

ASMI COMPLAINTS PANEL FINAL DETERMINATION
Meeting held April 12, 2011

Johnson & Johnson Pacific Pty Limited (“JJP”) v. Nycomed Pty Ltd
Somac advertising to consumers

The Complaint

1. JJP complains that the display by Nycomed of empty packs of Somac (the proton pump inhibitor pantoprazole, 20mg) on shelf in front of counter in pharmacy breached clauses 5.3.2.2 and 5.3.3.1 of the ASMI Code of Practice (“the Code”) and that Nycomed’s failure to remedy the breaches in a timely manner justifies the imposition of the maximum fine of \$40,000 for a Severe Breach.
2. JJP found empty Somac packs so displayed at one pharmacy on February 26, 2011. JJP found more empty Somac packs so displayed at another pharmacy on March 24, 2011 (the day on which JJP initiated the ASMI complaints procedure). In a letter from JJP to ASMI dated April 8, 2011 in reply to Nycomed’s supplementary response (both of which the Panel Chair determined should be put before the Panel pursuant to clause 8.4.2.10 of the Code), JJP said it found four further examples in Marrickville, an assertion Nycomed has not sought to deny.
3. JJP notes that this matter was first raised with Nycomed in March, 2009 by GlaxoSmithKline (“GSK”). On March 7, 2009, Nycomed assured GSK that *“supply of Somac empty packs upon request of pharmacists has ceased”* and stated that a directive had been issued to representatives *“to inform pharmacist to remove any supplied Somac empty packs they may have in front of shop. During the next call cycle representatives will remove any observed packs”*. JJP says Nycomed has not fulfilled its undertaking over 2 years after having provided it.

The Response

4. In its formal response of April 1, 2011 to the complaint, Nycomed assured JJP that Nycomed representatives went to the two pharmacies JJP had nominated to ensure that the Somac packs were removed from front of counter. JJP found this response unsatisfactory, since it was limited to the two pharmacies specified in the complaint, and gave informal notice of its intention to proceed with its formal complaint. Nycomed thereupon took further action which it described in its supplementary response dated April 7, 2011. That supplementary response revealed that additional action had been taken following the formal complaint which had not been mentioned in the formal response.

5. Accordingly, on the material before the Panel the sequence of events appears to have been as follows:

Prior to 2009 – empty Somac packs provided to pharmacies.

[Precise date not known but prior to March 7, 2009] – supply of empty packs ceased.

March 7, 2009 – undertaking in above terms given by Nycomed to GSK. Standing instruction given to Nycomed sales representatives to remove branded Somac packs wherever they are observed at front of counter. Nycomed sales representatives continuously reminded to advise pharmacists to remove any branded Somac packs from front of counter.

February 28 and March 7, 2011 - JJP raised the matter informally with Nycomed.

March 24, 2011 – formal complaint, which includes photographs of Somac branded packs on shelves at a pharmacy in Paddington, taken on February 26, 2011 and at a pharmacy in Surry Hills, taken on March 24, 2011.

March 24, 2011 – Nycomed Gastroenterology Marketing Manager asks the Pharmacy Sales Team to pay full attention to the removal of Somac packs from front of shop in Sydney CBD especially Paddington.

March 28, 2011 – Nycomed Medical Director sends internal email saying: *“Should/Could we send a letter to Pharmacies that purchase from us just reminding them not to have it on the counter? If it only shows our commitment, I think it is good”*.

April 1, 2011 – formal response confined to the two pharmacies mentioned in the formal complaint.

April 1, 2011 – informal notice to ASMI of JJP’s intention to proceed with a formal complaint, copied to Nycomed.

April 6, 2011 - telephone discussion between the JJP Medical Director and the Nycomed Medical Services Manager.

April 6, 2011 - Nycomed Gastroenterology Marketing Manager thanks the Pharmacy Sales Team for acting in-store as well as through telecommunications and asks: *“Please continue to check in case any pharmacy has not had the opportunity to act on it.”*

April 6, 2011 – Nycomed issues a faxstream to pharmacies seeking removal and destruction of any branded Somac “mock” trade packs on display.

April 7, 2011 – Nycomed’s supplementary response.

April 8, 2011 – JJP’s reply asserting more empty Somac packs found in Marrickville.

6. Nycomed says that, at the time when the empty Somac packs were supplied to pharmacies, the Code permitted the use of empty packs as promotional/educational tools. It submits there has been no breach of the Code given that the supply of empty packs ceased in 2009. This, coupled with the actions undertaken by Nycomed since that time and on an ongoing basis to remove non-compliant packaging from front of counter demonstrates a commitment by Nycomed to comply with clause 5.3.2.2 of the current Code.

Panel consideration

7. Somac is a Pharmacist Only Medicine listed in Schedule 3 but not in Appendix H of the Standard for the Uniform Scheduling of Drugs and Poisons (“SUSDP”). Accordingly, pursuant to section 42DL of the *Therapeutic Goods Act 1989* (Cth), Somac may not be advertised to consumers. That section was introduced by the *Therapeutic Goods Amendment Act (No.1) 2003 – Schedule 1* which came into force on November 27, 2003. Previously a similar regime had applied pursuant to section 6(e) of the *Therapeutic Goods Regulations 1990* (initially without the dispensation afforded by listing in Appendix H, which was introduced following a review conducted in 1997).
8. Clause 5.3.2.2 of the Code provides:

“For those Pharmacist Only Medicines (Schedule 3 substances) not permitted to be brand advertised to the general public, advertisements should be directed to healthcare professionals only and must not be directed to pharmacy assistants or other non-qualified personnel.”
9. In 2009, that clause was numbered 5.4.2.2. Prior to July, 2009, the explanatory note in relation to that clause provided:

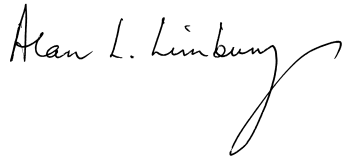
“Except for those Pharmacist Only Medicines (Schedule 3 substances) for which direct to consumer advertising is permitted, promotional or advertising material relating to Pharmacist Only Medicines (Schedule 3) must not be visible to the public.”

Advertising and promotion of Pharmacist Only Medicines (Schedule 3) not listed in Appendix H of the SUSDP by way of empty packs does not constitute a breach of the requirements.”

10. In July, 2009, the last sentence was deleted following legal advice to ASMI that it was incorrect. Accordingly, at the time when the empty Somac packs were distributed (and there is no evidence of distribution after March 2009), the Code encouraged empty pack advertising of S3 products, even though it was unlawful. Under these circumstance, the Panel is not disposed to find Nycomed to have breached the Code in supplying the empty Somac packs prior to the deletion of the incorrect sentence of the explanatory note, even though the more generally-worded Clause 4.2 of the Code requires ASMI Members to comply with the relevant provisions of Commonwealth Acts and Regulations which pertain to the functions and operations in the industry.
11. Accordingly, the complaint is dismissed.
12. The Panel nevertheless wishes to record its disapproval of the way in which Nycomed failed to ensure the recovery and destruction of the empty packs in March, 2009 and for two years thereafter. The undertaking it gave to GSK and the standing instruction it gave to its representatives recognized that, despite its requests to pharmacists, Nycomed representatives might very well observe front of counter empty packs on their subsequent visits. It was not until April 6, 2011, after the formal complaint had been delivered and after the formal response failed to satisfy JJP, that Nycomed requested pharmacists to destroy the packs.
13. Far from demonstrating a commitment to ensuring compliance with the Code, the Panel considers that Nycomed has for two years given merely the appearance of such a commitment, while recognizing in its instructions to representatives the continuing possibility of front of counter displays by pharmacists still in possession of empty Somac packs (who would themselves be contravening the law by doing so).
14. Further, the Panel considers that the parties should have been able to resolve the recovery issue between them, without resort to the formal complaint process. The fact that this was not possible is no reflection on JJP, however.
15. In light of these considerations, although the complaint is dismissed, the Panel determines, pursuant to clause 8.4.2.2 of the Code, that each party should contribute 50% of ASMI's out-of-pocket expenses associated with the determination of this complaint.

Dated: May 5, 2011

For the ASMI Complaints Panel

A handwritten signature in black ink, reading "Alan L. Limbun". The signature is fluid and cursive, with a long, sweeping tail that extends to the right.

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.