MEDSAFE
NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
www.medsafe.govt.nz

22 September 2011

Dear

Re: Dabigatran etexilate and the Intensive Medicines Monitoring Programme (IMMP)

Thank you for your letter of 23 August 2011 in relation to PTAC's recommendation to include dabigatran on the IMMP. The purpose of your letter was to request that Medsafe reconsider its decision not to fund an IMMP study of dabigatran.

In your letter you state that dabigatran should be monitored in IMMP in order to determine the incidence of bleeds in New Zealand. While the rate of bleeding with dabigatran in New Zealand patients is of academic interest, from the regulatory perspective it would not provide data that would result in a change to Medsafe's regulatory activities. Medsafe has already warned healthcare professionals about the risk of bleeding and the need to be careful when treating the elderly. There is no reason to suppose that the risk of bleeding in New Zealand with dabigatran, when used as intended as stated in the data sheet, is any different to that found in the RE-LY trial.

In your letter you note that haematologists in New Zealand have decided to assess the risk of haemorrhage and raise concerns that any other non-hematological adverse effects will not be reported. This is the reason why the Ministry of Health funds the collection of spontaneous reports of suspected adverse reactions by the Centre for Adverse Reactions Monitoring (CARM). Anyone can report suspected reactions to CARM. To date, CARM has received a number of reports of non-haematological suspected adverse reactions.

Medsafe would like to reassure you that we take the safety of dabigatran seriously. The collection and analysis of spontaneous reports of suspected adverse reactions is considered to provide the best method of identifying new safety issues to medicines in a timely fashion[1]. Medsafe is also reviewing safety information provided by companies, other regulators and that published in the

[1] Davis S, King B, Raine JM 2007 'Spontaneous reporting – UK' In Pharmacovigilance: Second Edition; Mann RM and Andrews EB (Eds) John Wiley & Sons, West Sussex, England.

scientific literature. Medsafe is discussing the safety of dabigatran with other international medicines regulators and has sought expert advice from the Medicines Adverse Reactions Committee (MARC).

The MARC was presented with a review of the company's European Risk Management Plan and the latest Periodic Safety Update Report for dabigatran at its meeting on 8 September 2011. The committee considered that:

- the benefits of use of dabigatran continue to outweigh its risks; and
- the post-marketing safety monitoring plan (Risk Management Plan) that has been developed by the product manufacturer is sufficient and that no further monitoring or additional research from New Zealand is required at this time.

A copy of the Medsafe report on dabigatran presented to the MARC is enclosed. Please note that this report is provided in confidence to PTAC members to enable the committee to gain a better understanding of the post-market safety plan in place for this medicine.

Medsafe considers that the benefits of dabigatran use outweigh the risks, and that the company is adequately monitoring the safety of this medicine and adequately investigating its use in the post-market setting.

Medsafe has not yet been presented with any reason from regulatory perspective that would support the need to contract an IMMP study for dabigatran. Of course other organisations are free to contract an IMMP study if they feel this would answer any questions they have on dabigatran.

I hope this additional information addresses your concerns that adequate safety monitoring systems are in place for dabigatran in the absence of an IMMP study of this medicine.

Yours sincerely