

30 September 2005

To all Suppliers and Interested Parties  
By facsimile or email (3 pages)

Level 14, Cigna House,  
40 Mercer Street, PO Box 10-254,  
Wellington 6001, New Zealand  
Phone 64 - 4 - 460 4990  
Fax 64 - 4 - 460 4995  
www.pharmac.govt.nz

**Proposals to:**

- **list glatiramir acetate (Copaxone) in Section B of the Pharmaceutical Schedule**
- **widen access to oxaliplatin (Eloxatin)**
- **contract for oxaliplatin (Eloxatin), colaspase/L-asparaginase (Leunase) and docetaxel (Taxotere)**

PHARMAC has entered into a provisional agreement with Aventis Pharma Limited (Sanofi Aventis Group) in relation to the proposals outlined above. Further details of the proposals are provided below. If you would like to comment on any aspect of the proposals, please forward your comments to Steffan Crausaz at PHARMAC by **Friday 14 October 2005**. Comments received by that date will be considered by the PHARMAC Board. If the proposals are accepted by the PHARMAC Board, the earliest possible implementation date would be 1 December 2005.

***In relation to glatiramir acetate (Copaxone)***

It is proposed that:

- PHARMAC would list glatiramir acetate (Copaxone), 20mg pre-filled syringes in Section B of the Pharmaceutical Schedule at a price and subsidy (ex manufacturer, GST excl.) of \$1,089.25 per 28 syringes, as soon as practicable once the required regulatory consents have been notified nationally in the *Gazette*.
- Aventis Pharma Limited would pay PHARMAC a confidential rebate on every pack of 28 pre-filled syringes of Copaxone subsidised.
- Copaxone would be listed subject to the same Entry and Stopping criteria as interferon beta 1 alpha (Avonex) and interferon beta 1 beta (Betaferon)<sup>1</sup>. This means that patients for whom a subsidy has been granted by the Multiple Sclerosis Treatments Assessment Committee (MSTAC) would have the option of trying each of the three agents.
- Distribution arrangements for Copaxone would be the same as for Betaferon and Avonex:
  - Prescriptions would be initially dispatched by a distributor (agreed between PHARMAC and Aventis Pharma) to each patient's appointed clinician (specialist or GP) in the first instance, or subsequently their nominated pharmacy. However, once/if patients are confident and capable of administering the injections themselves, they may request direct delivery. All prescriptions dispensed would be checked by a pharmacist prior to delivery.
  - Deliveries would be sent out on pre-determined days throughout the year so that patients or their doctors would know when to expect them and so that patients do not run out of medication. Storage requirements for the product would be adhered to throughout transit and delivery.
  - The usual requirement for patient co-payments would be waived for Copaxone.

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<sup>1</sup> PHARMAC is currently consulting on amendments to these criteria which, if approved, would also apply to Copaxone

***In relation to oxaliplatin (Eloxatin)***

It is proposed that:

- PHARMAC would list oxaliplatin (Eloxatin) 50mg injection in Parts II and Part V of Section H of the Pharmaceutical Schedule from 1 December 2005 at a price (ex manufacturer, GST excl.) of \$410.00 per injection and oxaliplatin (Eloxatin) 100mg injection at a price (ex manufacturer, GST excl.) of \$800.00 per injection.
- PHARMAC would amend the current restriction applying to both presentations of oxaliplatin (Eloxatin) in Part V of Section H as follows (amendments from current criteria highlighted):
  1. Metastatic colorectal cancer – ~~post fluoropyrimidine and irinotecan failure~~ **first or second line use as part of a combination chemotherapy regimen**; or
  2. Metastatic colorectal cancer – ~~post fluoropyrimidine failure and unsuitable for irinotecan~~ as a single agent chemotherapy in fluoropyrimidine-relapsed disease
- Both presentations of oxaliplatin (Eloxatin) would be listed in Section B of the Pharmaceutical Schedule from 1 January 2006 at a price and subsidy (ex manufacturer, GST excl.) of \$410.00 per 50mg injection and \$800.00 per 100mg injection under the following Special Authority criteria

OXALIPLATIN – specialist – PCT Only

Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

- 1 The patient has metastatic colorectal cancer; and
- 2 Either
  - 2.1 To be used for first or second line use as part of a combination chemotherapy regimen; or
  - 2.2 As a single agent chemotherapy in fluoropyrimidine-relapsed disease

Renewal only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

- 3 The patient requires continued therapy; or
- 4 The tumour has relapsed and requires re-treatment.

- This proposal has been granted support from the District Health Board Chief Executives to proceed. Unless significant concerns are raised in consultation, no further approval is required before the PHARMAC Board can make a decision.

***In relation to colaspase/L-asparaginase (Leunase)***

It is proposed that:

- PHARMAC would list colaspase/L-asparaginase (Leunase) 10,000iu injections in Parts II and Part V of Section H of the Pharmaceutical Schedule from 1 December 2005 at a price of \$102.32 per injection.
- This product would be listed in Section B from 1 January 2006 at a price and subsidy of \$102.32 per injection.

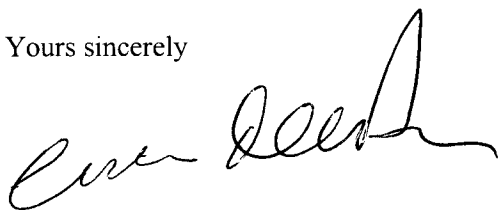
*In relation to docetaxel (Taxotere)*

It is proposed that:

- PHARMAC would list docetaxel (Taxotere) 20mg injection in Parts II and Part V of Section H of the Pharmaceutical Schedule from 1 December 2005 at a price (ex manufacturer, GST excl.) of \$460.00 per injection and docetaxel (Taxotere) 80mg injection at a price (ex manufacturer, GST excl.) of \$1,650.00 per injection.
- While listed in Part V of Section H, both presentations would remain listed restricted under the following existing criteria:
  1. Initial chemotherapy in ovarian, fallopian or primary peritoneal cancer
  2. Subsequent chemotherapy in ovarian, fallopian or primary peritoneal cancer not previously treated with taxanes
  3. Metastatic breast cancer – post-anthracycline relapse
  4. Metastatic breast cancer – anthracyclines contraindicated
  5. Lung cancer – non-small cell: advanced disease or part of combined chemo-radiotherapy
  6. Lung cancer – small cell: as second line therapy
- Both presentations of docetaxel (Taxotere) would be listed in Section B of the Pharmaceutical Schedule from 1 January 2006 at a price and subsidy (ex manufacturer, GST excl.) of \$460.00 per 50mg injection and \$1,650.00 per 100mg injection under Special Authority criteria.

If you have any questions or concerns about these proposals, please contact me ([cristine.dellabarca@pharmac.govt](mailto:cristine.dellabarca@pharmac.govt) Ph (04) 9167 514).

Yours sincerely



Cristine Della Barca  
Manager, Supply Side