

27 August 2010

Proposal relating to darunavir, etravirine, doripenem and methylphenidate

PHARMAC and Janssen-Cilag Pty Ltd have entered into a provisional agreement that would result in the funding of two new antiretrovirals, a new hospital antibiotic and amending the terms of listing of one currently funded pharmaceutical.

In summary, the proposal involves:

- funding the HIV therapy darunavir (Prezista);
- funding the HIV therapy etravirine (Intelence);
- establishing a national contract for the supply of the hospital antibiotic doripenem (Doribax); and
- amending the confidential rebate that currently applies to funded methylphenidate hydrochloride extended-release (Concerta).

Further details of this proposal can be found on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Monday, 13 September 2010** to:

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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 (all prices & subsidies are ex-manufacturer, excl. GST)

Darunavir (Prezista)

- Prezista 300 mg tablet and 400 mg tablet would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 November 2010 at the following prices and subsidies:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Darunavir	300 mg tablet	Prezista	120	\$1,190.00
Darunavir	400 mg tablet	Prezista	60	\$837.50

- Prezista 600 mg tablet would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 March 2011 at the following price and subsidy:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Darunavir	600 mg tablet	Prezista	60	\$1,190.00

- A confidential rebate would apply to all community subsidies and hospital sales of Prezista, which would reduce its net price.
- Prezista would have protection from delisting and subsidy reduction until 30 June 2013.
- Funded access to all presentations of Prezista in Section B of the Pharmaceutical would be subject to the same Special Authority that currently applies to all oral antiretrovirals for HIV treatment.

Etravirine (Intelence)

- Intelence 100 mg tablet would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 November 2010 at the following price and subsidy:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Etravirine	100 mg tablet	Intelence	120	\$770.00

- A confidential rebate would apply to all community subsidies and hospital sales of Intelence, which would reduce its net price.
- Intelence would have protection from delisting and subsidy reduction until 30 June 2013.
- Funded access to all presentations of Intelence in Section B of the Pharmaceutical would be subject to the same Special Authority that currently applies to all oral antiretrovirals for HIV treatment.

Doripenem (Doribax)

- Doribax 500 mg vial would be listed in Part II of Section H of the Pharmaceutical Schedule from 1 November 2010 at the following price:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Doripenem	500 mg vial	Doribax	10	\$454.50

- Doribax would have protection from reduction in purchase price until 30 June 2013.

Methylphenidate hydrochloride (Concerta)

- Concerta would remain listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the following prices and subsidies:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Methylphenidate hydrochloride	Extended-release tablet 18 mg	Concerta	30	\$58.96
Methylphenidate hydrochloride	Extended-release tablet 27 mg	Concerta	30	\$65.44
Methylphenidate hydrochloride	Extended-release tablet 36 mg	Concerta	30	\$71.93
Methylphenidate hydrochloride	Extended-release tablet 54 mg	Concerta	30	\$86.24

- The confidential rebate currently applying to all community subsidies and hospital sales of Concerta would be increased from 1 November 2010, which would reduce its net price.
- Concerta would have protection from delisting and subsidy reduction until 30 June 2013
- Funded access to all presentations of Concerta would remain subject to the same Special Authority as currently apply.

Background

Darunavir (Prezista)

Darunavir (with low dose ritonavir as pharmacokinetic enhancer) is indicated, in combination with other antiretroviral agents, for treatment of human immunodeficiency virus (HIV-1) infection.

In September 2007 PHARMAC received a funding application for darunavir 300mg tablets for heavily treatment-experienced HIV patients. In December 2007 PTAC recommended funding with a medium priority, and referred the application to the Anti-Infective Subcommittee for further review. In December 2008 the Anti-Infective Subcommittee recommended funding with a high priority.

In March 2010 PHARMAC received a funding application for darunavir 400 mg tablets for treatment naïve and early treatment experienced HIV patients. In May 2010 PTAC reviewed the application and recommended funding if cost neutral when compared to atazanavir (Reyataz).

PTAC and the Anti-Infective Subcommittee minutes can be found on PHARMAC's website, at:

<http://www.pharmac.govt.nz/2009/07/15/2009-05%20PTAC%20minutes.pdf>

<http://www.pharmac.govt.nz/2009/04/29/2008-12%20Anti-Infective%20Subcommittee%20Minutes.pdf>

<http://www.pharmac.govt.nz/2010/06/29/2010-05-06%20PTAC%20web%20minutes%232.pdf>

Etravirine (Intelence)

Etravirine in combination with other antiretrovirals agents is indicated for the treatment of HIV-1 infection in antiretroviral treatment experienced adults who have evidence of viral replication and resistance to NNRTIs and other antiretroviral agents.

In September 2009 PHARMAC received an application for the funding of etravirine for heavily treatment-experienced HIV patients failing other NNRTI therapies. PTAC recommended that the listing of etravirine be deferred until after any listing of darunavir as all the evidence for etravirine was in combination with the currently unfunded protease inhibitor darunavir.

PTAC's minutes can be found on PHARMAC's website, at:

<http://www.pharmac.govt.nz/2010/01/29/2009-11%20PTAC%20minutes%20for%20web%20publishing.pdf>

Doripenem (Doribax)

Doripenem is an injectable beta-lactam antibiotic of the subgroup carbapenem, used in the hospital setting for treatment of nosocomial pneumonia, complicated intra-abdominal infection and urinary tract infections caused by susceptible bacteria. DHBs Hospitals are currently purchasing doripenem for use in hospital, and this proposal would establish a national contract its supply.

Methylphenidate hydrochloride (Concerta)

Concerta is a once daily form of methylphenidate hydrochloride, indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Concerta was first listed in the Pharmaceutical Schedule in November 2008.

Concerta is currently funded under Special Authority for patients with diagnosed ADHD where immediate release methylphenidate is not effective due to compliance or administration difficulties or there is concern regarding diversion of immediate release methylphenidate.