

20 December 2010

Notification - various pharmaceuticals supplied by Mylan

PHARMAC is pleased to announce the approval of the agreement with Mylan New Zealand Limited (Mylan) relating to the listing of various pharmaceuticals in the Pharmaceutical Schedule.

This proposal was the subject of a consultation letter dated 4 October 2010 that can be found on PHARMAC's website at <http://www.pharmac.govt.nz/2010/10/04?q=various>.

All aspects of the proposal as consulted upon were approved. A summary of the decision is provided below; please refer to the consultation letter for full details.

- Mylan's brands of metoprolol succinate (Myloc CR) and lansoprazole (Lanzol Relief) will be listed on the Pharmaceutical Schedule from 1 March 2011.
- Mylan's brands of candesartan (Candestar) and mycophenolate mofetil (Ceptolate) will be listed on the Pharmaceutical Schedule following all the necessary regulatory consents being obtained and subject to the current Special Authorities.
- Subsidy and delisting protection will be provided to the above brands until:

Chemical	Brand	Protection expires on:
Metoprolol succinate	Myloc CR	31 January 2012
Lansoprazole	Lanzol Relief	31 October 2012
Candesartan	Candestar	30 June 2012
Mycophenolate mofetil	Ceptolate	1 July 2012

- The terms of listing for verapamil hydrochloride (Verapamil SR), celiprolol (Celol), labetalol (Hybloc), nifedipine (Adefin XL), isosorbide mononitrate (Duride), and propranolol (Cardinol LA) will be amended including the provision of subsidy and delisting protection until 30 June 2014 with an option for PHARMAC to extend the listing terms until 30 June 2017.
- Reference pricing of nifedipine (Arrow-Nifedipine XR to Adefin XL). This will result in the subsidy for Arrow-Nifedipine XR being reduced to the level of the subsidy for Adefin XL from 1 July 2011. A patient surcharge will occur if the supplier of Arrow-Nifedipine XR does not reduce its price to the new subsidy level for Adefin XL as follows (prices and subsidies are ex-manufacturer, excluding GST):

Brand	Form	Pack size	Current price/subsidy	Subsidy from 1 July 2011	Potential patient surcharge from 1 July 2011
Adefin XL	Tab 30 mg	30	\$8.56	No change	Fully funded
Adefin XL	Tab 60 mg	30	\$12.28	No change	Fully funded
Arrow-Nifedipine XR	Tab 30 mg	30	\$10.70	\$8.56	\$3.98*
Arrow-Nifedipine XR	Tab 60 mg	30	\$15.35	\$12.28	\$5.71*

* The patient surcharge is based on an assumed 86% pharmacy mark-up, and no change in price.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by Tuesday 19 October 2010 were considered in their entirety in making a decision on the proposed changes.

The following issues were raised in relation to the proposal:

Theme	Comment
<p>It was questioned as to whether the Special Authority access criteria for Mycophenolate are appropriate. Specifically that mycophenolate should also be funded for:</p> <ul style="list-style-type: none">▪ Induction of remission of Lupus Nephritis (and other autoimmune disease) where Cyclophosphamide is contraindicated.▪ Maintenance of remission where azathioprine has failed or has had intolerable side effects.	<p>The proposal did not include any changes to the Mycophenolate Special Authority criteria. We will however review the proposed criteria to determine if any changes are appropriate.</p>
<p>Concerns were raised regarding the listing of generic medicines specifically:</p> <ul style="list-style-type: none">▪ Multiple brands of medication should not be listed on the basis that switching patients is time consuming and errors can occur.▪ It may result in sole supply.	<p>Pharmaceuticals can be provided with market exclusivity by virtue of intellectual property rights. In such cases only a single supplier exists.</p> <p>Once the exclusivity time expires the products are open to usual market competition. In the context of PHARMAC funding this would often result in either:</p> <ol style="list-style-type: none">1. Multiple brands being funded, with product selection being made by the clinician and pharmacist, in line with current regulations regarding substitution.2. PHARMAC seeking to introduce price competition through a reduction in the number of funded brands. <p>The introduction of competition for pharmaceutical technologies is important. It enables pharmaceutical access to be increased to a greater extent than budget increases alone would allow, as it result in price reductions.</p> <p>Indefinite monopoly status for the original product would not be a practical or desirable approach.</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.