July 2013 PBAC Meeting Outcomes - Deferrals

Drug and Form	Drug Use and Type	Listing Requested by Sponsor	PBAC Outcome and Comments
Afatanib, tablets, 20 mg, 30 mg, 40 mg and 50 mg, Giotrif®/Tomtovok® Boehringer Ingelheim Pty Ltd Major submission	Lung cancer	Authority required listing for locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer as first line therapy in a patient with activating mutation(s) of the EGFR gene.	The PBAC deferred the submission in order to ascertain whether the applicant is prepared to offer a reduced price for a pack of twenty-eight 40 mg tablets, and if so, to consider the implications of this reduced price for revising the cost-effectiveness of listing afatinib as indicated by the PBAC.
		Sponsor's comments:	Boehringer Ingelheim continues to work with the PBAC to list afatinib on the PBS for patients with non-small cell lung cancer.
Erlotinib, tablets, 25 mg, 100 mg and 150 mg, Tarceva® Roche Products Pty Limited Major submission	Lung cancer	Extend the current Authority required listing to include treatment, as monotherapy of locally advanced (stage IIIB) or metastatic (stage IV) non-squamous or not otherwise specified (NOS) non-small cell lung cancer in patients where there is evidence that the patient has an activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material.	The PBAC deferred the re-submission in order to ascertain whether the applicant is prepared to offer a reduced effective price for all use of erlotinib under the proposed restriction to patients with non-small-cell lung cancer who are EGFR mutation positive as indicated by the PBAC, and if so, to consider the implications of this reduced price for revising the cost-effectiveness of listing erlotinib. The PBAC considered that the evolution of clinical evidence of TKI use in NSCLC no longer supports the retention of the current nonspecific later-line listing for erlotinib. The PBAC considered that the best available care should be available to patients in the last-line setting, and that this is not the case for erlotinib in EGFR mutation negative patients where there is mounting evidence of net harm. For these reasons, the PBAC advised that the proposed erlotinib restriction would need to replace the existing erlotinib restriction such that no line of therapy would be specified for erlotinib in EGFR mutation positive patients.

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		Sponsor's comments:	Roche disagrees with the statement regarding mounting evidence of harm in EGFR mutation negative patients in the last-line setting, where best supportive care is the only alternative option. No clinical evidence supports the statement that there is a net harm associated with erlotinib in this specific patient group. For patients no longer suitable for chemotherapy, erlotinib remains a safe and effective treatment, regardless of mutation status, as shown in the BR.21 trial. This use of erlotinib in the last-line setting is supported by Australian and international treatment guidelines.
Gefitinib, tablet, 250 mg, Iressa® AstraZeneca Pty Ltd Major Submission	Lung cancer	Extend the current Authority required listing to include initial and continuing first line treatment of locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer in patients where there is evidence that the patient has an activating mutation(s) of the epidermal growth factor receptor (EGFR) gene in tumour material.	The PBAC deferred the re-submission in order to ascertain whether the applicant is prepared to offer a reduced effective price for all use of gefitinib under the proposed restriction to patients with non-small-cell lung cancer who are EGFR mutation positive, and if so, to consider the implications of this reduced price for revising the cost-effectiveness of listing gefitinib.
		Sponsor's comments:	The sponsor has no comment.
Ivacaftor, tablet, 150 mg, Kalydeco®: Vertex Pharmaceuticals Major Submission	Cystic fibrosis	Requests Section 100 (Highly Specialised Drugs Program) listing or inclusion on the Life Saving Drugs Program (LSDP) for treatment of cystic fibrosis in patients aged six years and older who have a G551D mutation in the CFTR gene.	The PBAC formed the view that the Pharmaceutical Benefits Scheme (PBS) is the most appropriate mechanism for subsidising ivacaftor for Australian patients, but that, at the price proposed in the submission, the cost per Quality Adjusted Life Year (QALY) is too high and too uncertain. The PBAC decided to defer making a recommendation to allow the sponsor the opportunity to consider the Committee's views and to submit a new price proposal for PBS listing.

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		Sponsor's comments:	The Sponsor is pleased that PBAC recognises the "clinically significant and important" outcome of the pivotal trials for ivacaftor and that ivacaftor represents "an advance over current subsidised treatments for cystic fibrosis". Given the urgent need for improved treatment among those with this rare, life-shortening disease, the Sponsor looks forward to meeting with the PBAC to find a rapid and practical solution to achieve equitable access to Kalydeco through the appropriate funding mechanism.
Levonorgestrel, intrauterine system, 13.5 mg, Jaydess® Bayer Australia Limited Major Submission	Contraception	Restricted benefit listing for contraception.	The PBAC deferred the submission to await finalisation of the product's TGA registration.
		Sponsor's comments:	The sponsor has no comment