

**EXCERPT FROM THE MINUTES OF THE PHARMACEUTICAL MANAGEMENT
AGENCY (PHARMAC)**

BOARD MEETING, 27 MAY 2011

Funding of dabigatran

resolved to list Pradaxa (dabigatran) in the Oral Anticoagulants therapeutic subgroup, Blood and Blood Forming Organs therapeutic group of Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 July 2011 at the following prices/subsidies (ex-manufacturer, excl. GST);

Pharmaceutical	Brand	Form	Strength	Pack Size	Packaging	Proposed subsidy/price
Dabigatran	Pradaxa	Capsules	75mg	60 OP	Bottle	\$148.00
Dabigatran	Pradaxa	Capsules	110mg	60 OP	Bottle	\$148.00
Dabigatran	Pradaxa	Capsules	150mg	60 OP	Bottle	\$148.00

resolved to include a tablet restriction on the 75 mg dose – no more than 2 tabs per day;

resolved to apply Original Pack dispensing to dabigatran in the bottle packaging;

resolved to include a restriction in Section B of the Pharmaceutical Schedule that dabigatran will not be funded Close Control in amounts less than 4 weeks of treatment;

resolved to approve the 1 April 2011 agreement with Boehringer Ingelheim (NZ) Limited subject to the Chief Executive not delaying implementation (as below);

resolved to direct the Chief Executive to delay implementation if by 12 June 2011:

- The PHARMAC initiated working group has not produced guidance for DHB hospitals on how to manage dabigatran-associated bleeding; or
- Guidance to General Practitioners cannot be developed.

resolved to direct PHARMAC staff to recommend to the Ministry of Health to add dabigatran to the Intensive Medicines Monitoring Programme;

resolved to direct PHARMAC staff to notify the Health Quality and Safety Commission that dabigatran will soon be listed in New Zealand, and that it should consider studying whether there are differential outcomes to warfarin treatment;

noted that the agreement with Boehringer Ingelheim (NZ) Limited allows an alternative blister pack packaging to be listed and PHARMAC intends to list it once it becomes available instead of the bottle packaging to avoid the need for ongoing Original Pack dispensing; and

resolved that the consultation on this proposal was appropriate, and no further consultation is required.

Anne Kolbe / David Kerr (**carried**)