ASMI COMPLAINTS PANEL FINAL DETERMINATION
Meetings held on April 10 and 14, and (by email) on April 23, 2015.

Bayer Australia Limited ("Bayer") v. Johnson & Johnson Pacific Pty Limited ("JJP").

Zyrtec® advertisements.

1 Bayer complains that television and print advertisements for Zyrtec® anti-hayfever medication directed to consumers, which include a comparative claim against Bayer's product Claratyne®, breached sections of 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.

2 JJP denies all the alleged breaches and submits that the Complaint has been used simply as a competitive tool, in breach of the Code, section 9.4.2.1.

Procedural matters

1. Rejection of Second Formal Complaint

3 On January 5, 2015 Bayer sent a formal complaint to JJP ("the Original Formal Complaint"). JJP formally responded on January 20, 2015 ("the Formal Response").

4 On February 9, 2015 Bayer served on JJP another formal complaint about the same advertisements ("the Second Formal Complaint") which included responses to the Formal Response and the results of consumer research conducted for Bayer between December 16 and 23, 2014 and reported to Bayer on January 12, 2015 ("the Market Research Report").

5 On February 11, 2015, the Executive Director of ASMI invited the parties to provide written submissions as to the appropriate process for dealing with Bayer's complaint. JJP did so on February 13, 2015 and Bayer replied on 19 February, 2015. These submissions were provided to the Panel Chair, who advised ASMI as follows on February 20, 2015 ("the Advice"):

> "1. Because the Second Formal Complaint contains matter responding to the Formal Response, it is not appropriate for the Panel to accept the Second Formal Complaint since to do so would be contrary to the intent of the Code, paragraphs 9.4.2.4 and 9.4.2.10. Accordingly, if Bayer wishes to proceed, it should submit to ASMI only the Original Formal Complaint and JJP's Formal Response, in accordance with paragraph 9.4.2.6.

2. The fact that the results of the survey became known to Bayer after it had notified JJP of the Original Formal Complaint may justify a finding of exceptional circumstances by me as Panel Chair or by the Panel under paragraph 9.4.2.10, permitting Bayer to put those results before the Panel, together with any submission as to the significance of those results, and permitting JJP to have an opportunity to respond. However, having regard to the timeline set out by JJP, which is not disputed by Bayer, it appears that Bayer initiated the survey before it notified JJP of its Original Formal Complaint. This fact may be relevant to the question whether a finding of exceptional circumstances is justified in this case. Given the importance and precedental character of the decision, I think it is a decision that should be made by the Panel as a whole.

3. Accordingly, if Bayer wishes to proceed as contemplated in paragraph 1 above and wishes the Panel to receive the survey results, Bayer should provide those results to ASMI, together with a submission in support of exceptional circumstances. JJP should be invited to respond to that submission. The Panel should also receive the submissions from JJP and Bayer upon which this advice is based and this advice. Only if the Panel asks for them should the Panel receive the survey results."

6 On February 25, 2015 ASMI informed the parties that ASMI would be following the Advice and instructed the parties as to the next steps should Bayer wish to proceed with the complaint.

7 On March 18, 2015 Bayer submitted to ASMI the requisite copies of the Original Formal Complaint, the Formal Response and the Market Research Report, together with its submissions, pursuant to sub-paragraph 9.4.2.10 of the Code, that exceptional circumstances warrant consideration of the Market Research Report by the Panel. On April 8, 2015 JJP submitted to ASMI a response to Bayer's submissions on that issue.

2. Whether exceptional circumstances exist

Bayer

8 This is a summary of Bayer's submissions.

9 The circumstances regarding the Market Research Report are exceptional (i.e. unusual) in that:

(a) Bayer received the Market Research Report after it lodged the Original Formal Complaint;

(b) that report has significant probative value to the issues to be determined by the Panel in resolving the Complaint; and

(c) Bayer has been denied the opportunity to rely on the Second Formal Complaint, which, in Bayer's view, constituted a valid formal complaint pursuant to the Code.

10 Procedural fairness, as contemplated under sub-paragraph 9.1 of the Code, mandates that a party be permitted to submit additional relevant evidence, particularly when it clarifies issues in dispute, and that the other party be provided with an opportunity to respond. Accordingly, it is simply not open to the Panel to proceed as though the Market Research Report does not exist.

11 Bayer does not accept the statement in the Advice that it would be *contrary to the intent of the Code, paragraphs 9.4.2.4 and 9.4.2.10*, for the Panel to accept the Second Formal Complaint, which Bayer saw as preferable to introducing the Market Research Report under sub-paragraph 9.4.2.10 because it avoided the need for the Panel to receive separate submissions from the parties regarding the Market Research Report and allowed the parties a further opportunity to resolve the dispute informally. It was therefore incorrect of the Panel to regard acceptance of the Second Formal Complaint as allowing Bayer to submit new evidence with its formal complaint, contrary to sub-paragraphs 9.4.2.4 and 9.4.2.10.

12 Having regard to the Panel's decision to disregard the Second Formal Complaint, the Panel must [Bayer's emphasis] consider the Original Formal Complaint in light of the Market Research Report in order properly to afford Bayer procedural fairness.

13 In light of the above, the need for the Panel to afford Bayer procedural fairness gives rise to "exceptional circumstances" warranting its consideration of the Market Research Report under section 9.4.2.10 of the Code.

JJP

14 This is a summary of JJP's submissions.

15 The "exceptional circumstances" contemplated in section 9.4.2.10 of the Code must be circumstances in which, for reasons beyond its control, the complainant was unable to submit the material as part of its formal complaint. Here, Bayer had control over when it commissioned the market research; was aware that it had done so when it prepared and submitted the Original Formal Complaint; and could have awaited the Market Research Report before filing that complaint. Yet Bayer chose not to do so. Accordingly, the circumstances around the Market Research Report not being included in the Original Formal Complaint were completely within Bayer's control and therefore are not "exceptional" for the purposes of section 9.4.2.10, irrespective of the probative value of that report and irrespective of the rejection of the Second Formal Complaint.

16 The Market Research Report addresses consumer take-out, a matter for the Panel to determine objectively, in the same manner as judges determine whether

conduct is misleading or deceptive or likely to mislead or deceive (citing *Australian Competition and Consumer Commission v Jewellery Group Pty Limited* [2012] FCA 848 at para 62). Accordingly, the probative value (if any) of the report does not require its consideration by the Panel.

17 Bayer's argument as to the rejection of the Second Formal Complaint would completely undermine sections 9.4.2.4 and 9.4.2.10 of the Code, since it would allow a complainant, in effect, to include new material outside its formal complaint simply by attempting to submit, in breach of the Code, a new formal complaint. There is nothing exceptional about being denied the opportunity to breach the Code. Nor do those provisions, as applied by the Panel Chair, in any way subvert "ordinary administrative and judicial rules", since the Code allows evidence to be submitted in exceptional cases. Bayer has not been denied the opportunity to present relevant evidence to the Panel. It had the opportunity to do so when filing the Original Formal Complaint but chose not to do so. It cannot now argue that it is unfair that it does not now have such an opportunity.

Panel ruling on exceptional circumstances

18 The Panel met by teleconference on April 10, 2015 to consider whether it should consider the Market Research Report in determining Bayer's complaint. The Panel had before it the Original Formal Complaint and JJP's Formal Response; the parties' submissions of February 13 and 19, 2015; the advice of the Panel Chair of February 20, 2015; and the parties' submissions of March 18 and April 8, 2015. The Panel did not have before it the Market Research Report and chose not to see that report in addressing the issue of exceptional circumstances.

19 The Panel determined that the Second Formal Complaint was correctly rejected, because it contained new material in the form of the Market Research Report and responses to JJP's Formal Response. This was contrary to the intent of the Code, paragraphs 9.4.2.4 and 9.4.2.10, which make it clear that, unless exceptional circumstances can be shown, a complainant must include in the formal complaint everything on which it intends to rely. Paragraph 9.4.2.4 of the Code imposes the same requirement on a respondent.

20 The Panel unanimously determined that, for the reasons advanced by JJP and summarised above, there are no exceptional circumstances that would justify consideration by the Panel of the Market Research Report and there was nothing procedurally unfair in disallowing it.

The advertisements

21 The print advertisement is a display advertisement used at bus stops and pharmacy stores. There are two television advertisements, one of 15 seconds, the other of 30 seconds. All the advertisements contain the claim, in relation to Zyrtec®: "starts to work faster than Claratyne for hayfever relief*" (Claim 1). The

asterisk links to a disclaimer below: "*Based on the first dose of Cetirizine (Zyrtec®) vs. Loratadine (Claratyne) tablets" (the Disclaimer). In the print advertisement the Disclaimer is referenced to five named journal articles, which JJP provided to Bayer upon request in October 2014[1]. In the television advertisements the Disclaimer is followed by the statement: "Data on file". The television advertisements also depict a package labelled "Zyrtec®" next to the statement: "Serious about hayfever allergies" (Claim 2).

Claim 1: Zyrtec®starts to work faster than Claratyne for hayfever relief.

Bayer's complaint

22 This is a summary of Bayer's submissions.

23 Claim 1 makes two representations to the reasonable consumer, namely the express representation that Zyrtec® "starts to work faster than Claratyne for hayfever relief" and the implied representation "that the brand Zyrtec® starts to work faster than the brand Claratyne® in any dose form". Both representations are unsubstantiated and misleading, in breach of the Code, sections 5.1.3 and 5.2.2 and of the TGAC, sections 4(1)(b), (4) and (5)

<u>The express representation that Zyrtec® starts to work faster than Claratyne for hayfever relief</u>

24 The Disclaimer qualifies that the express representation is based on cetirizine (Zyrtec®) compared to loratadine (Claratyne®) "tablets" only. However, in the Meltzer *et al.* 1996 and the Day *et al.* 1998 and 2001 studies, subjects in the loratadine treatment group were administered encapsulated loratadine tablets, not loratadine tablets *per se,* as stated in the Disclaimer. While Day *et al.* 1998 and 2001 reported that the dissolution of the encapsulated loratadine tablet was equivalent to that of loratadine tablets alone, there is no explanation as to how this was determined and no correlation between the *in vitro* dissolution result and *in vivo* performance. Meltzer *et al*.1996 contains no information regarding the comparison of the encapsulated loratadine tablet versus the tablet form. Encapsulation may have contributed to a slower onset of action in these studies so it is misleading to rely on them to support a claim related to cetirizine and loratadine "tablets".

25 None of the Journal Articles disclosed the brand or formulation of loratadine and cetirizine administered to study participants. Factors including bulking agent, other excipients and tablet compression can vary between different brands and even different formulations of the same brand marketed in different countries. This can have a material effect on the dissolution and absorption rate of the active

[1] Meltzer et al. J Allergy Clin Immunol 1996; Day et al. J Allergy Clin Immunol 1998; Day et al. Asthma Immunol 2001; Greisner. Allergy and Asthma Proc 2004; and Ellis et al. Allergy, Asthma & Clin Immunol 2013.

ingredient, which will necessarily affect the product's onset of action. Without further information regarding the study formulations and a comparison of those formulations with the formulations of Zyrtec® and Claratyne® marketed in Australia, Claim 1, as qualified by the Disclaimer, is misleading to the reasonable consumer.

26 The studies did not undertake head-to-head statistical comparisons of the onset of action of cetirizine versus loratadine. Rather, they compared the onset of action of cetirizine versus placebo with the onset of action of loratadine versus placebo. Claim 1 is therefore highly misleading.

27 Since onset of action for antihistamines varies considerably from person to person, crossover studies are required to substantiate comparative onset claims for anti-allergy and relief of hayfever indications. Of the Journal Articles, only Ellis *et al* 2013 used a crossover study but is inadequate to substantiate Claim 1 for the reasons already given. The Greisner 2004 article is a literature review.

<u>The implied representation that the brand Zyrtec® in any dose form starts to work faster than the brand Claratyne® in any dose form</u>

28 The ARTG lists many dosage forms for Zyrtec®. Claratyne® is available in the Australian market as tablets, oral liquid, chewable tablets, liquid capsules and effervescent tablets. The reference to "tablets" in the Disclaimer is insufficient to qualify the implied representation, given the way in which it is presented in the television advertisements, and accordingly the implied representation is misleading.

29 The phrase "first dose" in the Disclaimer, even if sufficiently prominent to be read and understood, is so ambiguous as to be potentially misleading, since it could mean:

(i) the first time a consumer takes cetirizine or loratadine in their life;

(ii) if the consumer takes medication every day for a number of days, the first dose on the first day; or

(iii) if the consumer takes the medication as a single dose only when needed (*i.e.* not on consecutive days), the first dose that is taken for every hayfever episode.

30 Since the usual span of a hayfever episode is more than one day, hayfever sufferers generally take consecutive doses of the medication throughout hayfever episodes. Such dosing allows consumers to reach a "steady-state" during which there is no delay in the onset of relief. Thus if the reasonable consumer understands the Disclaimer to carry the meaning in paragraph 29(ii) above, this would also be misleading.

31 Even if the Disclaimer is sufficiently prominent to be appreciated by the reasonable consumer, the reference to "tablets" is inaccurate and ambiguous and misleads consumers into believing that all forms of Zyrtec® tablets have faster onset of relief than all forms of Claratyne® tablets (conventional, chewable and effervescent), since the Disclaimer does not qualify what types of tablets are being compared.

JJP's Response

32 This is a summary of JJP's submissions.

33 The complaint does not question the common understanding in the scientific community, supported by the body of scientific evidence, that unlike cetirizine, loratadine, which itself has limited antihistaminic activity, undergoes first pass metabolism in the liver in order to produce the chemical that provides the main antihistaminic activity, descarboethoxuloratadine. Pharmacokinetic analysis has shown the time to maximum plasma concentration for loratadine as 2 hours and for descarboethoxuloratadine as 2.43 hours[2]. Cetirizine reaches its maximum plasma concentration in 30 minutes and has multiple studies showing onset of action within 1 hour. That is why cetirizine acts faster pharmacologically than loratadine.

<u>The express representation that Zyrtec® starts to work faster than Claratyne for hayfever relief</u>

34 This refers only to Zyrtec starting to work "faster" without claiming any quantified difference in the rates of onset of symptomatic relief.

35 The encapsulation of tablets is a common method of blinding the treatment/placebo arms of clinical studies. Encapsulation would not be used if clinical scientists believed it would compromise results. The Meltzer *et al* study was peer reviewed and published in the very well respected Journal of Allergy and Clinical Immunology. The institutional review boards would not have approved the Meltzer *et al* study if the integrity of the results were to be compromised by the encapsulation (blinding) of the loratadine tablet. The study clearly demonstrates that loratadine's onset of action takes place sometime after 6 hours versus placebo, compared to 2 hours for cetirizine. Even if encapsulation did have an impact on dissolution or absorption, the difference would not significantly reduce this 4 hour time difference and would not change the fact that cetirizine starts to work faster than loratadine to reduce the symptoms associated with hayfever allergies. Nor would any person-to-person variation be sufficient to

[2] T Kosoglou *et al* Pharmacokinetics of Loratadine and Pseudoephedrine Following Single and Multiple Doses of Once- Versus Twice-Daily Combination Tablet Formulations in Healthy Adult Males, Clinical Therapeutics®, Vol.19, No.5, 1997.

account for the 4 hour time difference. The Meltzer *et al* study should not be considered invalid because the loratadine tablet was encapsulated.

36 The same points apply with respect to the two Day *et al* studies, in which the loratadine tablet was also encapsulated and the difference in onset of action times was reported as at least 2 hours. In addition, the 1998 study stated: "The dissolution of the encapsulated loratadine tablet was equivalent to that of the loratadine tablet alone" and the 2001 study stated: "The dissolution of the encapsulated loratadine tablet was demonstrated to be equivalent to that of the loratadine tablet alone". Clearly the authors satisfied themselves, the study reviewers and the journal editorial board that the dissolution was equivalent between encapsulated tablet and tablet form.

37 As to differences in formulation and excipients, the performance of immediate release dosage forms of loratadine are not formulation dependent. According to the Australian Regulatory Guidelines for OTC Medicines, Appendix 1: "Guidelines on the efficacy and safety aspects of OTC applications":

(i) a product is considered to be a generic product if it has the same quantity and similar quality of active ingredient as the already registered originator product and *inter alia* has the same pharmaceutical form; and

(ii) the various immediate-release oral dosage forms (e.g. tablets, capsules, oral liquids or suspensions) can be considered to be one and the same pharmaceutical form.

At no time are excipients expected to be identical. Again, the differences in release times shown by Meltzer *et* al and Day *et al* due to differences in excipients would be all but negligible.

38 The comparison of cetirizine and loratadine with placebo was used to determine onset of action. Without comparison against placebo, onset of action could not be determined, since there would be no control against the placebo effect. The US-FDA, in its draft Guidance for Industry – "Allergic Rhinitis: Clinical Development Programs for Drug Products" (which is relied upon and used by industry in Australia) defines onset of action as:

> "the first time point after initiation of treatment when the drug demonstrates a change greater than the placebo treatment from baseline in the primary efficacy endpoint. This statistically significant difference between drug and placebo should be maintained for some period from this point onward".

39 The Ellis study (funded by Bayer) was a head to head study which correctly concluded that onset of action for cetirizine is faster than for that of loratadine.

40 Crossover studies are not required to substantiate comparative onset claims for anti-allergy and relief of hayfever indications. Neither the Code nor the TGAC expressly require cross-over studies in support of advertising or comparative claims. The US-FDA draft Guidance for Industry – "Allergic Rhinitis: Clinical Development Programs for Drug Products" provides:

> "Because onset of action information in labelling may be used as a superiority claim, at least two studies are recommended to support a particular onset of action claim…The two trials do not have to be identical in design, nor do they have to evaluate both SAR and PAR. Since onset of action is in large part a pharmacodynamic issue, a number of different study types could be used. Following are three study types that have been used.
>
> - Standard phase 3 allergic rhinitis efficacy trials in which symptom scoring data are collected frequently for the first few days
>
> - A single-dose, parallel group, placebo-controlled study of patients in a *park setting* in which patients are exposed to relevant outdoor seasonal allergens and, following dosing, have nasal symptoms evaluated on an hourly basis
>
> - An inhalation chamber study (also known as an environmental exposure unit or EEU) in which previously asymptomatic patients are exposed to a relevant allergen …in a controlled indoor setting and, following dosing, have their nasal symptoms evaluated on an hourly basis
>
> Onset of action data can come from any of these study types…"

41 The Greisner 2004 literature review should not be disregarded since it evidences the body of scientific evidence at the date of publication "on the onset of actions for the relief of allergic rhinitis symptoms after a single, oral dose of second-generation antihistamine" and validates the observations that "for all comparisons, cetirizine had a shorter onset of action than loratadine". JJP has conducted a robust literature search which did not yield any other studies or similar literature review that contradicts the claim and Bayer has not produced any evidence to suggest that the body of science contradicts the results of the studies.

<u>The implied representation that the brand Zyrtec® in any dose form starts to work faster than the brand Claratyne® in any dose form</u>

42 Bayer's arguments relate only to the Disclaimer in the television advertisements, suggesting that Bayer has no issue with the prominence of the Disclaimer in the print advertisement. In the television advertisements the Disclaimer is sufficiently prominent and its prominence and duration give the consumer ample time to read

it. In any event, only the Zyrtec tablets and Children's oral suspensions have been marketed in Australia to date. Accordingly, given that the tablet form is the only dosage form for adults, the reasonable consumer would clearly understand Claim 1 to refer to the tablet form.

43 Based on the naming convention of dosage formats for medicines in the Australian marketplace, reasonable consumers easily understand "tablets" to mean conventional tablets that are swallowed whole.

44 In any event, even if Claim 1 were understood to cover all dosage formats, this would still be correct and not misleading because the different dosage forms of Claratyne are bioequivalent. To gain ARTG listing those different dosage formats would have had to demonstrate bioequivalence or at least provide *in vitro* dissolution data demonstrating similar performance across solid unit dosage formats. Therefore, based on pharmacology, JJP would not expect the time to onset of action of symptomatic relief of hayfever to be significantly different between different types of solid unit dose of Claratyne (and certainly not significant enough to account for the onset of action times demonstrated in the studies). The claim is based on the sound body of evidence that cetirizine acts faster than loratadine for symptomatic relief of hayfever.

45 The purpose of the "first dose" disclaimer is to ensure that consumers do not understand Claim 1 as applying to subsequent doses in relation to an episode that lasts more than one day (i.e. when a consumer may have reached a steady state). The reference to "first dose" communicates this to the consumer. The studies demonstrate that the onset of action for cetirizine is earlier than that of loratadine outside of the steady state. In each of the scenarios presented by Bayer the consumer will not have reached the steady state. Accordingly, whether "first dose" means the first dose in a consumer's life or the first dose on the first day or even as a single one off dose when needed, the claim is true. Consumers who suffer from hayfever will clearly know that the usual span of an episode is more than a day, and understand "first dose" to refer to the first dose in that episode.

Claim 2: implied representation that only Zyrtec® is serious about hayfever allergies and Claratyne® is not.

Bayer's complaint

46 This is a summary of Bayer's submissions.

47 As presented in context on screen and in voiceover in the television advertisements, the statement "serious about hayfever allergies" impliedly represents to the reasonable consumer that only Zyrtec® is serious about hayfever allergies and Claratyne® is not. This misleadingly conveys that Claratyne® is not serious or efficacious for the relief of hayfever symptoms.

JJP's Response

48 This is a summary of JJP's submissions.

49 The tagline "Zyrtec, serious about hayfever allergies" has been used extensively in advertising campaigns since August 2013. No comparative claims have been made in conjunction with that tagline prior to October 2014. In the context of the television advertisements under consideration, the claim "serious about hayfever allergies" will be understood by the reasonable consumer as meaning that Zyrtec "takes hayfever seriously", unlike non-sufferer members of the population, not other competing products. Accordingly, even before the current advertisements were broadcast, consumers would have understood that the "serious about allergies" claim was a simple reference to the Zyrtec product only and made no suggestions of comparison against competing products. In the current television advertisements, apart from Claim 1, no other claim mentions Claratyne; there is only one other product claim, namely that Zyrtec "provides 24 hour relief"; and there is no connection between onset of action and "seriousness". The fact that Zyrtec starts to work faster than Claratyne does not in itself suggest that Claratyne is not serious about hayfever allergies. Further, the reasonable consumer clearly understands the difference between onset of action (i.e. starts to work) versus efficacy (i.e. whether a product works at all). No suggestion that Claratyne is ineffective arises.

50 Bayer's complaints and reasoning are baseless, scientifically flawed, illogical and without foundation. Therefore this complaint is merely an attempt to use the ASMI complaints procedure as a competitive tool, in breach of section 9.4.2 of the Code.

Panel consideration

51 As this Panel noted in its August 3, 2009 determination in *Wyeth v. Reckitt Benckiser*, 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, including the astute and the gullible, the intelligent and the not so intelligent, the well educated and the poorly educated, acting reasonably.[3] 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.[4]

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[3] *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.

[4] TGAC 3(2).

52 Here the class of consumers likely to be affected by the advertisements comprises adults concerned about hayfever, namely adults suffering from hayfever and the parents of children suffering from hayfever. As to the latter, the Panel notes that the 30 second television advertisement at one point depicts a child standing with her family.

The print advertisement

53 The disclaimer in the print advertisement appears prominently. The Panel considers that hayfever sufferers and the parents of children who suffer from hayfever would read the disclaimer and understand Claim 1 to refer to tablets. Accordingly the implied representation for which Bayer contends does not arise in the print advertisement. Further, because hayfever sufferers and the parents of children who suffer from hayfever would regard it as important to take appropriate medication as soon as symptoms appear, they would be likely to understand the reference to "first dose" to mean the first dose of a hayfever episode. The Panel finds no ambiguity in those words.

54 The Panel considers that Claim 1 is substantiated by the studies on which JJP relies and reflects the body of scientific evidence, for the reasons set out below in relation to the television advertisements. Accordingly the Panel finds no breach of the Code or the TGAC from publication of the print advertisement.

The television advertisements

55 As in the June 2, 2014 determination of *Sanofi-Aventis Healthcare Pty Ltd v. Pfizer Australia Pty Ltd*, the Panel has considered the television advertisements in the context of the following principles laid down in a number of Federal Court of Australia decisions:

(a) members of the public watch a commercial after and before viewing other things, rather than in isolation. They do not carefully view the commercial with a special interest in noting and memorizing its features, they view it against a background of distractions, such as domestic activity, or simply a preoccupation with other more interesting or pressing concerns. Usually they do not know in advance that the commercial is about to commence[5];

(b) a television commercial simultaneously stimulates the visual and auditory senses. There are subtleties of suggestion not available from a reading of the transcript[6];

(c) the consumer is drawn to the medium of television to watch the program, not the advertisement. The broadcast of an advertisement by television is an ephemeral communication to a consumer. It is a transient communication that leaves a dominant impression in the mind of a consumer. A consumer cannot turn to a fixed reference point to check or re-check messages conveyed by the

[5] Gillette Australia Pty Ltd v Energizer Australia Pty Ltd [2002] FCAFC 223 per Merkel J at [47].
[6] Gillette Australia Pty Ltd v Energizer Australia Pty Ltd [2002] FCAFC 223 per Merkel J at [49].

advertisement. The consumer must deal with the cognitive cues triggered by the dominant impression the advertisement makes in the space of time the advertisement is screened[7];

(d) whether the words convey the making of the representation is always a question of fact to be determined having regard to all of the contextual circumstances within which something was said or done. The question is, "whether the misconceptions, or deceptions, alleged to arise or to be likely to arise are properly to be attributed to the ordinary and reasonable members of the classes of prospective purchasers". The focus of the inquiry is whether a not insignificant number within the class or cohort have been misled or deceived or are likely to be misled or deceived by the conduct, whether in fact or as a matter of inference;[8]

(e) where the viewer is inevitably drawn to the images on the screen and the language of the voiceover, it is easy to miss or disregard the writing on the bottom of the screen. Unless the viewer's attention is adequately brought to it, it is highly unlikely that the viewer would read and absorb it[9]; and

(f) in television advertising, the message is basically one of the impressions conveyed. Where a false dominant impression is conveyed, its message will not be ameliorated by the accuracy of the detailed message which is derived from a careful analysis of all of the constituent parts of the advertisement[10].

Claim 1

56 In both television advertisements the voiceover and the images proceed extremely quickly, except when the image of the Zyrtec pack is displayed. Claim 1 appears onscreen and through voiceover at the same time as a vehicle speeds towards the viewer. The words “FASTER THAN CLARATYNE” are the largest words onscreen. Meantime the Disclaimer appears at the foot of the screen in small font, having been preceded, in the packshot frame, by a different small font disclaimer: “Always read the label. Use only as directed. If symptoms persist see your healthcare professional.”

57 The Panel considers that consumers of the relevant class, acting reasonably, would not appreciate the terms of the Disclaimer. Most would be unaware of it, being distracted by the bold print, the voiceover and the speeding vehicle. Those who might have perceived the previous disclaimer are unlikely to have paid sufficient attention to realise that the Disclaimer is different. Accordingly, they would be left with the dominant impression that Zyrtec, in any form, starts to work faster that Claratyne in any form.

[7] Global One Mobile Entertainment Pty Ltd v Australian Competition and Consumer Commission [2012] FCAFC 134 at [84] -[85].
[8] Global One Mobile at [108].
[9] Global One Mobile at [88].
[10] Stuart Alexander & Co. (Interstate) Pty Ltd v Blenders Pty. Ltd (1981) 37 ALR 161 at 163.

58 As to whether this representation is true, the Panel considers that the journal articles on which JJP relies do establish that Zyrtec tablets (in conventional form) start to work faster than Claratyne tablets (in conventional form). In reaching this conclusion, the Panel accepts that encapsulation of the loratadine tablets, a legitimate process of blinding unlikely to have a significant effect on time to onset of action, would not affect the outcome sufficiently to overcome the 4 hour time difference observed by Meltzer *et al* 1996 or the 2 hour time difference observed by Day *et al* 1998 and 2001. Nor would any person-to-person variation be sufficient to account for the time difference.

59 The Meltzer 1996 study was conducted in keeping with the *park setting* type of study and the Day *et al* studies were conducted in an EEU. Both forms accord with the US-FDA draft Guidance followed in Australia.

60 The Panel considers it legitimate and in accordance with usual and proper practice for JJP to compare the onset of action of Zyrtec with that of Claratyne based on studies measuring the onset of action of cetirizine versus placebo and the onset of action of loratadine versus placebo, which themselves conclude that cetirizine has an earlier onset of action than loratadine.

61 The Ellis study was a head-to-head study which the Panel accepts as supporting Claim 1. The Panel also accepts the Greisner 2004 literature review as evidencing the body of scientific evidence at the date of publication to the effect that cetirizine has a shorter onset of action than loratadine. JJP's literature search found nothing published since Greisner 2004 to the contrary.

62 Accordingly, the Panel is satisfied that JJP has shown that conventional Zyrtec tablets start to work faster than conventional Claratyne tablets and considers that differences in formulation and excipients would not detract from this conclusion.

63 Since viewers of the television advertisements are unlikely to have understood the comparison to be confined to tablets, the Panel has considered whether Claim 1 is misleading when applied to all available forms of Zyrtec versus all available forms of Claratyne in Australia. The Panel notes that cetirizine acts faster pharmacologically than loratadine; that the journal articles on which JJP relies demonstrate that cetirizine tablets have an earlier onset of action than loratadine tablets by 2 to 4 hours and reflect the body of scientific evidence.

64 However, because it is unlikely the Disclaimer would have been read and understood by viewers of the television advertisements, the Panel considers that JJP failed to make it clear in those advertisements that it was comparing Zyrtec tablets with Claratyne tablets. Viewers would therefore have understood the television advertisements to be comparing the two available forms of Zyrtec in Australia with all available forms of Claratyne available in Australia.

65 Explanatory Note 5.2 to the Code identifies as a technique which may be considered inappropriate and contrary to the Code:

> "where it is unclear with what the advertised non-prescription consumer healthcare product is being compared…".

66 The Explanatory Notes do not themselves constitute binding provisions of the Code and Explanatory Note 5.2 does not appear consonant with the language of Section 5.2 of the Code. It does appear consonant with Section 5.1.3 of the Code, which requires that information about non-prescription consumer healthcare products not mislead and that points of comparison should be based on facts which have been previously substantiated.

67 It is for the advertiser to show substantiation, so even though Bayer has not produced any evidence that Zyrtec does not start to act faster than one or more forms of Claratyne, the fact that JJP has not produced studies in substantiation of the claim, comparing the two available forms of Zyrtec in Australia with all available forms of Claratyne in Australia, constitutes a breach of Section 5.1.3. Further, JJP's failure to make it clear in the television advertisements that it was comparing Zyrtec tablets with Claratyne tablets was misleading, in breach of section 5.1.3 of the Code and section 4.5 of the TGAC. These are Moderate Breaches of the Code, having no safety implications but which will impact on the perceptions of consumers regarding the Zyrtec and Claratyne products.

Claim 2

68 This appears only in the 30 second advertisement, which begins by describing, somewhat irreverently, typical hayfever symptoms and hayfever sufferers, whose condition may be dismissed by others as "just hayfever". Claim 1 follows both visually and audibly. Immediately after Claim 1, the video depicts a clock with the words: "24-hour relief" and the voiceover continues: "and provides 24 hour relief". Next comes a screenshot of a woman hugging a tree, followed by the final frame of the advertisement, in which Claim 2 appears, being a shot of a Zyrtec pack, the words onscreen: "SERIOUS ABOUT HAYFEVER ALLERGIES" and the voiceover: "Zyrtec, serious about hayfever allergies".

69 Taken in its context, the Panel considers that, to the reasonable consumer in the relevant class, the dominant impression conveyed by Claim 2 would be that while some people do not take hayfever allergies seriously, Zyrtec does. The Panel does not accept Bayer's contentions that Claim 2 would be understood as representing that Claratyne is not serious about hayfever allergies and that Claratyne is not efficacious. Accordingly the Panel finds no breach of the Code or the TGAC in relation to Claim 2.

Whether the complaint has been used simply as a competitive tool

70 The Panel has upheld the Complaint in relation to the failure of the television advertisements to make clear what form of Zyrtec is being compared with what form of Claratyne and the failure of JJP to substantiate the points of comparison made by the television advertisements. Accordingly, despite the factors discussed below in relation to apportionment of costs, the Panel is not satisfied that the Complaint has been used simply as a competitive tool and finds no breach of section 9.4.2.1 of the Code.

Category of breach

71 As mentioned in paragraph 67, the Panel finds the breaches to be Moderate.

Section 10.1.3 factors

72 On the material before the Panel, the Panel has considered these factors as follows:

- *Whether publication has ceased*
  The Panel does not know whether broadcast of the television advertisements has ceased.

- *Whether steps have been taken to withdraw the material published.*
  There is nothing before the Panel to indicate that any such steps have been taken.

- *Whether corrective statements have been made.*
  No corrective statements appear to have been made.

- *Whether the breach was deliberate or inadvertent.*
  There is no evidence that the breach was deliberate.

- *Whether the Member that is the subject of the complaint has previously breached the Code.*
  On 8 January, 2012, JJP was found by the Panel to have breached the Code by claiming *inter alia* that Zyrtec is over twice as effective as Claratyne at relieving the combined symptoms of hayfever. Although some modifications to the Panel's sanctions were made on appeal by the arbiter, the finding of breach was not disturbed.

- *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 consumers are likely to have been and will be affected but not adversely.

Sanctions

73 The Panel requires JJP to pay a fine of $5,000 for the Moderate Breaches.

74 The Panel requires JJP forthwith to cease broadcasting the television advertisements in their present form and to give an undertaking in writing to the Executive Director of ASMI:

(a) to cease comparing onset of action of Zyrtec with the onset of action of Claratyne without making clear what forms of them are being compared; and

(b) except in relation to conventional tablet forms, to cease publication forthwith in any media, until it can be supported by clinical evidence, of any representation, express or implied, to the effect that a form of Zyrtec starts to work faster than a form of Claratyne.

75 In considering section 9.4.2.2 of the Code, the Panel has taken into account the following factors:

(a) JJP's breaches had no safety implications;

(b) Bayer did not notify JJP of its wish to rely upon the Market Research Report until after it had received JJP's Response to the Original Formal Complaint;

(c) Bayer included responses to that Response in its proposed Second Formal Complaint, contrary to the intent of the Code, paragraphs 9.4.2.4 and 9.4.2.10;

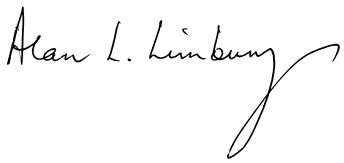
(d) all of Bayer's criticisms of the Journal articles on which JJP relies are unfounded, particularly Bayer's assertion that it is highly misleading to compare products with each other where each has been compared in the same study with placebo.

76 Having regard to these factors, the Panel determines, pursuant to section 9.4.2.2 of the Code, that Bayer should contribute two thirds and that JJP should contribute one third of ASMI's out-of-pocket expenses associated with the determination of this complaint.

77 Attention is drawn to sections 10.2.6 and 11.1 of the Code.

Dated: May 4, 2015

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.