ASMI COMPLAINTS PANEL FINAL DETERMINATION
Meeting held 10 November, 2009

Hamilton Laboratories ("HL") v. Johnson & Johnson Pacific ("JJP")
Neutrogena Ultra Sheer Dry-Touch Sunscreen Lotion

1. HL complains that an advertisement appearing at pages 28 and 29 of the *Australian Journal of Pharmacy*, August 2009 edition, breaches clauses 5.1.3, 5.2.2 and 5.4.1 of the ASMI Code of Practice.

2. HL's complaint is directed at a graph on page 29, which is preceded by a headline and text introducing "helioplex®" technology, "the highest protection possible against the harsh Australian sun". The graph, said to show "UVA efficacy", is set out as a bar chart depicting ten products, three of which, including one identified as "helioplex®", are coloured yellow and described as "Photostability PASS". The other seven, including HL's Opti SPF 30+ 4 hrs water resistant sunscreen ("the HL product"), are coloured blue and described as "Photostability FAIL".

3. The vertical axis is said to show "in vivo UVA scores", calibrated from 0 to 40. The top of each bar along the horizontal axis shows an SPF score. Beneath each bar is the name of the product and its label claim. The SPF score attributed to the HL product is 28. Its label claim is 30+. The SPF score attributed to helioplex® is 86. Its label claim is also 30+. The height of the relevant bars reflects the difference between the UVA scores of the products depicted.

4. The bars depicting the two yellow products with SPF 30 scores are much taller than all the bars depicting blue products, which have scores from SPF 28 to SPF 32. All the blue products are described as "sunscreens that break down after 1hr".

5. At the foot of the page, in fine print, appears the following:

> "SPF Water Resistance testing conducted in 2009 using the Australian/New Zealand standard AS/NZS2604: 1998 for Sunscreen Products – Evaluation and Classification, N=3 PFA testing conducted as per the Colipa In Vitro method for Determination of UVA Protection provided by Sunscreens. Photostability tested as per the Colipa In Vitro method for Determination of Photostability of Sunscreens. JCIA for UVA protection factor (PFA).

6. HL contends the advertisement is misleading, inaccurate and unbalanced and makes points of comparison that do not reflect the body of scientific evidence. In particular, HL objects to the SPF of 28 attributed to the HL product, which is less than the SPF claimed for it and considerably less than the SPF as tested, which HL says is 38.

7. HL says the graph is extremely confusing; the products have been selected in a prejudicial manner, since Hamilton has other products with higher SPFs after 4 hours of water testing than the Neutrogena product; the SPFs quoted are for different periods of water exposure; if n=3 means that only 3 subjects were tested for each product the results are not statistically significant; there is no standard in Australia or elsewhere relating to photostability of sunscreens; hence the graph misleadingly attempts to combine data from a mixture of Australian and international sources in one presentation. While some of the data are derived from standard methods incorrectly applied, some are derived from proposed methods that have [*scil*. not] as yet been ratified.

8. JJP denies these alleged breaches, saying, *inter alia*:

> "…we do not doubt that Hamilton would have SPF water resistance data on file for 10 subjects as per the AS/NZS 2604: 1998 standard; however, that data was not available to us. The SPF water resistance data in the table therefore is purely an indicative result based on a 3-person test; this is made clear to pharmacists in our footnotes".
>
> "…All products tested in the graph underwent a fair comparative test of 4 hours water immersion testing. The sample size for competitive products was n=3 rather than n=10 as for Neutrogena Ultra Sheer Sunscreen Lotion SPF 30+; however, this is clearly detailed in the footnotes".

9. HL also complains that the advertisement does not meet the minimum requirements for an advertisement to Health Care professionals, in breach of clause 5.4.1 of the Code, in that it does not list any active ingredients nor does it contain the statement "For full active ingredients, see the label". JJP admits this breach.

Panel consideration

10. Contrary to JJP's assertion, the data in support of the HL product's SPF 30+ label claim were available to JJP pursuant to the Code, clause 5.1.4, since HL is an ASMI member.

11. Under the AS/NZS 2604:1998 standard, numerical label protection factors greater than 30 are not permitted. Hence a label protection factor of 30+ signifies that the product's tested protection factor in accordance with the method set out in Appendix B to the Standard is 30 or more. Paragraph B4.2.3 of Appendix B provides that the number of test subjects used to determine the mean sun protection factor of a single sunscreen product shall be not less than ten. JJP must have been fully aware of this because its own product carries an SPF 30+ label and, according to its Response, its product was tested on 10 subjects.

12. The footnotes, which are not referenced to any part of the graph or text, are in extremely fine print and would not be seen by most pharmacists reading the advertisement. The fine print does not effectively qualify the representation made by the graph that all the products depicted were tested according to the standard, ie. on 10 subjects for each product, and that, in the case of the HL product, the SPF derived from such testing was lower than its label claim, hence in underperforming its label claim the product "failed", i.e. was ineffective.

13. It is unnecessary to make findings on all the other points in contention, since the above suffices to find the advertisement in breach of the Code, clause 5.1.3 in that it is misleading and not based on facts which have been previously substantiated and clause 5.2.2 in that it describes or shows the HL product as ineffective. These breaches are Moderate breaches. The admitted breach of clause 5.4.1 is a Minor breach.

Sanctions

14. The Panel has considered the factors set out in the Code, clause 9.1.3. It is not clear that publication has ceased; no steps appear to have been taken to withdraw the material; no corrective statements have been made; the breach was deliberate in that JJP knew a test on 3 subjects was insufficient to comply with the standard and would not yield statistically significant results yet chose to use such results to reflect adversely on a competitor's product; JJP has not relevantly breached the Code before; there are no safety implications and the perceptions of health care professionals will have been affected.

15. Accordingly, the Panel requires JJP:

    (a) to give an undertaking in writing to the Executive Director of ASMI forthwith to cease publication in any media, until it can be supported by clinical evidence, properly conducted, of any claim to the effect that the SPF of any sunscreen product is less than its label claim;

    (b) to give an undertaking in writing to the Executive Director of ASMI forthwith to cease publication in any media of the results of any SPF test not conducted fully in accordance with the AS/NZS 2604:1998 standard "Sunscreen Products – Evaluation and Classification" or any standard replacing that standard from time to time;

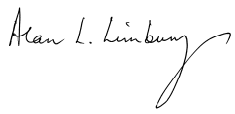
    (c) to publish in the next available issue of the Australian Journal of Pharmacy a retraction statement in the terms and in accordance with the directions set out hereafter; and

    (d) to pay the maximum fine for a Moderate breach of $20,000.

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

Dated 23rd November, 2009

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.

Retraction Statement:

"RETRACTION

In the August issue of the *Australian Journal of Pharmacy* Johnson & Johnson Pacific published an advertisement for a sunscreen which has been found by the ASMI Complaints Panel to be in breach of the ASMI Code of Practice.

In claiming superiority for its own product, JJP's advertisement misleadingly represented that Hamilton Laboratories Opti SPF 30+ 4 hrs water resistant sunscreen was ineffective, with an SPF lower than its 30+ label claim. Contrary to the AS/NZS 2604:1998 standard "Sunscreen Products – Evaluation and Classification", JJP tested the Hamilton product on only 3 subjects, not the required minimum of 10 subjects. Accordingly the results were not statistically significant and the advertisement was misleading and not based on facts which have been previously substantiated .

Johnson & Johnson Pacific has been ordered by the ASMI Complaints Panel to withdraw the aspersion cast on the Hamilton product by publishing this retraction."

Directions

1. The retraction statement is to be published in the next available issue of the Australian Journal of Pharmacy.

2. The retraction statement to be full page, within the first 15 pages of the Australian Journal of Pharmacy.

3. The same pale blue colour as appears at the foot of the advertisement to be used as background and 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.