

13 November 2012

Approval of proposal to list Atripla and Truvada

PHARMAC is pleased to announce that the approval of an agreement with Gilead Sciences NZ. This was the subject of a consultation letter dated 8 October 2012.

In summary, from 1 December 2012:

- Combination efavirenz with emtricitabine and tenofovir disoproxil fumarate tablets under the brand name Atripla will be listed; and
- Combination emtricitabine with tenofovir disoproxil fumarate tablets, under the brand name Truvada, will be listed;
- Both products will be listed under the current Special Authority that applies to all antiretroviral medications.

Details of the decision

- Efavirenz with emtricitabine and tenofovir disoproxil fumarate (Atripla), and emtricitabine with tenofovir disoproxil fumarate (Truvada) will be listed, from 1 December 2012, in Section B, and Part II of Section H, of the Pharmaceutical Schedule at the following prices and subsidies (ex-GST and ex-manufacturer):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Efavirenz with emtricitabine and tenofovir disoproxil fumarate	Tab efavirenz 600 mg with emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg	Atripla	30	\$1313.19
Emtricitabine with tenofovir disoproxil fumarate	Tab emtricitabine 200 mg with tenofovir disoproxil fumarate 300 mg	Truvada	30	\$838.20

- Efavirenz with emtricitabine and tenofovir disoproxil fumarate (Atripla), and emtricitabine with tenofovir disoproxil fumarate (Truvada) will be listed in the national Preferred Medicine List (PML) in Section H of the Pharmaceutical Schedule from the date of its implementation (currently estimated to be 1 July 2013);
- Efavirenz with emtricitabine and tenofovir disoproxil fumarate (Atripla), and emtricitabine with tenofovir disoproxil fumarate (Truvada) will be listed in the Pharmaceutical Schedule under the same criteria as all other funded antiretroviral medications.
- For the purposes of the restriction of subsidy for a combination of up to four antiretroviral medications in the Special Authority;

- Efavirenz with emtricitabine and tenofovir disoproxil fumarate will count as three antiretroviral medications
- Emtricitabine with tenofovir disoproxil fumarate will count as two antiretroviral medications
- From 1 January 2014 a confidential rebate will apply to all dispensings of Atripla and Truvada.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 22 October 2012 were considered in their entirety in making a decision on the proposal. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
<p>In Australia the listing of the combination products caused the efavirenz market to reduce to a 1/3 of its previous size. Generic suppliers have registered efavirenz and could enter the market.</p> <p>Previously launched generic products in the anti-retrovirals market have provided 70 and 90% savings. The proposal should be declined as greater long-term savings could be obtained by tendering the individual pharmaceuticals, and efavirenz should be included in the 2012/13 Tender.</p>	<p>The current supplier of efavirenz has subsidy and delisting protection until 30 June 2015. We do not consider it appropriate to include efavirenz in the 2012/13 Tender as a tender could not be awarded until at least 1 July 2015. It is likely that efavirenz would be included in a Tender at a later date. We would be prepared to consider a listing for another brand of efavirenz should a supplier wish to put forward a proposal.</p> <p>When developing the proposal and making its decision PHARMAC, in accordance with clinical advice, considered the costs (over the life of the patents and beyond) of the individual components of the combination products.</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.