

29 January 2010

## Proposal to fund ambrisentan (Volibris) for the treatment of pulmonary arterial hypertension

PHARMAC is seeking feedback on a proposal to list ambrisentan (Volibris) in the Pharmaceutical Schedule for the treatment of pulmonary arterial hypertension. In summary, the effect of the proposal would be that from 1 April 2010:

- Ambrisentan (Volibris) would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule for the treatment of pulmonary arterial hypertension.
- Ambrisentan would be subject to the same access restrictions as other treatments for pulmonary arterial hypertension.

### Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by 4 pm on **Thursday, 11 February 2010** to:

Stephen Woodruffe  
 Therapeutic Group Manager  
 PHARMAC  
 PO Box 10 254  
 Wellington 6143

Email: [stephen.woodruffe@pharmac.govt.nz](mailto:stephen.woodruffe@pharmac.govt.nz)

Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board or Chief Executive acting under delegated authority prior to making a decision on this proposal.

### Details of the proposal

PHARMAC and GlaxoSmithKline NZ Limited have entered into a provisional agreement relating to the listing of ambrisentan (Volibris) in the Pharmaceutical Schedule.

Ambrisentan would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 April 2010 at the following prices and subsidies (ex-manufacturer, exclusive of GST):

Chemical	Presentation	Brand name	Pack size	Price and subsidy
Ambrisentan	Tab 5 mg	Volibris	30	\$4,585.00
Ambrisentan	Tab 10 mg	Volibris	30	\$4,585.00

There would be a rebate arrangement between PHARMAC and GlaxoSmithKline relating to Volibris, and Volibris would be protected from delisting and subsidy reduction until 1 January 2014.

Ambrisentan would be listed under access restrictions applying to other treatments for pulmonary arterial hypertension, with Special Authority applications subject to approval by the Pulmonary Arterial Hypertension Panel, and a *Hospital Pharmacy [HP1]* restriction.

Ambrisentan would be listed under the Endothelin Receptors Antagonists heading in Section B of the Pharmaceutical Schedule. As such, once a patient received Special Authority approval for an Endothelin Receptor Antagonist, either ambrisentan or bosentan could be prescribed fully funded - Special Authority approvals would be interchangeable between the two products.

### **Background to the proposal**

In July 2009, three treatments for pulmonary arterial hypertension (bosentan, iloprost and sildenafil) were listed on the Pharmaceutical Schedule. Subsidy for these products is available via Special Authority upon approval by the Pulmonary Arterial Hypertension (PAH) Panel.

PHARMAC received an application for ambrisentan in late 2009. The Pharmacology and Therapeutics Advisory Committee (PTAC) recommended that it be listed on the Pharmaceutical Schedule under the current access criteria for pulmonary arterial hypertension treatments.