CONSULTATION

PHARMAC
Pharmaceutical Management Agency

23 October 2013

Proposal to widen funded access to erlotinib (Tarceva)

PHARMAC is seeking feedback on a proposal to:

- Reduce the prices and subsidies for erlotinib hydrochloride tablets 100 mg and 150 mg (Tarceva); and
- Widen funded access to erlotinib hydrochloride to include first line treatment for treatment naïve patients with locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC) expressing activating mutations of EGFR tyrosine kinase

through a provisional agreement with Roche Products NZ Limited.

This proposal would require that patients with advanced non-squamous NSCLC undergo testing for the presence of activating mutations of EGFR tyrosine kinase in order to access funding for first or second line erlotinib.

The proposal is consistent with advice from the Pharmacology and Therapeutics Advisory Committee (PTAC).

Overall, if implemented, the proposal is expected to be cost saving to the Combined Pharmaceutical Budget and DHBs.

Further details of this proposal, including how to provide feedback and background information, can be on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5 pm, Friday 8 November 2013** to:

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Therapeutic Group Manager	Fax: 04 460 4995
PHARMAC	Post PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

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Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the

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content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

Details of the proposal

- From 1 January 2014 the prices and subsidies for erlotinib hydrochloride tablets (Tarceva) listed in Section B and Part II of Section H of the Pharmaceutical Schedule would be reduced as follows:

Pharmaceutical	Brand	Presentation	Pack size	Current Price and Subsidy	Price and Subsidy from 1 January 2014
Erlotinib hydrochloride	Tarceva	Tab 100 mg	30	$3,100.00	$1,133.00
Erlotinib hydrochloride	Tarceva	Tab 150 mg	30	$3,950.00	$1,700.00

- The Special Authority criteria applying to all presentations of Tarceva listed in Section B of the Pharmaceutical Schedule would be amended as follows from 1 January 2014 (changes in bold and strikethrough):

> Erlotinib hydrochloride - Retail Pharmacy – Specialist - Special Authority
> Special Authority for Subsidy
> Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:
>
> ~~All of the following:~~
> ~~1 Patient has advanced, unresectable, Non Small Cell Lung Cancer (NSCLC); and~~
> ~~2 Patient has documented disease progression following treatment with first line platinum based chemotherapy; and~~
> ~~3 Erlotinib is to be given for a maximum of 3 months.~~
>
> **Either**
> **1 All of the following:**
> **1.1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and**
> **1.2 There is documentation confirming that disease expresses activating mutations of EGFR tyrosine kinase; and**
> **1.3 Either**
> **1.3.1 Patient is treatment naïve; or**
> **1.3.2 Both:**
> **1.3.2.1 Patient has documented disease progression following treatment with first line platinum based chemotherapy; and**
> **1.3.2.2 The patient has not received prior treatment with gefitinib; and**
> **1.4 Erlotinib is to be given for a maximum of 3 months, or**

2 The patient received funded erlotinib prior to 31 December 2013 and radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

Renewal application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

- The Restriction applying to all presentations of Tarceva listed in part II of Section H of the Pharmaceutical Schedule would be amended as follows from 1 January 2014 (changes in bold and strikethrough):

Erlotinib
Restricted
Initiation
Re-assessment required after 3 months
~~Both~~
~~Patient has advanced, unresectable, Non Small Cell Lung Cancer (NSCLC); and~~
~~Patient has documented disease progression following treatment with first line platinum based chemotherapy; and~~
Either

1 All of the following:
- **1.1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and**
- **1.2 There is documentation confirming that disease expresses activating mutations of EGFR tyrosine kinase; and**
- **1.3 Either**
  - **1.3.1 Patient is treatment naïve; or**
  - **1.3.2 Both:**
    - **1.3.2.1 Patient has documented disease progression following treatment with first line platinum based chemotherapy; and**
    - **1.3.2.2 The patient has not received prior treatment with gefitinib; and**
- **1.4 Erlotinib is to be given for a maximum of 3 months, or**

2 The patient received funded erlotinib prior to 31 December 2013 and radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

Continuation
Re-assessment required after 6 months
Radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

Background

In October 2010 PHARMAC funded the tyrosine kinase inhibitor (TKI) erlotinib, subject to Special Authority criteria, for the second line treatment of patients with advanced, unresectable, non small cell lung cancer (NSCLC) after failure of first line platinum based chemotherapy. Erlotinib has subsidy and delisting protection until 31 December 2013.

Since erlotinib was first funded the correlation between specific mutations in the tyrosine kinase domain of Epidermal Growth Factor Receptor (EGFR) and increased activity of TKIs (gefitinib or erlotinib) has become well established. Evidence demonstrates that in patients with advanced NSCLC expressing EGFR activating mutations TKI treatment significantly improves progression free survival and quality of life compared with standard platinum-

based chemotherapy. Conversely, patients without EGFR activating mutations do better with standard platinum-based chemotherapy.

In August 2012, PHARMAC funded the TKI gefitinib (Iressa) for the first line treatment for patients with locally advanced, or metastatic, unresectable, non-squamous NSCLC expressing activating mutations in EGFR tyrosine kinase. PHARMAC also made the decision to amend the funding criteria for erlotinib from 1 January 2014, such that it would no longer be funded as a second line treatment option for patients with NSCLC disease known to be negative for activating mutations of EGFR tyrosine kinase. At the time of making this decision erlotinib was not registered for first line use and was significantly more expensive than gefitinib.

In May 2013, following first line registration, PTAC recommended that erlotinib be listed on the Pharmaceutical Schedule for first line treatment, under the same Special Authority criteria as gefitinib, only if cost-neutral to gefitinib (minute available at http://www.pharmac.health.nz/about/committees/ptac/ptac-minutes)

This proposal reduces the price and subsidy of erlotonib to match that of gefitinib and widens access to erlotinib to include first line treatment, in line with gefitinib funding. The proposal would provide access to an alternative fully funded tyrosine kinase inhibitor for treatment naïve patients with locally advanced or metastatic, unresectable, non-squamous NSCLC with activating mutations of EGFR tyrosine kinase

Overall, the proposal is expected to be cost saving due to it creating savings in the existing, albeit already reducing, second-line erlotinib market and the lower dose option of erlotinib 100 mg tablet being less expensive than gefitinib 250 mg tablet in the first line setting.