Circ. No. 001/07 26th March 2007

TO EACH PARTICIPATING DOCTOR

Re: Protocol for THELIN on the High Tech Medicinal Products Scheme - Effective April 2007

Dear Doctor,

I am writing to you in connection with the addition of THELIN (Sitaxentan sodium) to the High Tech Medicinal Products Scheme with effect from April 2007.

THELIN is the subject of a Marketing Authorisation (MA) issued by the European Union (EU) Commission, which has been approved for Pulmonary Arterial Hypertension (PAH). Hospital consultants with the appropriate expertise, who have previously received approval from the Department of Health and Children (this responsibility now lies with the HSE), will prescribe THELIN for PAH.

The hospitals in which specific consultants have been approved, for the purposes of prescribing THELIN in PAH, are the Mater Misericordiae Hospital and Our Lady's Hospital for Sick Children, Dublin.

In accordance with the PAH Protocol, which contains agreed clinical criteria, the terms of the High Tech Medicinal Products Scheme must be observed with regard to prescribing and dispensing THELIN. This is for a maximum period of six months (after which further approval may be granted). Any patient to be prescribed THELIN, whether or not previously approved for a different High Tech Medicine, must register for THELIN. It should be noted that the maximum period of six months will also apply to the PAH Protocol for REVATIO.

THELIN is only being made available to eligible persons, on the High Tech Medicinal Products Scheme, in respect of the licensed indication of PAH and then only where the consultant, who has initiated therapy, has been approved. No other hospital, consultant or medical indication is covered for THELIN on the High Tech Medicinal Products Scheme.

Yours faithfully,

Patrick Burke,
Assistant National Director,
HSE – Primary Care Reimbursement Service