Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by Aspen Pharmacare Australia Pty Ltd

I, Jane Cook, Head, Office of Product Review, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health and Ageing for the purposes of section 42DF(1) of the *Therapeutic Goods Act 1989*, give notice that the restricted representations described in paragraph (a) below have been approved for use in advertisements directed to consumers, for the products identified in paragraph (b), provided the conditions identified in paragraphs (c) and (d) are met:

(a) Representations to the effect that advertisements to consumers for the goods described in paragraph (b) may refer to: "heart attack", "stroke", "cardiovascular disease" and "cerebrovascular disease" when used in the phrase: ***"Helps prevent blood clotting and reduces the risk of heart attack and stroke in patients with known cardiovascular or cerebrovascular disease. For use under medical supervision only."***

(b) CARTIA LOW DOSE ASPIRIN 100mg tablet blister pack reformulation with the Australian Register of Therapeutic Goods (ARTG) number 192506 supplied as a medicine by Aspen Pharmacare Australia Pty Ltd.

(c) The advertisements in which the representations are made must include:
   i. A warning for the patient to "use under medical supervision only" or words to that effect;
   ii. A statement that "The use of low dose aspirin may be only one component of your medical practitioner's management plan to prevent you having a further heart attack or stroke. You should discuss this plan with your medical practitioner" or words to that effect;
   iii. A warning "Do not substitute other medicines containing aspirin, for this medicine, without first consulting your pharmacist or medical practitioner" or words to that effect; and

(d) The advertisements in which the representations are made must give the same prominence to conditions (i) – (iii) above, as is required for mandatory statements by section 6 of the Therapeutic Goods Advertising Code.

Dated this 29 day of July 2013

Jane Cook
Delegate of the Secretary to the Department of Health and Ageing; and
Head
Office of Product Review

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