



Australian Government

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

THERAPEUTIC GOODS ACT 1989

I, Harald Rothenfluh, Head, Office of Medicines 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 the 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 anti-platelet agent for prophylaxis against acute myocardial infarction, unstable angina, transient ischemic attack and cerebrovascular accident (stroke)'* and *'Helps prevent blood clotting and reduces risk of heart attack and stroke in patients with known cardiovascular disease or cerebrovascular disease'*.
- (b) **AMCAL ASPIRIN EC 100 aspirin 100mg enteric coated tablet blister pack (AUST R 199476)**

Supplied as an over-the-counter medicines by **Probiotec Pharma Pty Limited**.

Dated this 27 day of August 2012.

Dr Harry Rothenfluh
Delegate of the Secretary to the
Department of Health and Ageing