevented a trader using the primitive club of direct misrepresentation, while leaving him free to employ the more sophisticated rapier of suggestion, which may deceive more completely."

30. Here the Panel is prepared to proceed on the basis that The Claim (*'they may be small but they dissolve in minutes to release their full dose of therapeutic nicotine three times faster than Nicabate gum')* is literally true. This by no means disposes of the Complaint because the Panel finds that, in the context of the TVC and the usual circumstances in which TVCs are communicated to and received by viewers, The Claim would be likely to be understood by viewers who had not seen the TVC considered by the CRP, acting reasonably, as making the representation (using "the rapier of suggestion") that the Nicabate Mini lozenge relieves nicotine craving three times faster than Nicabate gum.

31. On the material before it, the Panel is not satisfied that this representation is true. *Shiffman et al (2003)* compared Nicorette gum with placebo, not with Nicabate Minis, and concluded that Nicorette gum begins to relieve cravings in 15 minutes. There is no evidence before the Panel equating Nicorette gum with Nicabate gum. *Durcan et al (2004)* is an abstract, not a peer reviewed journal article. It compared a NiQuitin CQ 4 lozenge with placebo, not with Nicabate Minis, and concluded that the lozenge had a significant effect on craving relief

at 5 minutes post dose. The Panel was left to assume that the NiQuitin CQ 4 lozenge is the same as the standard Nicabate 4mg lozenge, which the PI for Nicabate Mini Lozenges describes as having been demonstrated to be bioequivalent to the standard lozenge in a single dose pharmacokinetic study. In the absence of any clinical study comparing speed of craving relief from Nicabate Minis versus Nicabate gum, these two studies provide insufficient support for the representation of superior speed of craving relief made by The Claim.

32. As for the contentions of GSK set out in paragraph 22 above, the onus is on GSK to substantiate its claims. It may be supposed that if the body of scientific evidence did support superior speed of craving relief, GSK would not be seeking to confine its claims to speed of dissolution.

33. Since the visual elements of the present advertisement are the same as were used in the TVC considered by the CRP, many viewers will have seen both. In the Panel's opinion, those viewers are unlikely to have distinguished between the two advertisements, save perhaps in that the comparison is presently with Nicabate gum.

34. The Panel finds that, despite the changes in the wording, the TVC here in question makes substantially the same misleading representation as was found by the CRP to breach the TGAC. The only difference is that the comparison is with Nicabate gum, not all NRT gum. With that exception, paragraphs 31 and 32 of the CRP determination are equally apposite to this TVC.

35. Accordingly the Panel finds the TVC to breach section 5.1.3 of the Code. The Panel does not regard The Claim as making a comparison with all NRT gum nor to be showing NRT or Nicabate gum to be ineffective. The complaint of breach of section 5.2.2 of the Code is dismissed.

Classification of breach

36. The Panel finds the breach to have no safety implications but that it will impact on the perceptions of consumers regarding the product and the competitor product Nicabate gum. (Although Nicabate gum is not a product of a competitor, it is still a 'competitor product' to the lozenge). This would normally be a Moderate Breach. As noted however, the definition of the Code includes (save where the context otherwise requires) the TGAC. There is nothing in the context here requiring otherwise. Since the Panel has found the TVC to have made substantially the same misrepresentation as was considered by the CRP, the present breach of the Code is the same or similar to the breach found by the CRP in April 2010 to be in breach of the TGAC. Accordingly the Panel finds the present breach to be a Repeat Breach of the Code.

Sanctions

37. The Panel has considered the factors set out in the Code, clause 9.1.3. On the material before the Panel:

- the Panel does not know whether publication has ceased;
- the Panel does not know whether steps have been taken to withdraw the material published;
- no corrective statements appear to have been made;
- given that GSK is a sophisticated marketer of therapeutic goods and a significant user of television advertising, and given that substantially the same advertisement was found in April 2010 to be misleading, the Panel cannot accept that in making the changes to that advertisement that it did, GSK was unaware that The Claim would convey substantially the same misrepresentation. Accordingly the Panel finds that the breach was deliberate;
- GSK has relevantly breached the Code before, as found by the CRP in decision No.2010-02-30; and
- there are no safety implications but the perceptions of health care professionals and consumers will have been affected.

38. Accordingly, the Panel requires GSK:

(a) to give an undertaking in writing to the Executive Director of ASMI to cease publication forthwith in any media, including on any website, until it can be supported by clinical evidence, of any representation, express or implied, to the effect that Nicabate Mini lozenges relieve nicotine craving three times faster than Nicabate gum;

(b) to give an undertaking in writing to the Executive Director of ASMI to cease forthwith the publication in any media, including on any website, of any representation, express or implied, relating to speed of nicotine release from Nicabate Mini lozenges unless that representation is suitably qualified by an equally prominent statement which makes it clear that the representation relating to the speed of nicotine release does not relate to the speed of craving relief; and

(c) to pay a fine of $50,000 for the Repeat breach found by the Panel.

39. The Panel notes that despite substantially the same misrepresentation being made in the TVC here in question as was the subject of the CRP determination,

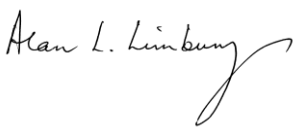
no disclaimer was included in the present TVC. The Panel notes the requests made to GSK in paragraph 38 of the CRP determination and the reference in paragraph 39 to sub-regulations 42ZCAI(3) and (4). The Panel recommends that the Executive Director of ASMI bring this determination to the attention of the CRP.

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

41. Although the Panel dismissed the complaint of breach of section 5.2.2 of the Code, this is insufficient to justify any determination by the Panel to change the usual application of clause 8.4.2.2.

Dated: September 3, 2010

For the ASMI Complaints Panel



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.