Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Circular No. 016/09

20th October 2009

Re: Protocol for VOLIBRIS on the High Tech Medicinal Products Scheme – Effective November 2009

Dear Pharmacist,

I am writing to you in connection with the addition of VOLIBRIS (Ambrisentan) to the High Tech Medicinal Products Scheme with effect from November 2009.

VOLIBRIS 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 VOLIBRIS for PAH.

The hospitals in which specific consultants have been approved, for the purposes of prescribing VOLIBRIS 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 VOLIBRIS. This is for a maximum period of six months (after which further approval may be granted). Any patient to be prescribed VOLIBRIS, whether or not previously approved for a different High Tech Medicine, must register for VOLIBRIS. It should be noted that the maximum period of six months already applies to the PAH Protocol for REVATIO and THELIN.

VOLIBRIS 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 VOLIBRIS on the High Tech Medicinal Products Scheme.

Yours faithfully,

Patrick Burke,
Assistant National Director,
Primary Care Reimbursement Service