November 2007 PBAC Outcomes – Subsequent decisions to defer

Drug name and Sponsor	TGA Indication	Current PBS Listing	Listing Requested by Sponsor	PBAC Outcome and Comments
Erlotinib, tablet, 25, 100 and 150 mg, Tarceva®, Roche Products Pty Ltd Major submission	Erlotinib is registered for the "treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior chemotherapy". Erlotinib in combination with gemcitabine is also registered for the treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.	Not PBS listed		The PBAC deferred a final decision on the submission to allow negotiation with the sponsor to achieve an approximate 10% decrease in the incremental cost-effectiveness ratio.
			<u>Authority required</u> Treatment as monotherapy for patients with locally advanced or metastatic non-small cell lung cancer with a WHO status of 3 or less where: (1) disease progression has occurred following treatment with docetaxel or pemetrexed; or (2) treatment with docetaxel and pemetrexed is contraindicated or cannot be tolerated. Treatment as monotherapy for patients with locally advanced or metastatic non-small cell lung cancer with a WHO status of 3 or less where disease progression has occurred following treatment with docetaxel or pemetrexed; Treatment as monotherapy for patients with locally advanced or metastatic non-small cell lung cancer with a WHO status of 3 or less where disease progression has occurred following treatment with at least two chemotherapy agents.	PBAC considered that any listing should require that the drug be restricted to patients with stage III or IV of NSCLC. Patients should be required to have received prior platinum therapy and reached a point where further cytotoxic therapy is not an option.

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			Comparator: best supportive care (BSC)	Accepted
			Clinical Claim: erlotinib is significantly more effective than BSC but has more toxicity	Accepted
			Economic claim:	Partially accepted. Although a treatment benefit was observed in the trial beyond the treatment period, the continuation of treatment benefit over the entire 4 years of the model was considered questionable. PBAC considered that re-modelling exercise with converging curves for survival gain more plausible. However, the incremental cost-effectiveness ratio per life-year gained was unfavourably high.
			Sponsor's comments	The sponsor will be considering its position regarding any future course of action.
Lapatinib, tablet, 250 mg, Tykerb®, GlaxoSmithKline Australia Pty Ltd Minor submission	Tykerb® in combination with capecitabine, is indicated for the treatment of patients with advanced/ metastatic breast cancer whose tumours over express HER2 (ErbB2) and whose tumours have progressed after treatment with an	Not PBS listed		The PBAC deferred the submission to allow for further investigation into accurately determining the proportion of patients who continue with trastuzumab after disease progression, and to reconsider, if appropriate, an appropriate subsidy price for lapatinib based upon the findings of this investigation. The PBAC emphasised its willingness to continue to work with the

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	anthracycline, a taxane and trastuzumab.			company in resolving this issue.
			Initiation of treatment in patients with HER2-positive metastatic breast cancer who have received prior therapy with an anthracycline and a taxane administered either concurrently or separately, except where the patient is intolerant or contra-indicated to those agents, and whose disease progresses despite treatment with trastuzumab or who meet trastuzumab exemption criteria (early recurrence of disease within 12 months of completing a course of trastuzumab for HER2-positive early breast cancer in patients receiving adjuvant treatment following surgery or presence of CNS metastases from breast cancer following appropriate local therapy. "patients must have documented evidence of HER-2 positive metastatic breast cancer determined by: •Positive immunohistochemistry (IHC) at the 3+ level; or •HER2 gene amplification by in-situ hybridisation (ISH – fluorescent or cromogenic)	PBAC considered that the revised requested restriction addressed most of its previous concerns, although it was considered inappropriate to allow use on the basis of an immunochemistry result as this would be inconsistent with the current PBS listing for trastuzumab in the adjuvant setting.
			Comparator: A weighted comparator of 6 regimens:	PBAC was not convinced that the submission had resolved the issue of the proportion of patients who

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			capecitabine, trastuzumab, trastuzumab + vinorelbine, trastuzumab + capecitabine, trastuzumab + taxane, gemcitabine (+ taxane)	continue with trastuzumab despite progression in Australian clinical practice.
			Clinical Claim: the clinical benefits and safety profile of lapatinib + capecitabine are comparable with the mixed comparators	PBAC's previous conclusion regarding the efficacy of lapatinib is unchanged.
			Economic claim: cost utility analysis	The PBAC noted that incremental cost-effectiveness ratio was very sensitive to the proportion of use of trastuzumab in patients whose disease is progressing while on trastuzumab.
			Sponsor's comments	The sponsor does not agree with all of the PBAC's conclusions but emphasises its continued commitment to working with the PBAC to resolve the outstanding issue.