

21 November 2012

Decision in relation to the Sole Supply of Sildenafil (Silagra)

PHARMAC is pleased to announce the approval of an agreement with Arrow Pharmaceuticals (NZ) Limited in relation to sildenafil (Silagra). This was the subject of a consultation letter dated 3 October 2012.

In summary, the effect of the decision is:

- Arrow Pharmaceuticals (NZ) Limited's brand of sildenafil (Silagra) will be the only funded brand of sildenafil in the community and the available brand in DHB hospitals (with community sole supply and hospital supply status).
- Patients being treated with sildenafil which is funded for Pulmonary Arterial Hypertension will be required to switch from the Viagra brand to the Silagra brand if they wish to remain on a funded product.
- Savings in excess of \$1 million per annum will be realised, making this money available for the funding of other medicines.

Details of the decision

Sildenafil is currently funded for patients with Pulmonary Arterial Hypertension (PAH) following approval of a Special Authority application by the PAH Panel. No changes to this process will occur as a result of this decision.

Arrow's brand of sildenafil tablets (Silagra) has been awarded Community Sole Supply Status and Hospital Supply Status. This means that Silagra will be the only brand of sildenafil tablets listed in the Pharmaceutical Schedule for use in the community, and the only brand available for use in DHB hospitals (subject to a 1% Discretionary Variance Limit).

The Silagra brand of sildenafil will be listed in Section B and Section H of the Pharmaceutical Schedule and the Viagra brand of sildenafil will be delisted (from both Sections) as follows:

- 1 December 2012 – Silagra 100 mg tablets will be listed (fully funded); Viagra 25 mg, 50 mg and 100 mg tablets will remain listed (fully funded).
- 1 March 2013 – Silagra 25 mg and 50 mg tablets will be listed (fully funded); all strengths of Viagra will remain listed (fully funded).
- 1 May 2013 – All strengths of the Viagra brand of sildenafil will be delisted and Silagra will have Community Sole Supply Status and Hospital Supply Status (a 1% Discretionary Variance Limit will apply for other brands of sildenafil used in DHB hospitals) until 30 June 2014.

The prices and subsidies (ex-manufacturer, excluding GST) that will apply to the Silagra brand of sildenafil are shown below:

Strength	Brand	Pack Size	Subsidy and Price
25 mg tablet	Silagra	4	\$1.85
50 mg tablet	Silagra	4	\$1.85
100 mg tablet	Silagra	4	\$7.45

*Subsidies and prices ex-manufacturer, excluding GST

A confidential rebate will apply to the 100 mg strength of Silagra. The effect of this rebate will be to reduce the net price of Silagra 100 mg tablets.

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:

Theme	PHARMAC Comment
<p><i>Notification of how the RFP was progressing.</i></p> <p>It was submitted that PHARMAC should have advised suppliers of how the RFP was progressing even if they did not submit a proposal in the RFP.</p>	<p>PHARMAC does not generally update non-bidding suppliers on the progression of an RFP. However, suppliers are always free to contact PHARMAC staff to ask about such matters; the details they could be given would be limited as proposals from suppliers are generally provided on a commercial in confidence basis.</p>
<p><i>The clarity of the proposal for Silagra funding.</i></p> <p>A concern was raised that it was unclear in the consultation documents whether sole supply status would apply to the use of sildenafil for PAH or whether it would apply to sildenafil (irrespective of indication).</p>	<p>We consider that the consultation documents was sufficiently clear. We did not receive any other similar comments and the submitter could have sought clarification if it considered the proposal to be unclear.</p>
<p><i>The use of rebates.</i></p> <p>The use of a confidential rebate will give Arrow a competitive advantage in subsequent price negotiations and there is no justification for the net price not being disclosed in consultation.</p>	<p>The proposal was the result of a Request for Proposals which included the ability for all bidding suppliers to include rebates in any proposal they made. Without using confidential rebates we would not have been able to obtain the savings that we have. A supplier does not need to know the price of its competitor product to make its best offer in any future negotiations.</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.