

ASMI COMPLAINTS PANEL FINAL DETERMINATION
Meeting held April 12, 2011

Nycomed Pty Ltd v. Johnson & Johnson Pacific Pty Limited (“JJP”)
Pariet 10 advertising to HCPs

1. Nycomed complains that advertisements directed to pharmacists for Pariet 10 (rabeprazole 10mg tablet), a proton pump inhibitor (“PPI”) recently permitted to be supplied OTC for acid reflux and heartburn relief, breached clause 5.1.3 of the ASMI Code of Practice (“the Code”).

The Complaint

2. Nycomed complains about the claims “fastest-working” and “fastest acting” in the following passages:
 - (a) “According to a referenced statement from Johnson & Johnson to the AJP, Pariet 10 is the fastest-working OTC PPI – superior to H2As and antacids – at stopping acid reflux and heartburn^{2,3}” appearing in the Australian Journal of Pharmacy (“AJP”), Vol 91, December 2010;
 - (b) “the fastest-acting OTC PPI” and “Of the PPI drug class, rabeprazole (Pariet) is the fastest acting, according to early pharmacology studies and a recent safety and efficacy review of PPIs.⁸ Its high pKa of ~ 5 means it can be activated at a higher pH than other PPIs, possibly resulting in a faster onset of action.¹⁰”, appearing in the AJP, Vol 92, February 2011;
 - (c) “Fastest acting OTC PPI”, appearing in Retail Pharmacy in February, 2011; and
 - (d) “the fastest acting OTC PPI” appearing in Pharmacy News, February, 2011.
3. Following informal correspondence between the parties, JJP replaced the “fastest-working” claim with the “fastest acting” claim. Nycomed says both claims convey to pharmacists the same false and misleading representation, namely “fastest onset of action”, and are unsupported by the references on which JJP relies: *Dadabhai A and Friedenbergs FK Expert Opinion on Drug Safety* 2009; 8(1) 119-126 (“*Dadabhai et al*”) and *Savarino V et al Pharmcol Res* 59 (2009) 135-153.

The Response

4. JJP says the complaint is groundless and that its advertising claims are accurate, balanced and not misleading, since the target audience, namely pharmacists, taking into account their background knowledge, expertise, experience and training as pharmacists in relation to pharmacodynamics and the way medicines (particularly OTC medicines) work, and who are familiar with PPIs and aware of the distinction between speed of activation and speed of symptom relief, would not understand the claims as representing that Pariet 10 provides any therapeutic advantage, rather they would understand that the claims represent simply that Pariet 10 converts to its active form faster than any other PPI. JJP says the references support this representation.
5. With respect to passage (a) set out in paragraph 2 above, JJP says the article in the AJP, December, 2010 should not be regarded as an advertisement or promotion by JJP because the author of the article prepared it using materials and information supplied by JJP at AJP's request, and thus prepared the article completely outside JJP's control. In any event, JJP says the references mentioned include *Dadabhai et al.* JJP contends that pharmacists would investigate the footnotes and references, read the statements in *Dadabhai et al* and understand the "fastest-working" claim to refer to conversion into active. This contention is also made in relation to passage (c) set out in paragraph 2 above, which also refers to *Dadabhai et al.*
6. With respect to passage (b) set out in paragraph 2 above, JJP says footnote 8 refers to *Savarino V et al*, footnote 10 refers to *Dadabhai et al* and the "fastest acting" claim, which appears twice in the publication, appears in the context of a subsequent claim that clearly distinguishes between activation and onset of action; identifies the speed referred to in the relevant studies as speed of activation rather than onset of action; and claims that this increased speed of action [*scil* activation] has a **possible** result of faster onset of action. Hence pharmacists would clearly understand that the message refers to speed of activation.
7. With respect to passage (d) set out in paragraph 2 above, JJP says that, as in the case of passage (a), the article was prepared by Pharmacy News based on information provided by JJP. JJP made no payment and did not review or approve the content of the article. It should not be regarded as an advertisement by JJP. Further, the information JJP provided included the relevant references but these were omitted by the publisher. Even so, the claim "*the fastest acting OTC PPI*", taken alone and with no context, will clearly be understood by pharmacists to mean conversion to active form rather than relief of symptoms.

Panel consideration

8. The Panel is of the firm view that, taking into account all the factors just mentioned, all the advertisements of which Nycomed complains would be likely to be understood by pharmacists as making a therapeutic claim of fastest onset of action. None of the cited references support this claim and accordingly all the advertisements are in breach of the Code, clause 5.1.3.
9. As to passages (a) and (d), JJP has not contended that the information it provided to the authors of the AJP, December, 2010 article and the Pharmacy News, February 2011 article differed from what was published (save that the references were omitted from the latter article), nor has JJP provided such information to the Panel, which accordingly proceeds on the basis that (save for the just mentioned exception) the articles correctly recorded the information provided by JJP. Since the information was provided in each case for publication, the Panel regards both as advertisements for which JJP is responsible under the Code.
10. As to passages (a) and (c), the Panel does not accept JJP's contention that pharmacists would investigate the footnotes and references, read the statements in *Dadabhai et al* and understand the "fastest-working" claim to refer to conversion into active. Rather they would expect the references to support the "fastest onset of action" representation, not qualify or contradict it, and in this they would be misled.
11. As to passage (b), the second reference to the "fastest acting" claim appears in the sentence: "*Of the PPI drug class, rabeprazole (Pariet) is the fastest acting, according to early pharmacology studies and a recent safety and efficacy review of PPIs.*⁸" The mention of a recent safety and efficacy review would be taken by pharmacists to mean that there is clinical support for the "fastest onset of action" representation made by the words "fastest acting". The following sentence: "*Its high pKa of ~ 5 means it can be activated at a higher pH than other PPIs, possibly resulting in a faster onset of action.*¹⁰" might give rise to some confusion but it does not follow that it would be interpreted as contradicting the "fastest onset of action" representation conveyed by the first sentence. An interpretation pharmacists could reasonably place on these two sentences is that there is a clinical study which found Pariet to have the fastest onset of action and a pharmacological study which found that Pariet can be activated at a higher pH than other PPIs and, since it was not a clinical study, speculated that faster onset of action is possible.
12. As to passage (d), the Panel is of the firm view that, whether taken in context or alone, the claim "*the fastest acting OTC PPI*" would be understood by pharmacists as representing fastest onset of action.

Classification of breach

13. The Panel finds the breach to have no safety implications but that it will impact on the perceptions of pharmacists regarding the Pariet 10 product and competing OTC PPIs. Accordingly, this is a Moderate Breach of the Code.

Sanctions

14. 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;
 - no steps appear to have been taken to withdraw the material published;
 - no corrective statements appear to have been made;
 - given that Nycomed raised with JJP its concerns about the “fastest-working” claim in December, 2010, the Panel finds that JJP must have been aware that, in changing the claim to “fastest acting”, the advertisements would convey to pharmacists substantially the same misrepresentation. Accordingly the Panel finds that the breach was deliberate;
 - In April, 2008, JJP was found to have breached the Code in advertising for Nicorette ActiveStop and required to publish a corrective advertisement and to send a corrective letter to pharmacists. The Panel found JJP to have engaged in reprehensible behavior in the conduct of the complaint process. In November and December, 2009, JJP was found to have breached the Code in advertising for Neutrogena Ultra Sheer Dry-Touch Sunscreen Lotion and required to publish a retraction statement and to pay the maximum fine for a Moderate breach. Although JJP has not previously been found to have breached the Code in relation to the advertising of PPIs, a factor common to the advertisements the subject of the earlier complaints and to the advertisements presently under consideration is that they all make unwarranted claims of superiority. This suggests that insufficient attention has been given by JJP, over a period of years, to the need to ensure compliance with the Code; and
 - there are no safety implications but the perceptions of health care professionals will have been affected.
15. The Panel notes that, in its formal response, JJP stated that, while standing by its “fastest-working” and “fastest acting” claims, it is in the process of replacing the current claim with “*fastest activating OTC PPI*”, to be qualified by a prominent disclaimer to the effect that “*theoretically, faster activation leads to faster symptom relief, however to date this has not been demonstrated in clinical studies*”. It is not for the Panel in the present proceeding to determine whether JJP’s intended changes would comply with the Code. The Panel notes, without drawing any conclusions, that the clinical study included with the formal complaint, reference 3, Pantoflickova D et al. *Acid inhibition on the first day of dosing: comparison of four proton pump inhibitors*, Aliment Pharmacol Ther 2003;17:1507-1514 at Figure 1 at p.1510 and under the heading “Onset of

antiseecretory action” at p.1511 found rabeprazole 20mg to have a slower onset of action (1.75h) than lansoprazole 30mg (1h), omeprazole MUPS tablet 20mg (1.25h) and omeprazole capsule 20mg (1.5).

16. The Panel requires JJP:

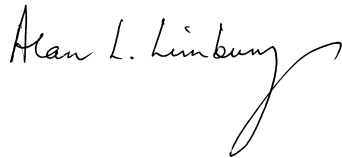
- (a) to give an undertaking in writing to the Executive Director of ASMI to cease publication forthwith in any media, including on any website, until it can be supported by clinical evidence, of any representation, express or implied, to the effect that:
 - (i) Pariet 10 is the fastest-working OTC PPI;
 - (ii) Pariet 10 is the fastest acting OTC PPI;
 - (iii) Pariet 10 has the fastest onset of action of any OTC PPI;
- (b) to publish a retraction statement in the terms and in accordance with the directions contained in the Attachment to this determination; and
- (c) to pay a fine of \$20,000 for the Moderate breach found by the Panel.

17. The Panel makes no determination to alter the usual operation of clause 8.4.2.2 of the Code.

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

Dated: May 5, 2011

For the ASMI Complaints Panel

A handwritten signature in black ink, appearing to read "Alan L. Limbun", with a stylized flourish at the end.

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.

Attachment

“RETRACTION – PARIET 10 onset of action

Recent advertising by Johnson & Johnson Pacific has been found in breach of the ASMI Code of Practice.

There is no clinical evidence to show that Pariet 10 has faster onset of action than other OTC PPIs.

Accordingly the advertised claims (“fastest-working” and “fastest acting”) were misleading and not based on substantiated facts.

Johnson & Johnson Pacific has been ordered by the ASMI Complaints Panel to publish this retraction.”

Directions

1. The retraction statement is to be published in the next available issues of the Australian Journal of Pharmacy, Retail Pharmacy and Pharmacy News.
2. The retraction statement to be full page, within the first 6 pages of the publication.
3. The JJP logo or name to appear prominently.
4. No other material emanating from JJP to appear on the same page nor on an adjoining page.
5. Font size of heading to be a minimum of 36 point in bold.
6. Font size of body copy to be a minimum of 28 point in bold.
7. All type to be black.