NOVEMBER 2012 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
ABIRATERONE, tablet, 250 mg (as acetate), Zytiga® Janssen-Cilag Pty Ltd Major submission	Prostate cancer	Requests a review of the PBAC's March 2012 recommendation to list abiraterone on a cost minimisation basis to cabazitaxel as an Authority Required benefit for the treatment, in combination with prednisone or prednisolone, of castration resistant metastatic carcinoma of the prostate in a patient who meets certain criteria.	The PBAC recommended listing on a cost-minimisation basis with cabazitaxel and cost-effectiveness basis when compared with best supportive care.
CIPROFLOXACIN, eye drops, 3 mg per mL (0.3%), 5 mL, CiloQuin® and Ciloxan®, Alcon Laboratories (Australia) Pty Ltd OFLOXACIN, eye drops, 3 mg per mL (0.3%), 5 mL, Ocuflox®, Allergan Australia Pty Ltd Optometrists Association Australia Minor submission	Eye infection	Change the current Authority Required listing under the Optometric schedule to remove the current requirement for optometrists to be under the supervision and direction of an ophthalmologist when prescribing these eye drops for bacterial keratitis.	The PBAC recommended that the listings in the general and optometric schedules for these two eye drops be made consistent by requiring the involvement of an ophthalmologist for both drugs in both the general and optometric schedule restrictions.
GLUCOSE INDICATOR – BLOOD, test strips, 50, DANA Blood Glucose® Managing Diabetes Pty Ltd Minor submission	Blood glucose monitoring	Unrestricted benefit listing.	Recommended.

IMATINIB, tablets, 100 mg and 400 mg, (as mesylate) Glivec® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Gastrointestinal cancer	Change the current Authority required listing in gastrointestinal stromal tumour to allow a maximum duration of treatment of 3 years (currently 12 months).	The PBAC recommended the extension to listing, contingent on price negotiations to achieve an incremental cost-effectiveness ratio consistent with the previous recommendation for 1-year adjuvant treatment.
IMIQUIMOD, cream, 50 mg per g (5%), 2 g multi-use pump, Aldara® iNova Pharmaceuticals (Australia) Pty Ltd Minor submission	Skin cancer	Listing of a 'pump' presentation for the same superficial basal cell carcinoma PBS indication as the existing single use sachets.	The PBAC recommended listing on a cost-minimisation basis.
IPILIMUMAB, concentrate solution for I.V infusion, 50 mg in 10 mL, 200 mg in 40 mL, Yervoy® Bristol-Myers Squibb Australia Pty Ltd Major submission	Melanoma	Section 100 (Efficient Funding of Chemotherapy) Authority Required (Streamlined) listing for the treatment of patients with unresectable stage III or stage IV malignant melanoma who have not responded to or were intolerant to prior systemic therapy for metastatic disease.	The PBAC recommended listing ipilimumab in the context of high-clinical need and no effective therapies being available, subject to risk-share arrangements addressing the following areas: <u>Appropriate use</u> o Development of a PBS restriction aligned with the TGA approved indication but that does not necessitate exposure to cytotoxic chemotherapy. Given the possible complexity of such a restriction, this will be finalised at a later date. In effect, this allows the subsided use of ipilimumab as first-line treatment at a dose of 3mg/kg. <u>Maintaining cost-effectiveness</u> o Implementation of a mechanism to verify the anticipated overall survival benefits of ipilimumab in real world clinical practice in Australia. This approach should be designed in such a way that it provides

			evidence of whether or not the extent of the survival benefit modelled in the submission and which was used in the calculation of cost-effectiveness, was realised in Australian clinical practice. The sponsor would be expected to rebate the cost of difference in performance between observed versus predicted benefits of ipilimumab. <u>Managing financial risk</u> o Negotiation of a suitable risk share agreement with significant rebates in order to manage the risks to Commonwealth financial expenditure in terms of number of patients and dose.
LACOSAMIDE, tablets, 50 mg, 100 mg, 150 mg and 200 mg, Vimpat® UCB Australia Pty Ltd Minor submission	Epilepsy	The following changes were sought: 1) Removal of the requirement in the continuation rule that patients be maintained on two or more other anti-epileptic drugs (AEDs) in combination with lacosamide; 2) Removal of reference to "…second line adjunctive agent…" from the restriction wording; 3) Changing the current Authority Required listing to Authority Required (Streamlined); and 4) Removal of the current Risk Share Arrangement.	The PBAC recommended that, at the current price and while maintaining the existing risk share arrangement, the continuing restriction be amended to allow prescribers to introduce lacosamide in combination with two other AEDs and then to remove the concurrent AEDs as a matter of clinically judgement. The PBAC also recommended that a Streamlined Authority Required indication would be reasonable while maintaining the existing risk share arrangement. Any further broadening of the initiation criteria would require a price reduction to a point equivalent with lamotrigine.
LEVONORGESTREL with ETHINYLOESTRADIOL, tablet, 100 micrograms – 20 micrograms, Femme-Tab ED® AFT Pharmaceuticals Pty Ltd	Oral contraceptive	Unrestricted benefit listing of a combined oral contraceptive with a lower strength oestrogen component (20 micrograms) compared with existing PBS-listed combined oral contraceptives.	The PBAC recommended listing on a cost-minimisation basis with levonorgestrel 150 micrograms with ethinyloestradiol 30 micrograms combination tablets.

Minor submission			
MACROGOL, sachets containing powder for solution, 17 g, 30, MediHealth ClearLax® Orion Laboratories Pty Ltd Minor submission	Laxative	Request to replace the current PBS listed presentation of powder for oral solution 510 g bottle with powder for oral solution 30 x 17 g sachets (510 g).	The PBAC recommended listing on a cost-minimisation basis.
MEASLES, MUMPS, RUBELLA and VARICELLA VIRUS VACCINE LIVE, injection, 0.5 mL, ProQuad® CSL Biotherapies (CSL Limited) Major submission	Childhood immunisation	Inclusion on the National Immunisation Program (NIP) Schedule for immunisation of children aged 18 months, as an alternative combination vaccine to the currently recommended vaccine, Priorix-Tetra.	The PBAC recommended listing on a cost-minimisation basis with Priorix-Tetra®.
NILOTINIB, capsule, 200 mg (as hydrochloride monohydrate), Tasigna® Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Leukaemia	To allow patients receiving nilotinib 400 mg twice daily in the TIDEL-II clinical trial to access nilotinib 200 mg capsules under the PBS.	The PBAC recommended this change in patients meeting certain circumstances only.
OLMESARTAN with AMLODIPINE, tablet, 20 mg – 5 mg, 40 mg – 5 mg and 40 mg – 10 mg (as besylate), Sevikar® OLMESARTAN with HYDROCHLOROTHIAZIDE, tablet,	High blood pressure	Change the wording of the existing restriction to 'Treatment of hypertension. Treatment should not be initiated with combination therapy'	The PBAC recommended amending the restriction to allow switching from drugs within class, rather than specifying individual agents.

20 mg – 12.5 mg, 40 mg – 12.5 mg and 40 mg – 25 mg, Olmetec® Plus Merck Sharp & Dohme (Australia) Pty Ltd Minor submission			
SAPROPTERIN, soluble tablet, 100 mg (as dihydrochloride), Kuvan® Merck Serono Australia Pty Ltd Minor submission	Hyperphenylalaninaemia	Inclusion on the Life Saving Drugs Program for the treatment of hyperphenylalaninaemia in patients demonstrated to have tetrahydrobiopterin deficiency.	The PBAC recommended listing on the PBS as an Authority Required listing for patients with proven tetrahydrobiopterin deficiency under the rule of rescue. The PBAC considered that the risk of leakage into patients with phenylketonuria (PKU) was considerable. Given that there are currently only 12 patients in Australia being treated with sapropterin, the PBAC recommended a risk share agreement with a 100% rebate should greater than 20 patients with BH4 deficiency access sapropterin.
SITAGLIPTIN with SIMVASTATIN, tablets, 100 mg–10 mg, 100 mg–20 mg and 100 mg–40 mg, Juvicor® Merck Sharp & Dohme (Australia) Pty Ltd Major submission	Type 2 diabetes and high cholesterol levels	Authority Required (Streamlined) listing for use in patients with Type 2 diabetes who are currently receiving treatment with simvastatin and who satisfy the criteria for prescribing DPP-4 inhibitors.	The PBAC recommended listing on a cost-minimisation basis with the individual components, and provided that, as claimed in the submission, the listing is cost neutral to the PBS. The PBAC recommended, as noted above that if this is not the case a review of the listing may be appropriate following the DUSC review of utilisation.
STRONTIUM RANELATE, sachet containing granules for oral suspension, 2 g, Protos® Servier Laboratories (Australia) Pty Ltd Minor submission	Osteoporosis	To change the basis of the PBAC's July 2012 recommendation to extend strontium's Authority Required (Streamlined) listing to include use for osteoporosis in males aged 70 years and over with a BMD T-score of -3.0.	The PBAC recommended that the basis of its July 2012 recommendation be changed to reflect risedronate sodium monotherapy being the appropriate main comparator in the proportion of the market that is related to male osteoporosis. The PBAC recommended that the weighted proportions as presented in the submission form the basis for calculating the price of strontium in this indication.

THIAMINE HYDROCHLORIDE, tablet, 100 mg, Betavit® Petrus Pharmaceuticals Pty Ltd Minor submission	Thiamine (vitamin B1) supplement	Authority Required (STREAMLINED) listing for the prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person.	The PBAC recommended listing on a cost minimisation basis compared with the currently listed thiamine 100 mg tablet.
TRIGLYCERIDES, MEDIUM CHAIN, oil, 500 mL, MCT Oil® TRIGLYCERIDES, MEDIUM CHAIN, emulsion, 250 mL, Liquigen® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Notification of minor formulation changes to MCT Oil and Liquigen and of a packaging change to Liquigen	The PBAC had no objections to the minor changes in formulation proposed, noting that no changes to the current PBS restrictions were requested.
ZOLEDRONIC ACID, solution for I.V. infusion, 5 mg (as monohydrate) in 100 mL, Aclasta® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Osteoporosis	Extend the current Authority Required (Streamlined) listing to include the treatment of patients aged 70 years of age or older, with a Bone Mineral Density (BMD) T score of -2.5 or less.	The PBAC recommended extending the current listing on a cost minimisation basis with alendronate. The equi-effective doses are alendronate 70 mg weekly for 52 weeks and zoledronic acid 5 mg per year, less the cost of infusing zoledronic acid, based on the established therapeutic relativity between treatments in osteoporosis.