Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by Reckitt Benckiser (Australia) Pty Ltd

I, Dr 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: ***"When used as directed by your doctor Disprin low dose aspirin helps to prevent heart attack and stroke in people with known cardiovascular or cerebrovascular disease."***

(b) DISPRIN LOW DOSE ASPIRIN 100mg tablet blister pack with the Australian Register of Therapeutic Goods (ARTG) number 156570 supplied as a medicine by Reckitt Benckiser (Australia) Pty Ltd.

(c) The advertisements in which the representations are made must include:
   i. A warning for the patient to "consult a medical practitioner prior to commencing use of Aspro Protect tablets" 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 27 day of March 2013

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