

10 June 2011

Dabigatran funding approved

PHARMAC is pleased to announce the approval of an agreement with Boehringer Ingelheim (NZ) Limited to fund dabigatran (Pradaxa) without Special Authority restriction, from 1 July 2011.

Dabigatran is an oral anticoagulant approved for use in:

- Atrial fibrillation; and
- Prevention of venous thromboembolism post major orthopedic surgery.

This was the subject of a consultation letter dated 8 April 2011 which can be found on PHARMAC's website at <http://www.pharmac.govt.nz/2011/04/08/2011-04>.

The effect of the decision is that:

- From 1 July 2011 dabigatran (Pradaxa) capsules will be listed in Section B (community) and in Part II of Section H (DHB hospitals) of the Pharmaceutical Schedule at the following prices and subsidies (expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size ¹	Price and subsidy
Dabigatran	Capsules 75 mg	Pradaxa	60 OP	\$148.00
Dabigatran	Capsules 110 mg	Pradaxa	60 OP	\$148.00
Dabigatran	Capsules 150 mg	Pradaxa	60 OP	\$148.00

¹ Due to the short shelf life of the product once opened, Original Pack dispensing arrangements will be in place.

- Dabigatran will be listed in Section B of the Pharmaceutical Schedule without Special Authority restriction; however, there will be a restriction to state that it will not be funded Close Control in amounts less than 4 weeks of treatment and the 75 mg capsule will be subject to a maximum capsule restriction of two funded capsules per day.
- The net price of dabigatran will be reduced through:
 - a confidential rebate applying to all strengths of dabigatran capsules; and,
 - a confidential agreed expenditure level above which additional confidential rebates will apply.
- Dabigatran will have protection from subsidy reduction and delisting until 30 June 2016.

- Pradaxa will initially be provided in a bottle presentation, which has a shelf-life of 30 days once opened, but we are working with the supplier to introduce a blister packaging.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses were considered in their entirety in making a decision on the proposed changes.

The vast majority of responses were supportive of the proposal as the funding of dabigatran is anticipated to improve anticoagulation management. The following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
<p>Educational support for clinicians is required given dabigatran is part of a new class of oral anticoagulant treatments and will be listed without Special Authority restriction.</p>	<p>PHARMAC is working with a group of clinicians including cardiologists, stroke physicians, geriatricians, haematologists, surgeons and general practitioners to develop educational material for clinicians working in primary and secondary care settings.</p> <p>The educational material will provide guidance for prescribing and overall anticoagulation management.</p> <p>The material will be developed in conjunction with the Best Practice Advocacy Centre (BPAC) and will be disseminated through various channels including articles in the Best Practice Journal (BPJ). A news-brief will be included in the June edition of the journal, along with an insert outlining key information about dabigatran. Further articles will be included in future editions of the BPJ. Resources for clinicians and patients will also be available on the PHARMAC website.</p>
<p>The safety of dabigatran given the risk of bleeding and the absence of a direct monitoring test or a specific reversal agent.</p>	<p>PHARMAC has worked with a group of clinicians including haematologists, a transfusion medicine specialist and a surgeon to develop hospital guidelines to address issues like: management of dabigatran in emergency situations; tests which can be done to measure its effect; and management of dabigatran perioperatively. These guidelines will be disseminated to hospitals and will be available on PHARMAC's website by 12 June 2011. These issues will also be covered in the planned educational material detailed above.</p> <p>Routine testing is not required during treatment with dabigatran but it may be required perioperatively or in the event of bleeding. Although there is no direct monitoring test for dabigatran, the activated partial thromboplastin time (aPTT) and thrombin time (TT) can give an indication of the anticoagulant effect of dabigatran.</p> <p>Although not specific reversal agents, recombinant factor VIIa or prothrombin complex concentrates (for example Prothrombinex-VF) can be used in emergency situations with haematology guidance to reverse dabigatran's anticoagulant effect.</p>

Theme	Comment
The future availability of other drugs in these classes of treatment.	There is no exclusivity to the funding of dabigatran as an anticoagulant. PHARMAC is happy to receive (and will consider) applications for the funding of other anticoagulant products. We would expect such applications to consider the changed dynamics as a result of dabigatran funding.
The blister rather than the bottle packaging is preferred due to the shortened shelf-life of 30 days after the bottle is opened.	PHARMAC is working with Boehringer Ingelheim (NZ) Limited to change the bottle to the blister pack.

More information

For further information about this decision, please phone PHARMAC on 0800 66 00 50 (9 am to 5 pm, Monday to Friday)..