

21 November 2012

## Decision in relation to bosentan (Tracleer)

PHARMAC is pleased to announce the approval of an agreement with Actelion Pharmaceuticals Australia Pty Limited in relation to bosentan (Tracleer). This was the subject of a consultation letter dated 1 October 2012.

In summary, the effect of the decision is:

- The subsidy and delisting protection periods for the Tracleer brand of bosentan have been extended; and
- The rebate levels that apply to the Tracleer brand of bosentan have been adjusted.

The decision does not include any changes to the eligibility criteria for bosentan funding (it will still require a Special Authority application to the Pulmonary Arterial Hypertension Panel).

### Details of the decision

From 1 January 2013, the terms and conditions for the listing of Tracleer will be amended to:

- Extend the subsidy and delisting protection period so that it will end on 31 December 2015.
- Increase the level of rebate that currently applies to Tracleer (effectively reducing the net price for Tracleer paid by the Funder).

There will be no change to the list price or subsidy of, or access to, Tracleer. The current eligibility criteria and application process to the PAH panel will remain and it will continue to be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the current prices and subsidies (ex-manufacturer, excluding GST) as follows:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Bosentan	Tablet 62.5 mg	Tracleer	60	\$4,585.00
Bosentan	Tablet 125 mg	Tracleer	60	\$4,585.00

### Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received were considered in their entirety in making a decision on the proposed changes. The following issues were raised in relation to specific aspects of the proposal:

Issue	PHARMAC Comment
<p>A generic supplier raised the following concerns:</p> <p><i>The process used to enter into the provisional agreement with Actelion.</i> It was submitted that a competitive process had not been used to grant what is effectively sole supply. The submitter also considered that it had been denied an opportunity to compete for the market as it considers that dual supply is not an option due to the market's small size.</p> <p><i>Actelion offering lower pricing due to the existence of generic suppliers.</i> The submitter considered that PHARMAC has leveraged this situation for its own benefit, in the process penalising generic suppliers by making them wait for an additional 2 years before they can enter the market rather than rewarding generic suppliers for bringing competition to the market.</p> <p><i>The use of rebates after patent expiry.</i> These were considered by the submitter to be a cost to DHBs (via wholesaler mark-ups) and it was submitted they give an unfair commercial advantage to the originator, as in a subsequent competitive process the generic supplier is bidding against undisclosed prices.</p>	<p>The status afforded through this agreement is not equivalent to sole supply. PHARMAC continues to be able to list other products at any time. All suppliers, including generic suppliers, had an opportunity to submit ACPs with respect to products proposed for inclusion in the 2012/13 ITT.</p> <p>Subsidy protection provides a supplier with certainty that its product will be funded for a defined time period; it does not guarantee a level of market share. The use of subsidy protection does not prevent other suppliers from also being listed. We consider other suppliers will still be interested in having their brands of bosentan funded, despite having to compete for market share.</p> <p>When assessing the overall cost of a proposal that includes rebates, PHARMAC takes into account the additional cost to DHBs (the rebates are returned to the DHBs). In general PHARMAC would prefer transparent pricing, however where we consider accepting rebates allows better overall value to be obtained we will consider this option.</p> <p>A competing supplier does not need to know current net pricing in order to make proposals setting out their own best commercial offer to PHARMAC.</p>

### More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.