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Circular No. 025/11

4 November 2011

**Re: Direct Thrombin Inhibitors associated with certain Elective Orthopaedic Surgical Procedures –
Dabigatran Etxilate and Rivaroxaban –**

Pradaxa Caps. 75 mg. 10 (5 Day Dose)	60612
Pradaxa Caps. 75 mg. 60 (30 Day Dose)	60628
Pradaxa Caps. 110 mg. 10 (5 Day Dose)	60659
Pradaxa Caps. 110 mg. 60 (30 Day Dose)	60684
Xarelto Tabs. 10 mg. 30	53342

Dear Doctor,

The HSE wishes to bring to your attention that the above currently marketed direct thrombin inhibitor and the direct factor Xa inhibitor medicinal products were included on the List of GMS Reimbursable Items in 2008 on the basis of their original indications i.e. the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.

Following a recent economic evaluation the HSE is assessing the availability of resources in 2012 to consider long term treatment with Pradaxa 150mg for the prevention of stroke in patients with Atrial Fibrillation. This is a complicated process with long term implications.

Pending the outcome of these deliberations the HSE wishes to clarify the current reimbursement position around Pradaxa (and any other new oral anticoagulants).

An economic evaluation in 2008 demonstrated that the reimbursement of both agents for the prevention of venous thromboembolism (VTE) in adult patients who have undergone *elective hip replacement surgery* or *elective knee replacement surgery* was cost effective for that indication.

We are aware that clinicians are considering whether to initiate patients on stroke prevention treatment by using the strengths already reimbursable under Schemes, which would entail treatment durations beyond those that follow elective surgery. **It is important to note that, with immediate effect, apart from the specified elective surgical indications the HSE will not reimburse such direct thrombin inhibitors.**

The prescribed therapy currently reimbursed should be a unitary course arising from a single elective surgical event with a recommended maximal extent.

GMS Repeat Prescription Forms should **not** be used when prescribing direct thrombin inhibitors. **Pharmacists have been informed that a second or subsequent month's supply will not be reimbursed on any of the Community Drug Schemes.**

Your co-operation is requested in ensuring cost-effective prescribing and dispensing of medicinal products on the GMS and Community Drug Schemes.

The HSE will continue to update you in relation to these matters.

Yours faithfully,

Patrick Burke
Primary Care Reimbursement Service