



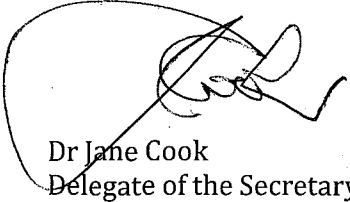
**Australian Government**  
**Department of Health and Ageing**  
Therapeutic Goods Administration

**Therapeutic Goods Act 1989**  
**Approval under section 42DF for use of restricted representations by Bayer**  
**Australia Limited**

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, Aspro Protect tablets help to prevent heart attack and stroke in people with known cardiovascular or cerebrovascular disease***".
- (b) ASPRO protect 100mg aspirin enteric coated tablet blister pack with the Australian Register of Therapeutic Goods (ARTG) number 151084 supplied as a medicine by Bayer Australia Limited.
- (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 5<sup>th</sup> September 2012

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