ASMI COMPLAINTS PANEL DETERMINATION
Meeting held August 10, 2010

Dr. Ken Harvey v. Aspen Pharmacare Australia Pty Ltd ("Aspen")
Nausetil® shelf wobbler.

1. Dr. Harvey complains that a "shelf wobbler" associated with Aspen's Nausetil tablets breached clause 5.3.3.3 of the ASMI Code of Practice ("the Code").

2. Although there is no brand name on the shelf wobbler, it is common ground that it is in the style of the Nausetil promotional material given to pharmacists with a "Dear Pharmacist letter", in which letter Nausetil is clearly described as indicated for nausea associated with migraine, listing several migraine triggers. The colours of the shelf wobbler are white and yellow on a blue background over a wavy blue and white graphic. The word "new" is prominent in an orange circle. There is an orange "stick figure" with what appears to be a throbbing stomach. The text reads:

"Nausea?
due to:
- Tummy upset
- Migraine
- Motion sickness
- Hangover
- Other causes

Ask your Pharmacist for advice. **NEW**

3. Nausetil is an S3 (Pharmacist Only) medication containing 5 mg of prochlorperazine maleate. The approved product information (PI) gives only one indication: "*For the treatment of nausea associated with migraine*". Prochlorperazine maleate does not appear in the SUSDP Appendix H, which lists Schedule 3 poisons permitted to be advertised.

4. Section 5.3.3 of the Code allows indirect/unbranded advertising of Schedule 3 medicines but is silent on whether the conditions that may be detailed must be in accord with the PI. Dr. Harvey submits that:

   - the "shelf wobbler" for Nausetil promotes the product (albeit indirectly) for indications outside the PI;
   - this does not encourage quality use of medicines;
   - this is in breach of the spirit (if not the fine print) of the ASMI Code; and
   - it may also encourage pharmacists to recommend the product "off-label" in breach of the PI.

5. In particular, Dr Harvey says that, instead of specifying the specific condition (in this case migraine) noted in Section 5.3.3.3 of the ASMI Code and in the "Dear Pharmacist" letter, the shelf wobbler highlights nausea due to a range of additional conditions that are not listed in the PI as indications for the product. Hence the "shelf-wobbler" is potentially in breach of the ASMI Code. Dr. Harvey accepts that, if judged to be a Code breach by the ASMI Code Complaints Panel, this was inadvertent.

6. Aspen submits that if this were a plain item with this print only, there would be little argument that patients with nausea should or could discuss nausea with their pharmacist. Aspen had no intention of advertising the brand directly to the consumer. Rather its intention was to support the professional role of the pharmacist in managing minor aliments by recommending that the consumer seek advice from the pharmacist (whose recommendation might range from antacid to medical advice), including for nausea associated with migraine, in a context in which migraine triggers and propensity for migraine have been appropriately identified.

7. Aspen further says the shelf-wobbler is not permitted to be located in or near the S3 section, so it would not be possible for the wobbler to be linked to the product in the mind of the consumer. Further, the wobbler does not particularly resemble the product pack, there are no therapeutic claims and the product name is not on the wobbler. The sponsor name is also not included on the wobbler, although this is permissible. As nausea is a relatively common complaint, with a variety of causes, including but not limited to migraine, this provides the pharmacist with the opportunity to offer professional advice to the customer. It is intended to meet both the written Code in 5.3.3, and the spirit of the Code in enhancing the role of the pharmacist as per the Explanatory notes for 5.3.3, and the Pharmacy Guild "Ask your Pharmacist" program for professional health management advice. It was with this in mind, that the bottom line of the wobbler does not use the permitted line "Ask your Pharmacist for advice about suitable products for you", as the advice given may not be product related.

Panel consideration

8. The intent of sections 5.3.3 and 5.3.3.3 is to limit the indications which may be specified in indirect advertising of S3 products to those that are permitted by the PI. This is clear from the terms of 5.3.3.3 itself, which refers to "generic information which details the condition or conditions or class of condition where Pharmacist Only Medicines (S3) have become available or where new indications....are allowed. The Explanatory Notes support this interpretation, saying "Indirect advertising of Pharmacist Only Medicines (S3) can provide relevant information to consumers and enhance their awareness that the treatments are available without a doctor's prescription, and can direct them to seek further information from their doctor or pharmacist about these

treatments" and "Indirect advertising simply indicates availability of the Pharmacist Only Medicines (S3) for certain conditions...." and "The requirements for indirect advertisements clearly limit the scope of allowable claims...".

9. Generic information is defined in the Therapeutic Goods Act as including any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of therapeutic goods, but does not include... an advertisement (ie. a representation intended to promote a product). The Act requires generic information to comply with some of the principles of the TGAC, which prohibits representations "likely to arouse unwarranted and unrealistic expectations of product effectiveness".

10. The Panel finds the shelf wobbler in breach of the Code, section 5.3.3.3 because, without naming any product, it conveys to the consumer, through its words and get-up, that there is a new product for nausea due to tummy upset, motion sickness, hangover and other causes, as well as migraine, the only condition for which the new product is indicated. The Panel also finds the wobbler in breach of that section for containing generic information that contravenes the principles of the TGAC.

11. The Panel classifies this as a Minor breach.

Sanctions

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

- It does not appear that publication has ceased nor that steps have been taken to withdraw the wobbler;
- it does not appear that corrective statements have been made;
- the breach was inadvertent;
- the Member has not previously breached the Code;
- there are no safety implications; and
- the perceptions of healthcare professionals or consumers are unlikely to have been affected.

13. Accordingly, the Panel requires Aspen:

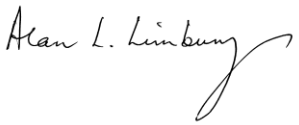
(1) to give an undertaking in writing to the Executive Director of ASMI to cease forthwith the distribution and publication of the shelf wobbler in question;

(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 the shelf wobblers in question.

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

Dated: August 16, 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.