ASMI COMPLAINTS PANEL FINAL DETERMINATION
Meeting held 8 December, 2009

Ego Pharmaceuticals Pty Limited ("Ego") v. Johnson & Johnson Pacific ("JJP")
Neutrogena Ultra Sheer Dry-Touch Sunscreen Lotion

1. Ego complains that a print advertisement for Neutrogena Ultra Sheer Dry-Touch Sunscreen Lotion directed to healthcare professionals ("HCPs"), published in *Australian Pharmacist*, August 2009, at pages 638-639 and in the *Australian Journal of Pharmacy*, August 2009, at pages 28-29 breached clauses 5.1.3, 5.1.4 and 5.2.2 of the ASMI Code of Practice ("the Code").

2. Ego also complains that print advertisements for the same product directed to consumers, published in Australian Women's Weekly, October 2009 and Madison magazine, November 2009 and a television commercial aired on Channels 7 and 9 on September 27, 2009 ("the consumer advertisements") breached clauses 5.1.3 and 5.2.2 of the Code.

Procedural issues

Delayed Response

3. The formal Complaint expressly drew attention to the Code, clause 8.4.2.5, which requires the formal Response to be delivered to the Complainant in hard copy and, to the extent practicable, electronically, within 10 working days of receipt of the hard copy of the formal complaint or within such further time as the Complainant, acting reasonably, may allow.

4. It appears the hard copy of the Response was mailed to the Complainant on the last day for its delivery and was not received until a day or so later. An electronic version was not delivered until the day after the last day for its delivery.

5. Pursuant to the Code, Clause 8.4.2.8, Ego provided copies of the Response to ASMI but objected to the Response being placed before the Panel. The Executive Director decided to place the Response before the Panel notwithstanding that no request for additional time was made by JJP.

6. The policy of ASMI set out in the Code, clause 8.1, is that all complaint procedures will be handled in accordance with general principles of fairness. These principles require that a respondent be given an opportunity to be heard unless its failure to comply with the requirements of clause 8.4.2.5 is shown to

be willful or unless the delay was significant or caused prejudice to the complainant.

7. Here, JJP's failure to deliver its Response within time appears, at worst, to be negligent rather than willful. The delay was insignificant and Ego suffered no prejudice from the delay. Despite the absence of any request on the part of JJP for an extension of time, the Panel considers the Executive Director was right to place the Response before the Panel. Accordingly it is appropriate for the Panel to take the Response into account notwithstanding that it was delivered to Ego out of time.

Similar complaint to the CRP

8. In its Response, JJP included a copy of an anonymous complaint lodged with the Complaints Resolution Panel about the consumer advertisements, claiming breaches of the Therapeutic Goods Advertising Code. JJP claimed this complaint was also lodged by Ego and submitted that the Panel should not make a ruling on those advertisements, saying, *inter alia*:

> "The CRP effectively represents the regulator, rather than industry self-regulation. In considering a complaint that is already before the CRP, the ASMI panel would be required to either make a decision contrary to the CRP (thereby undermining the CRP and making enforcement difficult, if not impossible), or make a decision that is consistent with the CRP (thereby making its decision redundant)."

9. Ego responded that there is no evidence that it lodged both complaints. It submitted that the Panel should consider all the advertisements the subject of its complaint in accordance with the Code.

10. The question whether this Panel should determine the entire complaint brought before it in accordance with the Code or refrain from considering those aspects of the Complaint which are pending before the CRP raises an issue of principle which does not turn on the identity of the complainant. Accordingly, the Panel addresses the question without making any finding as to whether both complaints are brought by Ego.

11. So far as concerns ASMI members, both complaints panels have concurrent jurisdiction over consumer advertising of therapeutic goods. The Code addresses HCP advertising also but the TGAC addresses consumer advertising only. To the extent that both codes address consumer advertising, their provisions differ in some respects and in others they overlap. Indeed the Code requires compliance with the TGAC (clause 4.3.1). The remedies available under the Code are different from and stronger than those available under the TGAC.

12. Consideration of the need for good administration and consistency of decisions leads to the conclusion that the integrity of the system of therapeutic goods advertising co-regulation would be jeopardized if this Panel were to determine an issue that is already the subject of a complaint lodged with the CRP.

13. Accordingly the Panel will consider only the advertisement directed to HCPs identified in the first paragraph of this determination and only insofar as the issues are not replicated in the CRP Complaint. That advertisement was the subject of an earlier complaint by Hamilton Laboratories ("the HL complaint"), determined by this Panel at its meeting on November 10, 2009, the final determination having been issued on November 23, 2009. Some aspects of Ego's complaint were addressed in the HL determination. Others were not.

The advertisement

14. The headline and text introduce "helioplex®" technology, "the highest protection possible against the harsh Australian sun". The product is claimed to provide "exceptionally high PFA (protection factor of UVA) providing broad, long lasting UVA protection, for up to 4 hours".

15. The following text includes the statement: "Helioplex® technology is so advanced it blocks 98% of UVB rays and 96% of biologically damaging UVA rays, for up to 4 hours.

16. A 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 two Ego products, Sunsense Ultra SPF 30+ 2 hrs water resistant and Sunsense Sport Milk SPF 30+ 4hrs water resistant ("the Ego products"), are coloured blue and described as "Photostability FAIL".

17. The vertical axis (y axis) is said to show "in vivo UVA scores", calibrated from 0 to 40. The top of each bar along the horizontal axis (x axis) shows an SPF score. Beneath each bar is the name of the product and its label claim. The SPF score attributed to each of the Ego products is 30. Their label claims are each 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.

18. 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".

19. Beneath the graph appear the words "…water resistant for up to 4 hours". Next to the graph is a depiction of the product, bearing the words "4 hrs water resistant".

20. 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).

The post immersion SPF of Neutrogena Ultra Sheer Dry-Touch Sunscreen Lotion

21. In prior correspondence, JJP provided to Ego a certificate from an overseas laboratory dated August 4, 2008 showing the post immersion SPF of the Neutrogena product, tested on 10 subjects, as ‹86.61. Ego says one of the subjects should not be validly considered under the applicable Australian standard since its SPF result was ‹54.39. Therefore the claimed post immersion SPF of 86 in the advertisement was not substantiated in accordance with the required standard.

22. JJP relies on both its initial testing, which it admits had some "minor variations", and on a subsequent test, conducted between September 14 and 16, 2009, which wholly conforms with the Australian standard and which JJP says confirms the results in the original testing. It says the results as presented on the advertisement are not in breach of the Code.

Panel consideration

23. Under the Australian standard, AS/NZS 2604:1998, Appendix B, paragraph B4.2.3, the number of test subjects used to determine the mean sun protection factor of a single sunscreen product shall be not less than ten.

24. JJP's initial testing did not substantiate the claimed post immersion SPF of 86 because that testing was not conducted on 10 eligible subjects, as required by the standard. Although the subsequent testing supports the claim, the advertisement was misleading and in breach of the Code, clauses 5.1.3 and 5.1.4 because the claim had not been substantiated at the time of the publication of the advertisement in August, 2009. Readers of the two publications would have been misled into believing that the claim had been substantiated through proper testing. These breaches are Moderate breaches.

Comparative advertising

25. Ego complains that the post immersion SPF testing of competitor sunscreens was conducted on only 3 subjects, contrary to the requirement of the Australian standard of 10 subjects.

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

> "…we do not doubt that Ego 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".

27. JJP says pharmacists would appreciate the indicative nature of the data and would not regard Ego's sunscreen as ineffective.

Panel consideration

28. This issue was determined in the HL complaint. Contrary to JJP's assertion, the data in support of the Ego products' SPF 30+ label claims were available to JJP pursuant to the Code, clause 5.1.4, since Ego is an ASMI member.

29. Under the 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 more than 30. The relevant passage in the standard is at paragraph 8.1.1(b):

> "Numerical label protection factors greater than 30 are not permitted. The terms '30+' or '30 plus' shall only be used on products with a tested protection factor of 31 or greater. The label protection factor shall be prefixed only by the expressions 'sun protection factor' or 'SPF'."

30. JJP must have been fully aware of this because its own product carries an SPF 30+ label and was twice tested on 10 subjects (albeit the results for one subject in the initial test were ineligible).

31. 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 Ego products, the SPF of 30 derived from such testing (ie. not more than 30) was lower than their label claims of 30+ (ie. 31 or greater), hence in underperforming its label claim the product "failed", i.e. was ineffective.

32. Accordingly the advertisement is 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 Ego products as ineffective. These breaches are Moderate breaches.

The use of test methods by JJP that are not in the AS/NZS 2604:1998

33. Ego says all sunscreens tested to the standard have already had photostability tested as part of their SPF assessment, hence the test methods used by JJP are without substantiation or scientific credibility, in breach of the Code, clause 5.1.3.

34. JJP relies on the requirement of the Code, clause 5.1.3, that points of comparison should be based on facts that have been previously substantiated and reflect the body of scientific evidence or experience at the time the advertisement is published. It says the current body of scientific evidence or experience can confirm that other methods of determining photostability and UVA protection are reliable and that the standard does not contain a ratified method for photostability.

Panel consideration

35. The Panel does not consider it a breach of the Code to use testing methods other than the Australian standard for determining photostability and UVA protection. Whether the methods used by JJP reflect the current body of scientific evidence and are reliable is considered below. This aspect of the Complaint is dismissed.

Photostability Pass/Photostability Fail

36. Ego says the test used to support the claims "Photostability PASS" and "Photostability FAIL" is described in the footnote as "COLIPA *in vitro* method for Determination of Photostability of Sunscreens". This implies official endorsement of that method by COLIPA, the European Cosmetics Industry Association. However, there is no such method listed on the COLIPA website. There is a COLIPA 2007 Guideline "Method for the *in vitro* determination of UVA protection", which is not included in the Australian standard, is not accepted internationally and has been shown to produce highly variable results. To use that guideline to "pass" or "fail" competitor products is to communicate to the reader that those sunscreens that fail this highly variable, inaccurate, unreliable and non-standard test are ineffective. This is misleading and unbalanced and denigrates competitor products without any basis whatsoever.

37. JJP admits it used the COLIPA 2007 Guideline and did not accurately describe it in the advertisement. JJP disagrees with Ego's assertions and says the method has been used in a number of studies and has been found to be reliable. Further, given the content of the graph and the context of the rest of the advertisement, pharmacists would understand the terms "Photostability PASS" and "Photostability FAIL" to refer only to photostability in UVA. Ego does not accept that the claim represents that those sunscreens that fail are absolutely ineffective.

Panel consideration

38. It is misleading to refer to a non-existent method of testing. The wording of the footnote represents that the (non-existent) method is a test for photostability generally and is not confined to photostability in UVA. More importantly (since it is highly unlikely that the footnote would have come to the attention of readers given its position and minuscule font), the graph itself, which is more likely to come to the attention of readers, refers to "photostability PASS and "photostability FAIL". Having regard to the way in which the graph is

presented, the words "UVA efficacy" would not necessarily be interpreted as applicable to the references to photostability, thus leaving the reader with the understanding that the sunscreens that fail are ineffective in other respects.

39. Further, the Panel accepts that the COLIPA 2007 Guideline method is controversial. The Panel is not satisfied that there exists a general scientific consensus that the method is reliable. It follows that the "pass", "fail" claims have not been substantiated, all the more so because the graph itself is highly confusing. In this respect the advertisements breach the Code, clauses 5.1.3 and 5.2.2. These breaches are Moderate breaches.

Breakdown of sunscreens

40. The graph depicts seven "sunscreens that break down after 1hr". Ego says its two SUNSENSE products identified in the graph not only deliver SPF protection of greater than 31 four hours after application, but after 4 hours in the water. Thus at least two of the seven do not break down after 1 hour.

41. JJP says the claim of breakdown is made in relation only to photostability and to UVA protection, not to SPF, and would be so understood.

Panel consideration

42. As mentioned, the graph is confusing. The competitor products claimed to break down after 1 hour are identified by an SPF number (such as 28) and, beneath, by their name and their SPF label claim (such as 30+), indicating that, on testing, those products are not as effective as claimed. It is likely that readers would take the "break down after one hour" claim as referring to SPF as well as to photostability. Accordingly the claim is misleading and in breach of the Code, clauses 5.1.3 and 5.2.2. These breaches are Moderate breaches.

In vivo UVA efficacy

43. The graph depicts "in vivo UVA scores". Ego says a footnote identifies the test used as "JCIA for UVA protection factor (PFA)", a Japanese testing method not included in the Australian standard. Ego says the use of this test without disclosing that it is not included in the Australian standard breaches the Code, clauses 5.1.3 and 5.2.2.

44. JJP says there is no ratified method for in vivo testing of UVA in the Australian standard and the current body of scientific evidence goes beyond the standard. The JCIA method has been endorsed in a number of studies and does reflect the current body of scientific evidence.

Panel consideration

45. As already mentioned, the Panel does not consider it a breach of the Code to use testing methods other than the Australian standard for determining UVA protection. The JCIA method does appear to reflect the current body of

scientific evidence. Ego did not contend otherwise. This aspect of the Complaint is dismissed.

"…up to 4 hours"

46. Ego refers to the statement "…providing…long lasting UVA protection, for up to 4 hours". It says "for up to 4 hours" would be likely to be taken as "for 4 hours" and is therefore misleading. Further, Ego asks what evidence JJP holds for the claim that the UVA protection of the Neutrogena product is water resistant for 4 hours, since the standard tests only SPF for water resistance.

47. JJP says Ego appears to be confusing two different claims, namely the claim in the middle of the page that the Neutrogena product provides up to 4 hours of UVA protection and the claim at the end of the page that it is water resistant for up to 4 hours. Given the locations and contexts in which the claims appear, JJP says it cannot see how the two claims would be read together by pharmacists. Further, JJP says it has tested the water resistance claim and is satisfied the product satisfies the requirements in the category "up to 4 hours".

Panel consideration

48. There are three references in the text (appearing in white print against a pale blue background and hence not at all easy to read) to "up to 4 hours". However the depiction of the product displays the claim (appearing in black print on a white background and therefore very easy to read) "4 hrs water resistant". Given the prominence of the depiction of the product and of the "4 hrs water resistant" claim, the Panel considers that pharmacists would be likely to understand all the references in the text to "up to 4 hours", including the reference to UVA protection (without water immersion), as "for 4 hours" and further to be likely to understand the advertisement as a whole as representing that the Neutrogena product provides 4 hours UVA protection with or without water immersion for 4 hours. This is misleading and unsubstantiated and in breach of the Code, clauses 5.1.3 and 5.2.2. These breaches are Moderate breaches.

No visible AUST L number

49. Ego says the Neutrogena product, with an SPF of 30+, is a therapeutic sunscreen, which must therefore have an AUST L number. The omission of this number from the pack, image or advertisement is misleading. Ego does not say how this is misleading.

50. JJP says the lack of an AUST L number would not mislead pharmacists into thinking the product is a cosmetic. The AUST L number does appear on the pack, though not in the advertisement.

Panel consideration

51. There is no requirement that advertisements to HCPs must display AUST L numbers. The Panel does not accept that pharmacists would be led by the

absence of an AUST L number to believe that the product is a cosmetic nor be otherwise misled. This aspect of the Complaint is dismissed.

Other aspects of the Complaint which are raised also in the consumer advertisements

52. As previously mentioned, the Panel considers it inappropriate to determine aspects of this complaint that are pending in the previously lodged complaint to the CRP. These include the claim in the CRP advertising "There is no higher protection under the Australian sun", which corresponds to the claim in the HCP advertisement "the highest protection possible against the harsh Australian sun" and the claim to exclusivity of the helioplex® technology, to mention only two.

53. The Panel considers that the understanding of pharmacists in relation to the replicated claims would be no different from the understanding of consumers. Accordingly, the Panel would expect JJP to give effect, in its HCP advertising, to any modifications which may be made to its corresponding claims in consumer advertising as a consequence of the determination of the CRP complaint.

Sanctions

54. The Panel has considered the factors set out in the Code, clause 9.1.3:

- the undertakings required by the Panel in its determination of the HL complaint have been given by JJP to ASMI by letter dated December 4th, 2009 so it may be accepted that publication has ceased and that steps have been taken to withdraw the material;

- no corrective statements have yet been made but in its Final Determination in the HL complaint dated November 23rd, 2009 (which concerned only the advertisement in the AJP), the Panel ordered that a full page retraction be published in the first 15 pages of the then next available issue of the AJP;

- the breach of the "Comparative Advertising" aspect of the Complaint 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;

- the other breaches were, in the Panel's view, inadvertent;

- JJP has not relevantly breached the Code before since the breach found to have occurred in the HL complaint arose from the same advertisement;

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

55. The undertakings already given to ASMI by JJP are continuing and are relevant here. They are in the following terms:

    (a) 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; and

    (b) 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.

56. Given that the claimed SPF of 86 for the Neutrogena product has been substantiated since the claim was published, it would be futile to require JJP to give an undertaking to cease publication of any claim that had not been substantiated when made, since the Code, clauses 5.1.3 and 5.2.2 already impose this obligation on JJP as an ASMI member.

57. The panel has already imposed a fine of $20,000, the maximum available for a Moderate breach, for the breach of the Code found to have occurred in the HL complaint. It would be inappropriate to impose a further fine for the same advertisement.

58. Accordingly, the Panel requires JJP:

    (a) to give an undertaking in writing to the Executive Director of ASMI forthwith to cease describing the COLIPA 2007 Guideline "Method for the *in vitro* determination of UVA protection" as the "Colipa in vitro method for Determination of UVA Protection provided by Sunscreens";

    (b) to give an undertaking in writing to the Executive Director of ASMI forthwith to cease publication in any media of any comparison of sunscreen products based on results obtained by the application of the COLIPA 2007 Guideline "Method for the *in vitro* determination of UVA protection";

    (c) to give an undertaking in writing to the Executive Director of ASMI forthwith to cease publication in any media of any claim, until it can be supported by scientific evidence, properly conducted:

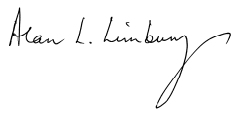
- that a competitor's sunscreen breaks down after 1 hour;
- that a competitor's sunscreen is ineffective;
- that Neutrogena Ultra Sheer Dry-Touch Sunscreen Lotion provides 4 hours UVA protection;
- that Neutrogena Ultra Sheer Dry-Touch Sunscreen Lotion provides 4 hours UVA protection with water immersion for 4 hours; and

(d) to publish in the next available issues of Australian Pharmacist and the Australian Journal of Pharmacy a retraction statement in the terms and in accordance with the directions set out hereafter.

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

Dated 30 December, 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 [*name of publication*] Johnson & Johnson Pacific published an advertisement for Neutrogena Ultra Sheer Dry-Touch Sunscreen Lotion 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 Ego Pharmaceuticals Pty Limited's sunscreen products, Sunsense Ultra SPF 30+ 2hrs water resistant sunscreen and Sunsense Sport Milk SPF 30+ 4 hrs water resistant sunscreen were ineffective, break down after 1 hour and had an SPF lower than their 30+ label claim. Contrary to the AS/NZS 2604:1998 standard "Sunscreen Products – Evaluation and Classification", JJP tested the Ego products 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 had been previously substantiated.

At the time of the publication of the advertisement, the claimed SPF of the Neutrogena product had not been substantiated in accordance with the Australian standard and Johnson & Johnson Pacific had not used a method generally agreed to be reliable to test the *in vitro* UVA protection of the Ego products and those of other competitors mentioned in the advertisement. Further, while disparaging the products of competitors, the advertisement made the unsubstantiated representation that the Neutrogena product provides 4 hours UVA protection with or without water immersion for 4 hours.

The ASMI Complaints Panel has directed Johnson & Johnson Pacific to withdraw the aspersions cast on the Ego products and on the other products of competitors mentioned in the advertisement by publishing this retraction."

Directions

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

2. The retraction statement is to be full page, within the first 15 pages of the publication.

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.