Thank you for your email of 30 September 2011 requesting information under the Official Information Act 1982. In a subsequent telephone conversation with on 30 September the scope of the request was narrowed to:

- Medsafe's clinical assessment of Boehringer's application for dabigatran/ Pradaxa.
- Advice received by Medsafe from any advisory committee before it approved the application.
- Reports on adverse reactions associated with dabigatran which Medsafe received since dabigatran was publicly funded in July.

Please find enclosed the information you have requested. Please note that there are two clinical assessments for dabigatran. The first assessment was for the indication for the prevention of venous thromboembolic events in patients who have undergone major orthopaedic surgery. This clinical assessment was performed on behalf of Medsafe by the Medicines Assessment Advisory Committee (MAAC). The second clinical assessment was performed by Medsafe for the indication for prevention of stroke in patients with atrial fibrillation.

Please note that the Centre for Adverse Reaction Monitoring (CARM), which is based at the New Zealand Pharmacovigilance Centre at the University of Otago in Dunedin, holds reports of suspected adverse reactions to approved medicines occurring in New Zealand. The Ministry of Health (through Medsafe) contracts the collection of these reports of suspected adverse reactions by CARM.

A summary of the suspected adverse reactions reported to CARM for dabigatran up to 30 September 2011 is provided. You are strongly recommended to read the accompanying information provided with these reports to assist in the interpretation of these data.

Some information has been deleted from the clinical assessment reports to protect the privacy of natural persons under section 9(2)(a) of the Official Information Act 1982 (the Act). In addition only summary data can be provided for the adverse reaction reports to ensure that the information released protects the privacy of natural persons under section 9(2)(a) of the Act.

You have the right under section 28(3) of the Act to ask the Ombudsman to investigate and review my decision not to release any of the information withheld.

Yours sincerely