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Media release

### **Papers reveal PHARMAC's cautious approach with new anticoagulant drug**

Papers released by PHARMAC today outline the careful consideration given before funding was approved for the new-generation anticoagulant drug dabigatran (Pradaxa).

Dabigatran, which belongs to a new class of drugs called direct thrombin inhibitors, was funded on 1 July this year and is expected to replace warfarin as doctors' preferred treatment to prevent blood clotting in suitable patients. Anticoagulant therapy is important in patients with heart conditions, and in patients who have had joint replacements such as knees or hips. More than 7000 New Zealanders are currently being prescribed dabigatran.

PHARMAC has released papers outlining the rationale behind its decision, the advice it received from clinical advisory committees, and feedback received during consultation on the funding proposal.

The papers outline that, while dabigatran and the previously funded anticoagulant warfarin were similarly effective, overall dabigatran would have greater population health benefits in reducing the incidence of strokes, because it is better tolerated and can be used by more people than warfarin.

The papers also demonstrate that clinicians and patient groups supported the proposal to fund dabigatran, and outlined ways in which they thought risks could be managed, says PHARMAC Medical Director Dr Peter Moodie. This feedback supported the advice PHARMAC had previously received from its clinical advisory committee PTAC, and its Cardiovascular Subcommittee.

"We were very aware of the risks around dabigatran and thought carefully about how these could be managed," says Dr Moodie. "It's important to remember that dabigatran has been developed as an alternative to warfarin, a drug that is difficult to manage. Warfarin levels in the blood can be affected by what people eat or other drug interactions; and it can't be tolerated by many patients who need it. As a result, many people who need anticoagulant therapy aren't adequately treated."

The benefits and risks of dabigatran were highlighted further during consultation in April this year, with some responses highlighting issues around transitioning patients from warfarin to dabigatran and for emergency management situations.

"We took that feedback on board and worked with experts to develop guidance on managing anticoagulation therapies, including dabigatran."

Developing clear guidance for doctors and hospital emergency departments became an integral part of the PHARMAC decision, Dr Moodie says.

“The implementation date of this funding decision was contingent on adequate information material being prepared and distributed and we were delighted with the support we received from hospital haematologists and other health professionals to enable us to meet the earliest possible listing date.”

Dr Moodie says PHARMAC used external experts to develop the guidance, including the Otago University-based BPACnz, the NZ Cardiac Society, the Stroke Foundation and other clinicians including haematologists, general physicians, general practitioners and a surgeon.

Dr Moodie says doctors are trained to recognise that all medicines have clinical benefits and risks. When new classes of medicine are introduced, PHARMAC often works to support their funding with information for doctors.

“While dabigatran has advantages over warfarin, it also has risks so it is important to take a cautious approach. This is the case for any new medicine, and is particularly the case when patients are transitioning from one medicine to another,” Dr Moodie says.

“While doctors have expertise in treating patients with a wide range of needs, including those requiring anticoagulant therapy, we agreed that additional information providing evidence-based advice on administering dabigatran would be useful.”

“We were very pleased with the high-quality work that has resulted; it has been valued by clinicians and, indeed, has been used as the basis for developing similar guidance in Australia.”

The papers outline that PHARMAC received feedback from a wide range of clinicians, pharmacists and patient groups, and that the funding decision followed nearly two years of consideration by PHARMAC’s clinical advisory committees.

They also reveal that PHARMAC negotiated a listing price for dabigatran nearly half that paid in the United States, and that this price is further reduced by a confidential rebate. This was a factor in the funding decision as it made the drug more cost-effective.

The dabigatran papers can be viewed [here](#).

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