

15 October 2003

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To All Interested Parties

*By facsimile (4 pages)*

**Wyeth proposal regarding venlafaxine (Efexor XR),  
etanercept (Enbrel) and ethinyloestradiol with  
levonorgestrel (Monofeme and Trifeme)**

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PHARMAC has signed a provisional agreement with Wyeth (NZ) Limited involving the listing of venlafaxine (Efexor XR) and etanercept (Enbrel) on the Pharmaceutical Schedule. The provisional agreement also includes a price decrease for ethinyloestradiol with levonorgestrel (Monofeme and Trifeme). The main features of this proposal are outlined further in this letter.

The PHARMAC Board will consider this proposal at its November 2003 meeting. If you have comments to make on this proposal and would like those comments to be considered by the PHARMAC Board then please send them to PHARMAC by **5 p.m. on Friday, 13 November 2003**. The PHARMAC Board will consider all comments submitted by this date.

***Venlafaxine (Efexor XR)***

1. PHARMAC proposes to list venlafaxine (Efexor XR) 75 mg and 150 mg modified release capsules in Section B and Section H of the Pharmaceutical Schedule at a price and subsidy of \$37.27 per pack of 28 capsules of 75 mg, and \$45.68 per pack of 28 capsules of 150 mg (prices and subsidies are ex-manufacturer, exclusive of GST), from 1 January 2004.

The listing of venlafaxine (Efexor XR) 75 mg and 150 mg modified release capsules in Section B of the Pharmaceutical Schedule would be subject to the following Special Authority criteria:

**Special Authority – Retail Pharmacy**

- a) Subsidised only for "treatment resistant" depression.
- b) Patients must have had a trial of two different anti-depressants and failed to respond to an adequate dose over an adequate period of time (usually at least 4 weeks).

OR

If the patient is currently a hospital in-patient as a result of an acute depressive episode, the patient must have had a trial of one other anti-depressant and failed to respond to an adequate dose over an adequate period of time.

- c) Initial applications to be made by a psychiatrist or psychiatric registrar and valid for 2 years.

- d) Reapplications to be made by any medical practitioner. Reapplications would be approved for those patients who have a high risk of relapse.

#### *Section H*

Under this proposal, venlafaxine (Efexor XR) 75 mg and 150 mg modified release capsules would be listed in Part II of Section H, but not with Hospital Supply Status. Therefore, DHB Hospitals would be free to purchase venlafaxine if they chose, but there would be no requirement or DV Limits.

#### *Etanercept (Enbrel)*

2. PHARMAC would list etanercept in Section B and Section H of the Pharmaceutical Schedule from 1 January 2004 as follows:

Chemical	Brand	Pack size	Proposed price and subsidy
Etanercept	Enbrel	Injection set containing: <ul style="list-style-type: none"> <li>• 4 vials with etanercept;</li> <li>• 4 pre-filled syringes containing 1 ml of sterile water for injections;</li> <li>• 8 needles 27G each; and</li> <li>• 8 alcohol swabs</li> </ul>	\$899.96

Note: price and subsidy is ex manufacturer, exclusive of GST.

The listing of etanercept (Enbrel) 25 mg injection set in Section B of the Pharmaceutical Schedule would be subject to certain Special Authority criteria and restrictions that are yet to be finalised. It is envisaged that the Special Authority criteria would be similar to those that are currently in use in Australia. PHARMAC will consult with relevant specialists over the exact wording of the Special Authority criteria before any implementation.

#### *Section H*

Under this proposal, etanercept (Enbrel) 25 mg injection set would be listed in Part II of Section H, but not with Hospital Supply Status. Therefore, DHB Hospitals would be free to purchase etanercept if they chose, but there would be no requirement or DV Limits.

#### *Oral Contraceptives*

3. Wyeth would reduce the prices of ethinylloestradiol with levonorgestrel (Monofeme and Trifeme) tablets effective from 1 January 2004 as follows:

Chemical	Brand	Pack size	Current price and subsidy	Proposed price and subsidy	Percentage reduction
Ethinylloestradiol with levonorgestrel	Monofeme	84	\$9.45	\$6.62	-30%
	Trifeme	84	\$9.45	\$6.62	-30%

Note: prices and subsidies are ex-manufacturer, exclusive of GST.

Following the price and subsidy reduction for Monofeme and Trifeme, PHARMAC proposes to apply reference pricing to the other brands of oral contraceptives currently listed in Section B of the Pharmaceutical Schedule from 1 January 2004 as follows (all prices and subsidies are ex manufacturer, exclusive of GST):

**Combined Oral Contraceptives**

	Current subsidy (Manufacturer's Price)	Proposed subsidy	Pack size	Brand or Generic Manufacturer
<b>ETHINYLOESTRADIOL WITH DESOGESTREL</b>				
	Currently no fully funded options			
Tab 20 mcg with desogestrel 150 mcg	\$9.45 (\$13.80)	\$6.62	63	Mercilon 21
Tab 20 mcg with desogestrel 150 mcg and 7 inert tab	\$9.45 (\$13.80)	\$6.62	84	Mercilon 28
Tab 30 mcg with desogestrel 150 mcg	\$9.45 (\$13.80)	\$6.62	63	Marvelon 21
Tab 30 mcg with desogestrel 150 mcg and 7 inert tab	\$9.45 (\$13.80)	\$6.62	84	Marvelon 28
<b>ETHINYLOESTRADIOL WITH GESTODENE</b>				
	Currently no fully funded options			
Tab 20 mcg with gestodene 75 mcg and 7 inert tab	\$3.15 (\$6.00)	\$2.21	28	Melodene
Tab 30 mcg with gestodene 75 mcg	\$9.45 (\$15.00)	\$6.62	63	Femodene 21
Tab 30 mcg with gestodene 75 mcg and 7 inert tab	\$9.45 (\$14.49) (\$15.00)	\$6.62	84	Minulet 28 Femodene 28
<b>ETHINYLOESTRADIOL WITH LEVONORGESTREL</b>				
Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tab	\$9.45 (\$16.50)	\$6.62	84	Loette Microgynon 20 ED
Tab 30 mcg with levonorgestrel 150 mcg	\$9.45 (\$15.00)	\$6.62	63	Microgynon 30
Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tab	\$9.45 (\$14.49) (\$15.00)	\$6.62	84	✓ <b>Monofeme</b> Levlen ED Nordette 28 Microgynon 30 ED
Tab ethinyloestradiol 30 mcg with levonorgestrel 50 mcg (6) and tab ethinyloestradiol 40 mcg with levonorgestrel 75 mcg (5) and tab ethinyloestradiol 30 mcg with levonorgestrel 125 mcg (10) and 7 inert tab	\$9.45 (\$14.49)	\$6.62	84	✓ <b>Trifeme</b> Triquilar ED Triphasil 28
Tab 50 mcg with levonorgestrel 125 mcg and 7 inert tab	\$9.45	\$6.62	84	Microgynon 50 ED
Tab 50 mcg with levonorgestrel 250 mcg	\$9.45 (\$13.80)	\$6.62	63	Nordiol 21
Tab 50 mcg with levonorgestrel 250 mcg and 7 inert tab	\$9.45 (\$13.80)	\$6.62	84	Nordiol 28
<b>ETHINYLOESTRADIOL WITH NORETHISTERONE</b>				
Tab 35 mcg with norethisterone 500 mcg	\$9.45 (\$14.52)	\$6.62	63	Brevinor 21
Tab 35 mcg with norethisterone 500 mcg and 7 inert tab	\$6.62	\$6.62	84	✓ <b>Norimin</b>

	Current subsidy (Manufacturer's Price)	Proposed subsidy	Pack size	Brand or Generic Manufacturer
Tab ethinyloestradiol 35 mcg with norethisterone 500 mcg (7) and tab ethinyloestradiol 35 mcg with norethisterone 1mg (9) and tab ethinyloestradiol 35 mcg with norethisterone 500 mcg (5) and 7 inert tab	\$9.45 (\$13.80)	\$6.62	84	Synphasic 28
Tab 35 mcg with norethisterone 1mg	\$9.45 (\$14.52)	\$6.62	63	Brevinor 1/21
Tab 35 mcg with norethisterone 1mg and 7 inert tab	\$9.45 (\$14.52)	\$6.62	84	Brevinor 1/28
<b>ETHINYLOESTRADIOL WITH NORGESTREL</b>				
Tab 50 mcg with norgestrel 500 mcg	\$3.15 (\$4.73)	\$2.21	21	Ovral
<i>(Ovral to be delisted 1 November 2003)</i>				
<b>ETHINYLOESTRADIOL WITH MESTRANOL</b>				
Tab 1 mg with mestranol 50 mcg	\$9.45 (\$13.80)	\$6.62	63	Norinyl-1/21
Tab 1mg with mestranol 50mcg and 7 inert tab	\$9.45 (\$13.80)	\$6.62	84	Norinyl-1/28

#### Progestogen-only Contraceptives

	Current subsidy (Manufacturer's Price)	Proposed subsidy	Pack size	Brand or Generic Manufacturer
<b>ETHYNODIOL DIACETATE</b>				
Tab 500 mcg	\$6.62	\$6.62	84	✓ <b>Femulen</b>
<b>LEVONORGESTREL</b>				
Tab 30 mcg	\$8.70 (\$13.80) (\$14.50)	\$6.62	84	Microval Microlut
<b>NORETHISTERONE</b>				
Tab 350 mcg	\$9.10	\$9.10	84	✓ <b>Noriday 28</b>

✓ fully subsidised

Sole Supply

If you wish to make comments on this proposal, please forward them to Natalie Ganley at PHARMAC by 5 p.m. on Friday, 13 November 2003.

Yours sincerely



Natalie Ganley  
Therapeutic Group Manager