

**ASMI COMPLAINTS PANEL DETERMINATION**  
**Meeting held April 13, 2010**

**Nycomed Pty Ltd (“Nycomed”) v. Bayer Australia Limited (“Bayer”)**  
**Citracal® promotional claims.**

1. Nycomed complains that promotional claims in advertisements for Bayer’s Citracal calcium citrate tablets breached clauses 5.1.3, 5.1.4 and 5.2.2 of the ASMI Code of Practice (“the Code”). The advertisements were published to pharmacists in a “leave behind” detailer; to consumers and health care professionals (“HCPs”) on a web site; and to pharmacy assistants in a “Contact” training manual, a Pharmacy News publication.
2. Nycomed describes the advertisement in “Contact” as being directed to HCPs. However pharmacy assistants are considered to be consumers for the purposes of the Therapeutic Goods Advertising Code (“TGAC”). See, for example, CRP determinations 2008-03-011 and 2008-03-004. The advertisement in “Contact” presently under consideration contains the statements required by clause 6(3) of the TGAC and was thus clearly directed to consumers.

Informal correspondence

3. In breach of the Code, clauses 8.4.1.1 and 8.4.2.7, Bayer included with its Response copies of informal correspondence passing between the parties 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

4. Neither the Complaint nor the Response complied with the “Guidelines for ASMI members for the preparation of Complaints and Responses in proceedings before the ASMI Complaints Panel – July 2008” in that the passages of the numerous studies provided, on which reliance was placed, were not identified by their page numbers and were not highlighted, thereby making the task of the Panel members in identifying those passages unnecessarily difficult and time-consuming.

The promotional claims

**1. “Compared to calcium carbonate”**

5. Nycomed says this statement, as used throughout the materials, is in breach of clause 5.2.2 because it is unclear with what the advertised non-prescription consumer healthcare product is being compared or upon what basis. Bayer says Nycomed has omitted the main claim which these words qualify.

Panel consideration

6. The words “Compared to calcium carbonate” appear only in qualification of the “harder working” and “superior absorption” claims considered below. It is inappropriate to consider them as a stand-alone statement. This aspect of the Complaint is dismissed.

**2. “Citracal has superior absorption by about 25% compared to calcium carbonate.”<sup>1-9</sup>**

7. Nycomed says this claim is in breach of clause 5.2.2 because it implies that the 25% superior absorption figure is based upon the outcome of fair comparative tests to which the advertiser’s product also has been subjected and the results of such tests are stated. The claim infers superior absorption versus all calcium carbonate products yet the data provided by Bayer is only valid for solid dose tablet formulations of calcium carbonate.
8. Bayer says this claim is fully supported by the references provided and that the evidence supports the theory that total bioavailability of calcium carbonate is not impacted by tablet type or formulation. Bayer has made no claims around speed of absorption, but has limited claims to total extent of absorption or bioavailability. In 2009, Nycomed agreed to withdraw claims as to equivalent absorption of calcium carbonate versus calcium citrate.

Panel consideration

9. The claim is a comparison of the amount of calcium absorbed from the Citracal calcium citrate product with the amount of calcium absorbed from all calcium carbonate products available in Australia.
10. The Panel has considered all the references provided by the parties but finds it sufficient to comment only as appears below.
11. The claim reflects the conclusion of the *Sakhaee et al* meta-analysis (1999) at page 320:

“In summary, this meta-analysis indicated that calcium citrate is better absorbed than calcium carbonate by about 25%, whether it is taken on an empty stomach or given with meals”.

12. The expression “about 25%” appears to be derived from the passage on the previous page:

“In the whole set as well as in the subsets, calcium citrate availability was significantly greater than calcium carbonate bioavailability, by 20% to 27%”.

13. In commenting (at p. 320) that:

“The conclusions derived herein should apply to commercial preparations of calcium carbonate and calcium citrate, as long as these formulations satisfy desired properties of disintegration and dissolution”,

the *Sakhaee et al* meta-analysis noted that the in vitro dissolution profile and bioavailability of Citracal had been found to be indistinguishable from those of pure calcium citrate powder.

14. Accordingly the Panel regards the findings of this meta-analysis applicable to the Citracal formulation and to provide (slender) support for the “about 25%” claim. This support is bolstered somewhat by the more recent (circa 2006) Position Paper of the ANZBMS “Calcium and Bone Health” (Bayer’s reference No. 5) which refers to the *Sakhaee et al* meta-analysis in concluding “...calcium citrate is more soluble and its bioavailability may be approximately 25% greater than that of calcium carbonate...” (at p.10).

15. Nycomed has not satisfied the Panel that this conclusion is inappropriate by reason of the Nycomed product being in chewable form, since form affects speed, not amount of absorption.

16. Accordingly, this claim does not breach the Code and this aspect of the Complaint is dismissed.

**3. “CITRACAL. THE HARDER WORKING CALCIUM\*. \* Compared to calcium carbonate”.**

17. Nycomed says this claim is in breach of clause 5.1.3 because it misleads the reader into believing that there is a clinically relevant difference in outcome in favour of Citracal over all calcium carbonate preparations. Further, this claim breaches clause 5.1.4 because the cited references do not support that representation.

18. Bayer denies any breach, saying no comparative claims of clinical efficacy have been made and that the claim (which relates to absorption) is supported by nine robust publications. Further, HCPs can interpret clinical data.

Panel consideration

19. The words “the harder working calcium” would be understood by reasonable consumers and reasonable HCPs alike as a representation of superior clinical effect to calcium carbonate.

20. The graphic, depicting workers on a construction site building a bone, reinforces this representation, as does the statement in the print advertisements “Citracal works hard...” and the statement on the website: “You, too, can rely on Citracal to work hard for you to deliver the calcium you need to help protect you in your fight against osteoporosis”. References 1-9 on which Bayer relies in the print advertisements do not support the clinical superiority representation, since they address absorption. HCPs who did not go to the references would expect them to support the represented efficacy claim. Even if they went to the references, many may be left with the impression that because of its superior absorption, Citracal has the superior effect to which the representation refers.
21. Accordingly, the Panel finds this claim to be in breach of clauses 5.1.3 and 5.1.4 of the Code and the breach to be a Moderate breach.

**4. Graphic comparing femur bones after taking Citracal or calcium carbonate**

22. Nycomed says this graphic is in breach of clause 5.1.3 because it is not accurate, not balanced and misleads the reader into believing that the % calcium absorption from Citracal is 100% and that from calcium carbonate is 75%. The literature does not support this. Further, the graphic breaches clause 5.2.2 because the bone depicting the scenario after taking calcium carbonate has 25% missing, implying that calcium carbonate products are ineffective at fulfilling their indicated use of aiding in the prevention and/or treatment of osteoporosis.
23. Bayer denies breach of clause 5.1.3 on the grounds that the graphic is a visual representation of a claim which is permitted; it is a visual aid only with no actual figures included on the graphic to mislead the reader; it is never used in isolation and only appears with explanatory text to describe relative absorption so is accurate and balanced; and HCPs would understand the manner in which the visual aid is presented.
24. Bayer denies breach of clause 5.2.2 on the grounds that the graphic does not imply that other calcium carbonate supplements are ineffective at fulfilling their indicated use; no other brands are mentioned or represented; no clinical efficacy or outcome claims are made; and the graphic is always accompanied by the qualifying descriptive relative absorption text.

Panel consideration

25. Taken in the context of the advertisement in question in each case, and having regard to the associated text, the graphic is confusing. Nevertheless, it is likely to convey to consumers that 100% calcium is absorbed from Citracal and that

only 75% of the calcium is absorbed from calcium carbonate products in the Australian market. Further, the “missing” portion of bone is likely to convey to consumers that those calcium carbonate products are ineffective. HCPs would have no different understanding of the graphic. Since these representations are untrue, the graphic breaches clauses 5.1.3 and 5.2.2. The breaches are Moderate.

#### **5. Absorption fraction graphic adapted from Levenson et al, 1994**

26. Nycomed says this graphic is in breach of clause 5.1.3 because the data points have been inaccurately reproduced and the source data and the curve of the data are misrepresented, although the conclusions of the data – that calcium absorption is dose dependent - are not altered.
27. Bayer denies breach because visual representations are acceptable in pharmaceutical marketing; the graphic accurately represents data published in *Levenson et al 1994*; and since the conclusions of the data are not altered, the graph is not misleading.

#### Panel consideration

28. Beneath the graph appearing in the *Levenson et al 1994* paper is a note: “(Copyright Robert P. Heaney: used with permission)”. In describing the graph appearing in its advertising as “Adapted from Levenson et al 1994”, Bayer has misrepresented its source. It is not for this Panel to consider any copyright issue that might be said to arise. Although inversion of the curve is permissible, Bayer’s adaptation of the graph is inaccurate and sloppy (because the data points have been inaccurately reproduced), albeit not misleading. Hence it is technically in breach of clause 5.1.3. This is a Minor breach.

**6(a). “Citracal + D meets vitamin D RDI at any age group unlike other calcium supplements<sup>13</sup> and**

**6(b). “Because Citracal® + D contains 12.5 micrograms of vitamin D3, it is one of the only calcium-D supplements which contains enough vitamin D to meet the recommended daily intakes for all age groups”.**

29. Nycomed says these two claims are in breach of clause 5.1.3 because a single tablet of Citracal + D contains only 500 IU (12.5 mcg) of vitamin D, which is lower than the RDI of 600 IU. The comparative nature of the claim “*unlike other calcium supplements*” is also in breach of clause 5.2.2 because it represents that all non-prescription consumer healthcare products containing calcium carbonate are ineffective in providing the RDI for Vitamin D, whereas such products are available (eg Calcia 1000mg + Vitamin D, which contains 800IU of vitamin D).

30. Bayer denies any breach, saying it does not intend to disparage the Calcia product, which was launched after the claims were made. Nor does Bayer claim to have the highest level of vitamin D on the market. A number of vitamin D-only products of higher strength are commercially available. Bayer does not make any direct comparisons to branded products including Calcia nor does it claim Citracal to be the only supplement on the market meeting the RDI for all age groups. The statement that other supplements do not meet the RDI for all age groups is accurate. Caltrate D, which contains 200 IU vitamin D in each tablet, with a dosing recommendation of 1-2 tablets per day, is an example, since the maximum achievable dose of vitamin D is 400 IU, which does not meet the RDI for the 71+ age group.
31. Bayer says it is not making any efficacy claims here and has limited statements in regard to vitamin D content claims, contrary to Nycomed's assertions.

Panel consideration

32. What the advertiser intends is irrelevant. What the advertisement represents to members of the target audience, acting reasonably, is what counts.
33. The Panel finds the statement "Citracal + D meets vitamin D RDI at any age group" to be correct because it is likely to be understood as referable to the dosage of 1 - 2 tablets per day, not to a single tablet. This aspect of the Complaint is dismissed.
34. The statement "unlike other calcium supplements<sup>13</sup>" breaches clause 5.1.3 because, in its context, it is likely to be understood as referring to all other calcium supplements available in Australia. So understood, it is incorrect because other supplements do meet vitamin D RDI at any age group at their prescribed dosage. This is a Moderate breach.
35. The second statement (which appears on the website) does not represent that one tablet meets the vitamin D RDI at any age group and does not claim to be the only calcium supplement to do so. This aspect of the Complaint is dismissed.

**6. "Citracal (calcium citrate 250mg) Citracal + D (calcium citrate 315mg / vitamin D 500IU)"**

36. Nycomed says this statement breaches clause 5.1.3 because it states that Citracal contains 250 mg of calcium citrate and that Citracal + D contains 315 mg of calcium citrate but these dosages are not approved by the Commonwealth Department of Health and Ageing.
37. Bayer says the 250mg and 315mg refer to elemental calcium content, as is clearly depicted by the pack shots in each piece. Bayer does not intend to understate the elemental calcium content of Citracal. To minimise further

confusion, it will ensure all future materials are clearer and will state the calcium in the following format:

“calcium (citrate) 250mg”.

Panel consideration

38. This statement breaches clause 5.1.3 because the figures used refer to elemental calcium, not, as stated, to calcium citrate. The figures on the pack shots are insufficiently legible and insufficiently prominent to correct the misstatement. Bayer’s proposed wording does not remedy the situation, since it amounts to another way of repeating the error. The wording used in the Training Manual is appropriate. This is a Minor breach.

**Sanctions**

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

- the website is continuing. The Detailer and the Manual are one-off publications;
- no steps have been taken to withdraw the material published;
- no corrective statements have yet been made, except the possible (inadequate) change in relation to content foreshadowed by Bayer in relation to statement 7;
- the breach in relation to statement 3 was deliberate;
- the other breaches were inadvertent;
- Bayer has not relevantly breached the Code before; and
- there are no safety implications but the perceptions of health care professionals and consumers will have been affected.

40. Also relevant to the question of sanctions, 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 there is none.

41. 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, in connection with Citracal or Citracal + D: “THE HARDER WORKING CALCIUM\* \*compared to calcium carbonate”;
  - (b) any representation that Citracal has superior clinical effect to calcium carbonate;
  - (c) the graphic comparing femur bones after taking Citracal or calcium carbonate;
  - (d) any representation that 100% of the calcium is absorbed from Citracal;
  - (e) any representation that 75% of the calcium is absorbed from calcium carbonate products in the Australian market;
  - (f) any representation that calcium carbonate products are ineffective;
  - (g) the absorption fraction graphic said to be adapted from Levenson et al, 1994 ;
  - (h) the statement “unlike other calcium supplements”, when used in conjunction with the statement: “Citracal + D meets vitamin D RDI at any age group”;
  - (i) the statement in relation to Citracal: “calcium citrate 250mg”;
  - (j) the statement in relation to Citracal + D: “calcium citrate 315mg / vitamin D 500IU”;
- (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 “leave behind” Detailers containing any such claims;
- (3) forthwith to publish on the Home page of its website at <www.citracal.com.au> and on the Home page of any other website on which the words set out in paragraph 41(1)(a) have been published, a Corrective Statement in the form set out below and to maintain that statement continuously on each such page for a period of six months;
- (4) to publish in the next available issue of Pharmacy News a Retraction Statement in the terms and in accordance with the directions set out below; and



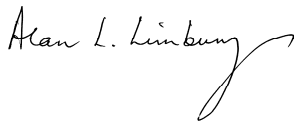
(5) to pay a fine of \$10,000 for the Moderate breaches found by the Panel.

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

43. 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: April 29, 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.

#### Correction statement for website home pages:

##### **CORRECTION**

**Citracal and Citracal + D are calcium citrate products. They are not more effective against osteoporosis than calcium carbonate products.**

**This correction is required to be published by the Complaints Panel of the Australian Self Medication Industry.**

#### Directions

Location:	Website Home page(s), so that it can be viewed without scrolling the page
Size:	No less than 500 pixels wide and 200 pixels high
Heading:	Arial or Helvetica Red on a white background

	The letters should be no less than 20 pixels in height, and should be no smaller than any other body text on the page Bold
Text:	Arial or Helvetica Red and black on a white background The letters should be no less than 14 pixels in height, and should be no smaller than any other body text on the page Bold
Duration:	6 months
HTML	The Correction is to be presented in ordinary and valid HTML 4 in the body of the page. Pop-ups, Flash objects, or images are not acceptable formats for website corrections.

### **Retraction Statement for Pharmacy News:**

#### **“RETRACTION**

**Material published by Bayer about its Citracal calcium citrate products in the 2010 “Contact” Training Manual for pharmacy assistants has been found by the ASMI Complaints Panel to have been misleading in claiming superior effectiveness to calcium carbonate products against osteoporosis and in portraying calcium carbonate products as ineffective against osteoporosis.**

**In fact Citracal has not been shown to be more effective against osteoporosis than calcium carbonate products, nor have calcium carbonate products been shown to be ineffective against osteoporosis.**

**Bayer has been required to publish this retraction by the ASMI Complaints Panel.”**

#### **Directions**

1. The retraction statement is to be published in the next available issue of Pharmacy News.
2. The retraction statement to be full page, within the first 15 pages of the publication.
3. No other material emanating from Bayer to appear on the same page nor on an adjoining page.
4. Font size of heading to be a minimum of 36 point in bold.

5. Font size of body copy to be a minimum of 28 point in bold.
6. All type to be black or red, as above, on a white background.