

5 January 2004

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To All Interested Parties

By facsimile (2 pages)

Roche proposal regarding rituximab (Mabthera)

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PHARMAC has signed a provisional amendment to the existing hospital supply agreement with Roche Products (New Zealand) Limited involving the widening of access to rituximab (Mabthera) to include CD20 positive, diffuse large cell B-cell Non-Hodgkin's Lymphoma (NHL) in combination with CHOP (cyclophosphamide, vincristine, doxorubicin and prednisone) in Part V of Section H of the Pharmaceutical Schedule. The main features of this proposal are outlined further in this letter.

If you have comments to make on this proposal and would like those comments to be considered by the PHARMAC Board (or Chief Executive under delegated authority pursuant to section 61 of the New Zealand Public Health and Disability Act 2000) then please send them to PHARMAC **by 5 p.m. on Friday, 16 January 2004**. The PHARMAC Board (or Chief Executive) will consider all comments submitted by this date.

PHARMAC proposes to:

- widen the access criteria under which DHBs must provide funding for rituximab by amending the existing listing in Part V of Section H of the Pharmaceutical Schedule as follows, from 1 February 2004 (changes in bold and underlined):

RITUXIMAB

Mabthera

Restricted indication

1. Transplant related non-Hodgkin's lymphoma (NHL) – initial therapy.
2. Low Grade NHL – post anthracycline failure.
3. Low grade NHL – post standard chemotherapy failure and unsuitable for anthracycline treatment.
4. post transplant lymphoproliferative disorder (B cell) – initial therapy.
5. follicular NHL – first or later relapsed disease with poor prognostic features (GELA or MDACC prognostic factors) in combination with anthracycline or fludarabine containing regimen or in combination with other regimen if anthracyclines or fludarabine contraindicated.
6. **CD20 positive, diffuse large cell B-cell NHL in combination with CHOP (cyclophosphamide, vincristine, doxorubicin and prednisone) chemotherapy.**

Supplies of rituximab to patients with CD20 positive, diffuse large cell B-cell NHL in combination with CHOP (cyclophosphamide, vincristine, doxorubicin and prednisone) chemotherapy made in February, March and April 2004 would be provided free-of-charge by Roche Products. Funding would be provided by PHARMAC from the community pharmaceutical budget for supplies in May and June of 2004. From 1 July 2004 DHBs would provide funding for all indications listed in Part V of Section H, and would be invoiced by Roche Products in the usual manner.

In order to be entitled to utilise the payment arrangements from 1 February 2004 to 30 June 2004, DHB hospitals would need to provide Roche Products with the following information:

- (a) name, address and NHI number of patient for whom Mabthera is to be supplied;
- (b) name, address, Medical Council number and signature of the prescriber;
- (c) DHB Hospital;
- (d) amount of Mabthera to be supplied (including strength and number of vials) and period of supply.

This information would be provided on a form, available from Roche Products, and the data would subsequently be made available to PHARMAC. Usage would be monitored by PHARMAC, and may be audited, to ensure that only sufficient quantities for this period are ordered and that supplies are made only for patients with CD20 positive, diffuse large cell B-cell NHL in combination with CHOP.

If approved by the Board (or Chief Executive) this proposal would be implemented on 1 February 2004. Notification would initially be via email to hospital pharmacists, D&T committees and DHB CEOs. The change would be published in the March 2004 update of the Pharmaceutical Schedule.

If you wish to make comments on this proposal, please forward them to Steffan Crausaz at PHARMAC by **5 p.m. on Friday, 16 January 2004**.

A copy of this letter can be found on PHARMAC's website at www.pharmac.govt.nz/consultation.asp.

Yours sincerely



Wayne McNee
Chief Executive