



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

**Approval under section 42DH to vary conditions 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, on receipt of a request from Reckitt Benckiser (Australia) Pty Ltd, approve the following conditions in the use of the statement '*Reduces blood clotting and reduces the risk of heart attack and stroke in patients with blood vessel disorders. For use under medical supervision only*' in consumer advertising of the product "Cardiprin 100 aspirin 100mg (ARTG R 15357) to the effect that advertisements in which the representations are made must include:

- *A warning for the patient to "Consult a medical practitioner prior to commencing use of CARDIPRIN 100 aspirin 100m" or words to that effect;*
- *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 healthcare professional" or words to that effect;*
- *A warning "Do not substitute other medicines containing aspirin, for this medicine, without first consulting your healthcare professional" or words to that effect; and*
- *Conditions (a) – (c) above must be given the same prominence in any advertising as is required for mandatory statements by section 6 of the Therapeutic Goods Advertising Code 2007.*

These conditions are in substitution for the following conditions imposed on 10 October 2007:

- *A call for the intervention or advice of a doctor before use must be included;*
- *An appropriate reference must be included to prevent substitution of the low-dose product with any other aspirin product without the advice of a healthcare professional;*
- *There must be appropriate advice about lifestyle factors that can reduce the risk of heart attack or stroke;*
- *There must be a reference to the benefit of an overall program for managing the risk of heart attack or stroke;*
- *The target audience needs to be appropriate, ie the advertising should target people who would be considered to be at risk of heart attack or stroke; and*
- *That the considerations outlined above be given appropriate prominence in advertising.*

Dated this 10 day of April 2013

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