

Australian Government

Department of Health and Ageing Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

I, SHELLEY TANG, Head of Office, Office of Devices Authorisation, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health and Ageing for the purposes of section 42 DK (1) of the Therapeutic Goods Act, give notice that the restricted representations described in paragraph (a) below, being representations that are necessary for the appropriate use of the therapeutic goods described in paragraph (b) below, may be included either on the label of the package of those goods or in information included in the package in which those goods are contained:

- (a) representations to the effect that the goods described in paragraph (b) below may be used "For the treatment of patients with known cardiovascular or cerebrovascular disease, as an antiplatelet agent for prophylaxis against acute myocardial infarction, unstable angina, transient ischaemic attack and cerebrovascular accident (stroke)."
- (b) SPREN 100 ASPIRIN 100mg tablet blister pack

supplied as an over-the-counter drug by Sigma Pharmaceuticals Australia Pty Ltd.

Dated this $2\sqrt{34}$ day of December 2010.

Shilley Tam

SHELLEY TANG Delegate of the Secretary to the Department of Health and Ageing