**ASMI COMPLAINTS PANEL FINAL DETERMINATION**
**Meeting held May 11, 2010**

**Wyeth Consumer Healthcare Pty Limited ("Wyeth") v. Bayer Australia Limited ("Bayer")**
**Citracal® promotional claims**.

1. Wyeth complains that promotional claims in advertisements for Bayer's Citracal calcium citrate tablets breached clauses 4.3.1, 5.1.3, 5.2.1 and 5.2.2 of the ASMI Code of Practice ("the Code"). The advertisements were published to pharmacists and to consumers in a "bottle neck tie", a "pharmacy leave behind piece", a "booklet", a "leaflet", a "pharmacy assistant training manual" and on a website.

Informal correspondence

2. Contrary to the Code, clause 8.4.1.1, both parties sought to communicate to the Panel in the Complaint and the Response the content of some of the informal correspondence passing between them prior to the formal Complaint. The Panel has disregarded this material and draws the attention of ASMI members to the provisions of this clause.

Presentation of the Complaint and Response

3. Although both the Complaint and the Response contained tabs clearly and helpfully dividing the various documents presented, some of the studies did not have the relevant passages highlighted and the Response reproduced in full many of the studies already contained in the Complaint, instead of merely reproducing the pages on which the Respondent relies. In these respects they did not comply with the "Guidelines for ASMI members for the preparation of Complaints and Responses in proceedings before the ASMI Complaints Panel – July 2008".

The promotional claims

4. Wyeth complains about the following claims:

   (a) "Citracal has superior absorption by about 25% compared to calcium carbonate" ("Absorption Claim");

   (b) "Citracal is the harder working calcium* *compared to calcium carbonate" ("Harder Working Claim");

   (c) "Citracal delivers the optimal dose of calcium" ("Optimal Dose Claim");

   (d) "Citracal + D meets vitamin D RDI at any age group" ("RDI Claim"); and

(e) "Citracal is absorbed by about 25% better than calcium carbonate to help promote bone density, build strength and prevent fractures" ("Bone Density Claim").

5. The Harder Working Claim was found in breach of the ASMI Code of Practice in *Nycomed v. Bayer*, 29 April, 2010 ("the Nycomed case") and remedial action was required by the Panel. Bayer has said it will not appeal and will abide by the Panel's decision. It is therefore unnecessary for the Panel to consider this claim.

6. The RDI Claim was dismissed in the Nycomed case. The claim appears in the pharmacy assistant training manual in close proximity to a reference to "Calcium citrate (250mg elemental calcium)". The Panel in the Nycomed case found the claim to be correct because it is likely to be understood as referable to the dosage of 1-2 tablets per day, not as referable to a single tablet. For the same reason, the Panel dismisses Wyeth's complaint about this claim.

7. The Optimal Dose Claim appears in close proximity to the RDI Claim and would also be likely to be understood as referable to the dosage of 1-2 tablets per day, not as a claim for a single tablet. As such, the Panel finds the claim substantiated. Accordingly, the Panel dismisses Wyeth's complaint about this claim also.

8. The Bone Density Claim, contained in the Pharmacy leave behind piece and the leaflet, implies superior efficacy due to superior absorption. Since there is no evidence that calcium citrate is more effective than calcium carbonate in promoting bone density, building strength and preventing fractures, the Panel finds this claim to be inaccurate and misleading, in breach of Clauses 5.1.3, 5.2.2 and 4.3.1 of the ASMI Code, the latter on the basis that it fails to comply with clauses 4(1)(b), 4(2)(c) and 4(5) of the TGAC. The breach is a Moderate Breach.

9. The Absorption Claim was dismissed in the Nycomed case. The Panel has considered the nine references cited in the advertisements in support of this claim, together with numerous other studies on which Bayer relies, conducted both before and since the Sakhaee et al (1999) meta-analysis ("Sakhaee"). The figure of "approximately 25%" appears only in:

    - Sakhaee; and
    - the "ANZBMS Position Paper" ("ANZBMS").

10. The Panel made specific reference to Sakhaee and ANZBMS in dismissing Nycomed's complaint about this claim, finding that Sakhaee provided "slender" support for the Absorption Claim and that ANZBMS "bolstered somewhat" that support. Nycomed's complaint about Sakhaee was that it used only studies of solid formulation tablets, whereas Wyeth has broader criticisms of the

methodology. Further, Wyeth says that although ANZBMS cited the Sakhaee conclusion that calcium citrate's "*bioavailability may be approximately 25% greater than that of calcium carbonate*", this statement was removed by the ANZBMS authors in a more recent version published in the *Medical Journal of Australia* ("MJA") in March 2009. Wyeth says this indicates the finding is not considered to be of sufficient medical or scientific merit to publish. Bayer says the MJA version is merely a summary and that no adverse inference should be drawn. The Panel agrees that the absence from the MJA summary should not give rise to any adverse inference.

11. Wyeth says Sakhaee was conducted 10 years ago and has since been "widely criticised" by a number of experts in published papers over the past decade. Bayer says the results stand because the criticisms are by three individuals, Albrecht (who had a conflict of interest), Heaney (whose study was excluded from the Sakhaee study) and Moses (who referenced only Albrecht). The Panel has considered those criticisms and the author's responses to the Heaney and Albrecht criticisms.

12. Wyeth relies also on findings by the National Advertising Division of the Council of Better Bureaus, Inc ("NAD"), which held in 2001 that Sakhaee did not support equal bioavailability of calcium citrate and calcium carbonate and in 2002 and 2003 that Sakhaee was inadequate to substantiate claims of calcium citrate's superior absorption as compared to calcium carbonate. Sakhaee was one of three studies found by NAD, and on appeal in 2003 by the National Advertising Review Board ("NARB"), to provide inadequate support for claims which included the Absorption Claim. Both bodies concluded that the studies analysed by Sakhaee were "*too disparate to support their combination for advertising substantiation purposes*". Bayer says the claims considered in those proceedings were different; the NAD and NARB findings are irrelevant to this complaint; that Sakhaee is sound and supported by Australian experts in ANZBMS and has not been displaced by any more recent meta-analysis; and that the scientific body of evidence has expanded since those findings were made.

13. The Panel notes that the Absorption Claim was amongst those considered by the NAD and the NARB and that the findings in those proceedings are therefore not irrelevant to this complaint. The Panel finds the reasoning of those bodies to be persuasive and that Sakhaee does not provide a sound scientific foundation for the Absorption Claim. Since ANZBMS merely cited the conclusion of Sakhaee, it does not, of itself, support the Absorption Claim. The remaining references cited in the advertisements appear to support better absorption of calcium citrate than calcium carbonate but do not support the "about 25%" claim.

14. As for the scientific body of evidence, both before and after Sakhaee, Wyeth says that over the last 30 years, a number of studies directly compared the absorption of calcium carbonate as against calcium citrate by different methods and different designs, and by using different sets of subjects. It says these

studies demonstrate that there is no significant difference in absorption of calcium carbonate and calcium citrate. Bayer disagrees and says the full body of evidence supports the Absorption Claim.

15. The Panel has considered all the studies on which the parties rely and the parties' detailed and comprehensive comments on them. Some of the studies demonstrated results in the order of 25%. However, they are insufficiently powered, so the results are not statistically reliable. The Panel concludes that none of them support the Absorption Claim, since it is only Sakhaee and ANZBMS (citing Sakhaee) that go so far as to postulate superior absorption by as much as "approximately 25%". Since the Panel has found those papers inadequate to support the Absorption Claim, the Panel finds that claim to be inaccurate and misleading, in breach of Clauses 5.1.3, 5.2.2 and 4.3.1 of the ASMI Code, the latter on the basis that it fails to comply with clauses 4(1)(b), 4(2) (c) and 4(5) of the TGAC. The breach is a Moderate Breach.

Sanctions

16. The Panel has considered the factors set out in the Code, clause 9.1.3. On the material before the Panel it appears that:

- Publication is likely to have ceased as a result of the Nycomed determination;

- For the same reason, steps are likely to have been taken to withdraw the material published, save in relation to the Absorption Claim and the Bone Density Claim;

- no corrective statements have yet been made, although it is likely the corrective statements required to be published as a result of the Nycomed determination will shortly be published;

- the Panel is prepared to give Bayer the benefit of the doubt as to whether the breaches constituted by publication of the Absorption Claim and the Bone Density Claim were deliberate or inadvertent;

- In light of the Nycomed determination, Bayer has relevantly breached the Code before but the present complaint concerns the same advertising campaign as in the Nycomed complaint; and

- there are no safety implications but the perceptions of health care professionals and consumers will have been affected.

17. Also relevant to the question of sanctions, as in the Nycomed complaint, the Panel considers that, in publishing these advertisements, Bayer has sought to imply a clinical advantage for its Citracal products over calcium carbonate products when this has not been established.

18. The Panel takes into account that Bayer has stated that it does not intend to appeal from the Panel's determination in the Nycomed case, which requires Bayer to give certain undertakings, to retrieve and destroy certain material, to publish a corrective statement and a retraction and to pay a fine of $10,000.

19. Accordingly, the Panel requires Bayer:

    (1) to give an undertaking in writing to the Executive Director of ASMI to cease forthwith the publication of the following in any media, including on any website, until they can be supported by clinical evidence, properly conducted:

        (a) the words "Citracal has superior absorption by about 25% compared to calcium carbonate" and any representation to like effect;

        (b) the words "Citracal is absorbed by about 25% better than calcium carbonate to help promote bone density, build strength and prevent fractures" and any representation to like effect; and

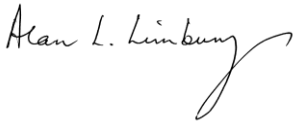
    (2) to use its best endeavours, within the next sales cycle and in any event within 10 weeks of the date of this Determination, to retrieve and destroy all Pharmacy leave behind pieces and all leaflets containing any such claims.

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

21. Although some aspects of this Complaint have been dismissed, they are minor by comparison with those aspects which have been upheld and are insufficient to justify any determination by the Panel to change the usual application of clause 8.4.2.2.

Dated: May 26, 2010

For the ASMI Complaints Panel



Chairman

Note: although this is called a Final Determination, each party has a right of appeal to the Arbiter. If no appeal is lodged this determination will be published on the ASMI website once the time for lodging an appeal has expired. If there is an appeal, the Arbiter's determination will be published on the ASMI website together with this determination. Until publication on the website, parties and their representatives should maintain the privacy of these proceedings.