ASMI COMPLAINTS PANEL FINAL DETERMINATION
Meeting held December 13, 2011

Schering Plough Pty Ltd ("MSD") v. Johnson & Johnson Pacific Pty Limited ("JJP")
Zyrtec® advertising.

1. MSD complains that an advertisement for Zyrtec® antihistamine (cetirizine HCl), published in the September, 2011 issue of Postscript (directed to pharmacists and to pharmacy assistants, who are considered consumers) and an advertisement for Zyrtec® between June and October 2011on the Internet website In The Know (ITK), which MSD says was accessible to consumers, 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.

Procedural issue

2. The formal Complaint included informal correspondence, contrary to the Code, section 8.4.2.7. This was removed by ASMI before the Complaint was transmitted to the Panel.

Claim 1

3. MSD says the claim in Postscript:*"Zyrtec® is over twice as effective as Claratyne® at relieving the combined symptoms of hayfever[2,5,6,7]"*, referenced to four studies, namely Day 1997[1]; Meltzer 1996[2]; Day 1998[3] and Day 2001[4], is inaccurate, unbalanced, misleading and not a reflection of the body of scientific evidence, in breach of the Code, sections 5.1.3 and 5.2 and the TGAC, sections 4(1)(b), 4(2)(c), 4(4) and 4(5).

4. MSD says there is no body of scientific evidence to support such a comparative superiority claim. The four cited studies consist of short duration (one or two dose) onset of action studies, which are not adequate support for the claim that Zyrtec is more effective than Claratyne.

5. MSD says that in 1997 and 2005 the U.S Food and Drug Administration (FDA) informed Zyrtec's then manufacturer, Pfizer, that claiming that Zyrtec is more

[1] Day JH et al. Onset of action and efficacy of terfenadine, astemizole, cetirizine, and loratadine for the relief of symptoms of allergic rhinitis. Ann Allergy Asthma Immunol 1997; 79:163-72.
[2] Meltzer EO et al. Comparative outdoor study of the efficacy, onset and duration of action, and safety of cetirizine, loratadine, and placebo for seasonal allergic rhinitis. J Allergy Clin Immunol 1996; 97: 617-26.
[3] Day JH et al. Cetirizine, loratadine, or placebo in subjects with seasonal allergic rhinitis: Effects after controlled ragweed pollen challenge in an environmental exposure unit. . J Allergy Clin Immunol 1998; 101:638-45.
[4] Day JH et al. Comparative onset of action and symptom relief with cetirizine, loratadine, or placebo in an environmental exposure unit in subjects with seasonal allergic rhinitis: confirmation of a test system. Ann Allergy Asthma Immunol 2001; 87:474-481.

effective than Claritin is unsubstantiated and misleading. In 2005, Pfizer ran a full page Zyrtec corrective advertisement admitting:

"Zyrtec has not been shown to be superior to other allergy medicines."

6. MSD is not aware of any head to head clinical efficacy studies conducted since then. All the studies used to attempt to substantiate the claims currently at issue predate the 2005 events.

7. MSD says that, in recent correspondence, JJP inappropriately attempted to support the comparative efficacy claims by pooling data from the studies cited above. Pooling data from studies that are not sufficient to support a comparative efficacy claim does not make them appropriate support. In addition, pooling data from studies with different study designs is not appropriate and requires a much more rigorous statistical analysis approach. JJP's suggestion that the comparative efficacy claims are substantiated on the basis of its own, non-published, non-peer reviewed, pooling of inappropriate data does not constitute adequate support for the comparative efficacy claims.

8. In response, JJP says the body of evidence clearly shows that Zyrtec has superior efficacy in the treatment of hayfever symptoms to Claratyne, and that this superior efficacy is more than 2 times greater in the treatment of hayfever symptoms. Accordingly, the comparative claim "*Zyrtec is over twice as effective as Claratyne at relieving the combined symptoms of hayfever*" is accurate, balanced, not misleading, is reflective of the body of scientific evidence and the data supports the comparative superiority claim.

9. JJP says it engaged an independent statistician to make a statistical analysis of pooled data from the Meltzer 1996, Day 1998 and Day 2001 studies, which JJP says it carefully selected from 206 studies (produced by an EMBASE literature search) as the most appropriate studies in English which directly compared cetirizine and loratadine (Claratyne®) in the treatment of seasonal allergic rhinitis symptoms. Those three studies represent 74% of the scientific literature comparing cetirizine and loratadine by population from all of the relevant studies. The results support the claim of greater than 2 times superiority of cetirizine over loratadine. JJP gives its reasons for rejecting MSD's criticisms of the different study designs.

10. JJP also relies upon the Day 1997 study as supporting the claim but excluded it from the pooling analysis because the range of symptoms being assessed was only a subset of those assessed in the other three studies. JJP says that whilst the Day 1997 primary end point of "clinically important relief" was not significant, the more difficult to achieve secondary end point of "definitive relief", defined as "clinically important relief" from symptoms without a subsequent loss of relief, was significant and shows cetirizine to be 2.05 times superior to loratadine.

11. As to the issues raised by the FDA letters, JJP submits that it is inappropriate to rely on the decisions of overseas regulators that are based on laws that are different from Australian laws. The FDA correspondence is irrelevant to the matter at hand, and the studies need to be considered on their own merit.

12. As to MSD's claims that because the studies in question are 2-day studies, they are inappropriate to substantiate the claims in question, JJP says that in its Determination 03/00 dated December 12, 2000, the ASMI Panel found that Schering-Plough did not provide sufficient evidence to refute the validity of Day 1997 and Day 1998 and was therefore entitled to accept those results. JJP submits that MSD have failed adequately to challenge the validity of the studies in this matter.

13. JJP attaches research (Project Tempest 2003), which demonstrates that 45% of hayfever episodes last 1-3 days with treatment, with 18% between 4 to 6 days and 11% up to 7 days with treatment (totaling 74% of hayfever episodes lasting for 7 days or less with treatment). JJP submits that since the largest proportion of hayfever sufferers need to treat for only 1-3 days, clinical studies lasting only 2 days are an appropriate level of support for a short term condition.

14. JJP indicated its willingness to include a reference that clearly identifies the studies as 2-day studies.

    Panel consideration

15. The Panel considers that the claim *"Zyrtec® is over twice as effective as Claratyne® at relieving the combined symptoms of hayfever [2,5,6,7]"* would be understood by reasonable readers of Postscript (primarily pharmacy assistants, who are influential in consumer purchasing decisions) as representing that it has been separately substantiated by each of the four referenced studies.

16. The first study was a 1-day study over 6 hours. The other three were 2-day studies. The Panel considers all the studies were too short to substantiate the claim, which would reasonably be understood to refer to the usual or average span of a hayfever episode. Project Tempest 2003 is headed "On Average, Allergy/Hayfever Attacks Last 10 days". Even taking into account from that material that 45% of hayfever attacks last 1-3 days, 1-day and 2-day studies are inadequate to demonstrate efficacy at "*relieving the combined symptoms of hayfever"*, let alone superior efficacy, for 3 days.

17. It follows that the Panel accepts MSD's submission that pooling data from studies that are not sufficient to support a comparative efficacy claim does not make them appropriate support.

18. The outcome of the pooling exercise is not a peer reviewed published paper .It is not clear to the Panel when JJP engaged in that exercise. Had it been conducted before making the claim, and assuming it was regarded by JJP as substantiating it, one would have expected it to have been cited instead of the individual studies that were pooled. Seeking to substantiate a claim after having made it, even if that endeavour turns out to be successful, does not render the claim compliant with the Code, which requires claims to have been already substantiated before they are made: Code section 5.1.3.

19. In the result the Panel finds the claim to be in breach of the Code, sections 5.1.3 and 5.2 and the TGAC, sections 4(1)(b), 4(2)(c), 4(4) and 4(5). This is a Moderate Breach. The clarification proposed by JJP (stating that the studies are 2-day studies) would not avoid breach of the Code and the TGAC.

Claim 2

20. MSD says that, for the same reasons as for Claim 1 above, the claim on the website: "*Zyrtec® is over twice as effective as Claratyne® for treating allergic rhinitis"*, referenced to Day 1997, is inaccurate, unbalanced, misleading and not a reflection of the body of scientific evidence, in breach of the Code, sections 5.1.3 and 5.2 and the TGAC, sections 4(1)(b), 4(2)(c), 4(4) and 4(5). Being based on Day 1997, this comparative superiority claim is not adequately validated with a sufficient level of evidence, and is misleading and inappropriate. This website was accessible to consumers.

21. JJP says the advertisement was directed to professionals. It was available directly on the "In The Know" website between June 1, 2011 and July 31, 2011 and thereafter on that website, but accessible only through targeted searches on search engines. It was removed from the website on October 31, 2011.

22. JJP maintains that the claim is supportable but concedes that allergic rhinitis is a collective term that can include Seasonal Allergic Rhinitis and Perennial Allergic Rhinitis. JJP therefore has agreed not to use the claim in this form in future. It has been used only on the ITK Advertisement which has now ceased publication.

23. In responding to MSD's comments that Day 1997 is inadequate to substantiate the claim, JJP refers, *inter alia*, to ASMI Complaints Panel Determination 03/00, which found Day 1997 and Day 1998 supported the claim, "*Zyrtec can provide faster and more effective relief from hayfever than Claratine*". It says that MSD's criticisms of the Day 1997 study are unfounded.

Panel consideration

24. Day 1997 addressed Seasonal Allergic Rhinitis. Quite apart from its insufficient duration, it provides no support for a comparative superiority claim in relation to "allergic rhinitis", which JJP concedes can include Perennial Allergic Rhinitis.

25. The claim considered by the Panel in complaint 03/00 and the criticisms made in that case of Day 1997 were different from those made here. The Panel found in that case that Schering Plough had not shown the results of Day 1997 or Day 1998 to be unreliable. Here it has shown the results of Day 1997 to be inadequate to support this claim.

26. Accordingly the Panel finds this claim to be in breach of the Code, sections 5.1.3 and 5.2 and the TGAC, sections 4(1)(b), 4(2)(c), 4(4) and 4(5). This is a Moderate Breach.

Claim 3

27. MSD says the claim in both advertisements: "*Zyrtec® can be used for extended periods and continues* [Postscript]*/will continue* [website] *to be effective over time"*, referenced to "Tachyphylaxis data on file", breaches the Code, sections 5.1.3 and 5.2 and the TGAC, sections 4(2)(c) and 4(5).

28. MSD says the claim in Postscript is the third dot point after previous dot points containing Zyrtec's alleged superiority claim over Claratyne. By inference this third dot point implies that Claratyne cannot be used for extended periods and is not effective over time, and only Zyrtec achieves this. The juxtapositioning of the competition question asking "Which *brand* can be used for extended periods and continues to be effective?" strengthens such an association. "brand" is singular so there could only be one correct answer. MSD is not aware of any data to support this claim. Both Zyrtec and Claratyne are approved by the TGA for Perennial Allergic Rhinitis.

29. Furthermore, MSD says the Tachyphylaxis data on file does not contain comparative data studies and does not support a comparative claim. The inference that Zyrtec is the only brand that can be used for extended periods and continues to be effective over time is misleading and unbalanced.

30. JJP says the claim appears as one of four separate and distinct claims relating to different issues. The main message of the advertisement is Zyrtec users' general satisfaction with the product. The superiority claims are clearly ancillary, being in a smaller font than the headline claim and near the bottom of the page under a pack shot with artwork. The context of the advertisement therefore does not impute a comparative nature on all claims made in the advertisement.

31. Accordingly, this claim makes no comment on whether or not Claratyne or any other competing product provides the same benefit. The mere presence of comparative claims does not suggest that all other claims about a product are also comparative.

32. Furthermore, the comparative claims in the Postscript advertisement are presented with the compared antihistamines clearly identified. The lack of a comparator or any comparison in this claim would suggest to pharmacy assistants that the claim is not a comparative claim at all.

33. Finally, JJP says the mere fact that one of the three competition questions refers to a brand in the singular is irrelevant. A pharmacy assistant would understand the question simply to refer the assistant to the particular claim in the advertisement, and not provide additional information (whether express or implied) through the inclusion of that question. JJP submits that MSD's argument and its reliance on the singular form of a word in a simple competition question to derive an implied meaning of a claim is a torturous and inappropriate interpretation of that claim, and would not be the interpretation of the reasonable pharmacy assistant.

34. Accordingly, JJP says that this claim is not false or misleading or in any way in breach of the Code.

Panel consideration

35. The Panel considers this claim, as presented on the website, not to be a comparative claim and accordingly finds it not to breach the Code or the TGAC.

36. As presented in Postscript, however, taking into account the advertisement as a whole, including the competition question, the claim would be likely to convey to pharmacy assistants, acting reasonably, the incorrect representation that only one brand, Zyrtec®, "*can be used for extended periods and continues to be effective over time"*.

37. In the context of the whole advertisement the reader is led to ask the question: "*Why recommend Zyrtec to your customers over other available antihistamine products?*" The answer is provided in the bullet points, two out of three of which directly refer to competitor products. As presented in this advertisement, a reasonable person's interpretation of the claim would be that although no other competitor product is mentioned, it is an implied comparative superiority claim.

38. The "Tachyphylaxis data on file" document provided to the Panel was prepared by JJP after the publication of the advertisements. The studies to which it refers were not provided. Those studies do not appear to be comparative studies however (save against placebo). Accordingly, whilst the tachyphylaxis data does provide support for the claim: *"Zyrtec can be used for extended periods",* there is no comparative data to suggest that other antihistamines cannot be used long term.

39. Accordingly the Panel finds this claim in Postscript to be in breach of the Code, sections 5.1.3 and 5.2 and the TGAC, sections 4(2)(c) and 4(5). This is a Moderate Breach.

Claim 4

40. MSD says the Postscript headline: *"9/10 people who use Zyrtec® are satisfied"*, referenced to "Jigsaw ZYRTEC® Brand Tracking 2009" breaches the Code, section 5.1.3 and the TGAC section 4(2)(c). It says that, because "satisfied" is not defined, it is most likely that the reasonable pharmacy assistant will link the superior efficacy claims to the headline, thus defining the "satisfied" claim with efficacy outcomes, making this claim misleading. This association is further strengthened by the accompanying three competition questions, which serve the purpose of emphasising Zyrtec's claim of superior efficacy.

41. JJP says Zyrtec has been registered by the TGA as an efficacious medicine for hayfever or seasonal allergic rhinitis and JJP is permitted to advertise its efficacy. Efficacy is just one of Zyrtec's attributes. The claim was taken directly from the responses to the survey. As with satisfaction surveys generally, satisfaction was not defined in the survey. The survey allowed respondents to indicate that they were satisfied with the Zyrtec product and they did so without defining the main attribute(s) giving rise to this satisfaction, which could include

the product's efficacy, side effect profile, tablet size, taste, pack size or a combination of these. As the data confirms, 9 out of 10 respondents who used Zyrtec were satisfied. Accordingly JJP does not agree that the claim is misleading directly or by implication.

42. JJP says the reasonable person would not analyse the advertisement and conclude that all of the claims are somehow interlinked and refer to each other as suggested by MSD. There is clear separation of the 9/10 claim from the other claims and it is clearly intended to stand alone in the context of the competition and the questions that are being asked.

43. JJP indicated a willingness to include, in relation to any similar future presentations of the 9/10 Claim, a citation along the following lines: "User satisfaction may include such factors as efficacy, side effect profile, and cost".

Panel consideration

44. The Panel considers that, since "satisfied" is not defined in the headline, the reader is likely to look for what follows as providing an explanation. Accordingly, the headline is likely to be read by pharmacy assistants, acting reasonably, in conjunction with the efficacy claims. The wording of the footnote, if taken into account at all, given the fine print in which it appears, is unlikely to dispel the impression created by the advertisement as a whole that the reason why 9/10 people are satisfied with Zyrtec® is because of its superior efficacy. Since the survey did not explore respondents' reasons, the claim is misleading. The Panel finds this claim in breach of the Code, section 5.1.3 and the TGAC, section 4(2)(c). The breach is a Moderate Breach.

45. The Panel notes that the survey on which JJP relies was conducted in 2009 and that it included results for the years 2007, 2008 and 2009. The advertisement was published in 2011. There is nothing before the Panel to indicate whether or not the survey was conducted in 2010 and/or 2011, nor whether any such surveys supported the 9/10 figure.

Claim 5

46. MSD says the association on the website of Claim 2 with the visual image of Zyrtec® Children's liquids is misleading, in breach of the Code, sections 5.1.3 and 5.2 and the TGAC, sections 4(2)(c), 4(4) and 4(5) because it infers that the claims also apply to the children population. To the best of MSD's knowledge, there are no comparative studies of cetirizine and loratadine in children.

47. JJP says the association of Claim 2 with the visual image of Zyrtec Children's liquids has not been made in advertising to consumers but was to professionals and the advertisement in question appeared only in the ITK Advertisement. JJP says it inadvertently used a range shot in the advertisement showing both adult and children's Zyrtec products. The advertisement now has been removed from the ITK website. JJP has agreed that in future, it will qualify the claims and use appropriate images to apply to the adult population only, until such point in time that data in children becomes available.

48. JJP says that since it has already had the advertising removed and agreed to address this issue in future, it does not understand why this complaint is still being included in MSD's formal complaint, as JJP would consider this part of the informal complaint resolved.

Panel consideration

49. The Panel does not understand JJP to deny that the advertisement on the ITK website was accessible to consumers, albeit that it intended to direct the advertisement to professionals. Since it is conceded by JJP that Claim 2 is inappropriate in relation to Zyrtec Childrens liquids, the Panel formally finds the association of Claim 2 with Zyrtec Childrens liquids in breach of the Code, sections 5.1.3 and 5.2 and the TGAC, sections 4(2)(c), 4(4) and 4(5). The breach is a Moderate Breach. Since this matter was resolved prior to the formal Complaint, the Panel will not impose sanctions for this breach.

Sanctions

50. On the material before the Panel, the Panel has considered the factors set out in the Code, clause 9.1.3, as follows:

- *Whether publication has ceased.* It appears the Postscript advertisement was published in the September, 2011 issue. The Panel does not know whether publication of that advertisement in any medium has ceased altogether. JJP has stated that the ITK advertisement was removed from the web site on 31 October 2011.

- *Whether steps have been taken to withdraw the material published.* JJP has withdrawn the ITK advertisement. It is not clear whether steps have been taken to withdraw the Postscript advertisement from that or any other publications.

- *Whether corrective statements have been made.* No corrective statements appear to have been made. In relation to Claim 5, JJP has agreed to ensure that images associating children with claims for Zyrtec® are not used until clinically justified. The changes JJP has indicated it would make to Claim 1 (adding a reference to 2-day studies); to Claim 2 (not referring to "allergic rhinitis"); and to Claim 4 (indicating the range of factors that may be included in user satisfaction) would not remedy the breaches of the Code found by the Panel.

- *Whether the Member that is the subject of the complaint has previously breached the Code.* In its Final Determination dated May 5, 2011, the Panel found JJP to have breached the Code in relation to the advertising of proton pump inhibitors ("PPIs"). The Panel then said:

> "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."

- *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 health care professionals and consumers will have been affected.

51. The present case is yet another example of JJP making unwarranted claims of superiority. Having regard to the frequency and timing of the previous breaches mentioned above, the Panel regards this as a case of Repeat Breaches, as defined in the Code, section 9.1. Although each of the breaches of the Code is a Moderate Breach, each breach is also a Repeat Breach. In this case the Panel intends to treat all the breaches as constituting a single Repeat Breach, with the result that the maximum available fine is $50,000. The Panel does not regard itself as bound to adopt this approach in future.

52. The Panel notes that, prior to the presentation to ASMI of the formal Complaint, JJP agreed not to use the term "allergic rhinitis" when referring to Seasonal Allergic Rhinitis and not to represent that Zyrtec® Children's liquids are superior to Claratyne®.

53. 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:
    - Zyrtec® is over twice as effective as Claratyne®.
    - Only Zyrtec® can be used for extended periods and continues/will continue to be effective over time;

- Customer satisfaction with Zyrtec® is associated with efficacy;

(b) to publish retraction statements in the terms and in accordance with the directions contained in the Attachment to this determination; and

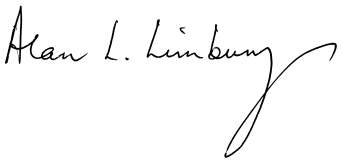
(c) to pay a fine of $40,000 for the Repeat Breaches (other than in relation to Claim 5) found by the Panel, which in this case the Panel is prepared to treat as a single Repeat Breach.

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

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

Dated: January 8, 2012

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.

Attachment

Retraction No.1

"RETRACTION – ZYRTEC® effectiveness

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

There is no clinical evidence to support the advertised claim that Zyrtec® is twice as effective as Claratyne® at relieving the combined symptoms of hayfever.

Accordingly the advertised claim was misleading and not based on substantiated facts.

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

Directions for Retraction No. 1.

1. Retraction No.1 is to be published in the next available issue of Postscript.
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.

Retraction No.2

"RETRACTION – ZYRTEC® effectiveness

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 Zyrtec® is twice as effective as Claratyne® for treating allergic rhinitis.

Accordingly the advertised claim was misleading and not based on substantiated facts.

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

Directions for Retraction No. 2.

1. Retraction No.2 is to be published as soon as practicable directly on the "In The Know" website for two consecutive calendar months and thereafter for the following three successive calendar months on that website, accessible only through targeted searches on search engines.

2. The retraction statement to be a full webpage.

3. The JJP logo or name to appear prominently.

4. No other material emanating from JJP to appear on the same webpage nor on an adjoining webpage.

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.