MARCH 2013 PBAC MEETING OUTCOMES - Deferrals

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
DABRAFENIB, capsule, 50 mg and 75 mg, Rafinlar ® GlaxoSmithKline Australia Pty Ltd Major submission	Melanoma	Authority Required listing for treatment of BRAF V600 mutation positive advanced (unresectable stage III) or metastatic (stage IV) melanoma in a patient with a WHO performance status of 2 or less.	The PBAC deferred the submission in order for the Department to consider an appropriate arrangement for data collection related to BRAF testing, and to enable price negotiations between the Department and the sponsor. The PBAC also recommended deferring in order to be informed of the TGA delegate's proposed registration and rationale.
		Sponsor's comments:	The sponsor had no comments.
ESOMEPRAZOLE STRONTIUM TETRAHYDRATE, capsules, 20 mg and 40 mg, Esonova®	Gastro-oesophageal reflux disease (GORD)	Authority Required listing for the treatment of gastro-oesophageal reflux disease for 20 mg and 40 mg capsules with bioequivalence to Nexium® 20 mg and 40 mg tablets.	The PBAC deferred consideration of this submission in view of the outstanding regulatory issues for esomeprazole strontium tetrahydrate.
iNOVA Pharmaceuticals Australia Minor submission		Sponsor's comments:	The sponsor had no comments.
LINAGLIPTIN + METFORMIN, tablet, 2.5 mg-500 mg, 2.5 mg-850 mg and 2.5 mg-1000 mg, Brand name to be confirmed Boehringer Ingelheim Pty Ltd Major submission	Diabetes	Authority Required (STREAMLINED) listing for treatment of type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a gliptin, glitazone or a glucagon-like peptide-1 despite treatment with metformin and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated (dual oral therapy).	The PBAC deferred consideration of the application pending finalisation of the TGA registration process, particularly the final indication and confirmation of bioequivalence with the single components given concomitantly; and to allow further consideration of predicted utilisation and financial implications based on the DUSC utilisation analysis. The application was subsequently considered at the April 2013 PBAC Special meeting and the outcome will be published at a later date.
		Sponsor's comments:	The sponsor had no comments.

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MANNITOL, capsule containing powder for oral inhalation, 40 mg (for use in inhaler device), Bronchitol® Pharmaxis Ltd Minor submission	Cystic fibrosis	Amend the continuation rule to simplify the current Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority required (STREAMLINED) listing for treatment of Cystic Fibrosis.	The PBAC deferred making a recommendation, to seek further advice on the appropriate objective measures of assessment of lung function.
		Sponsor's comments:	Pharmaxis look forward to assisting the PBAC in gaining additional clinical input, and in preparing appropriate revised wording.
SAXAGLIPTIN WITH METFORMIN, tablet, 2.5 mg-500 mg, 2.5 mg-850 mg, 2.5 mg-1000 mg, Kombiglyze® Bristol-Myers Squibb Australia Pty Ltd Major submission	Diabetes	Authority required (STREAMLINED) listing for treatment of type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a gliptin, glitazone or a glucagon-like peptide-1 despite treatment with metformin and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated (dual oral therapy).	The PBAC deferred consideration of this application pending finalisation of the TGA registration process, particularly the final indication and confirmation of bioequivalence with the single components given concomitantly; and to allow further consideration of predicted utilisation and financial implications based on the DUSC utilisation analysis. The application was subsequently considered at the April 2013 PBAC Special meeting and the outcome will be published at a later date.
		Sponsor's comments:	The Sponsor will work with the PBAC to facilitate the earliest possible PBS listing of Kombiglyze.
VEMURAFENIB, tablet, 240 mg, Zelboraf® Roche Products Pty Ltd Major submission	Melanoma	Re-submission for an Authority required listing for initial and continuing treatment of previously untreated, unresectable, stage IIIC or stage IV, BRAF V600 mutation positive metastatic melanoma with a WHO performance status of less than or equal to 2.	The PBAC deferred the submission in order for the Department to consider an appropriate arrangement for data collection related to BRAF testing, and to enable price negotiations between the Department and the sponsor. The PBAC did not consider that vemurafenib was acceptably cost-effective compared with DTIC on the basis of the modelled economic evaluation provided.

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DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
		Sponsor's comments:	Roche is extremely disappointed with the PBAC's decision. Roche has held a post-PBAC meeting with the PBAC Chair, but is unable to meet the requirements of the PBAC.